The BEST Project Initiative

Excellence in Clinical Research in Medicines

Directory of Early Stages Clinical Research Units in Spain

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MEDICAMENTOS INNOVADORES
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INTRODUCTION

This is the third edition of the **Directory of Early StagesClinical Research Units in Spain**. This current version has been developed with the collaboration of **37 Early Stages Units** and a network of centres within the BEST Project initiative. With respect to the second edition fourteen new Phase Units have been added, some of very recent creation.

The BEST Project is supported by the pharmaceutical industry, and involves many public and private stakeholders for the development of a Platform of Excellence in **Clinical Research** of Medicines in Spain. The BEST Project is included within the Clinical Research Area of the Spanish Technological Platform for Innovative Medicines. (www.medicamentos-innovadores.org)

The main objective of this Directory is to promote the selection of the Spanish Units in performing early stages clinical trials, and consequently to make an attractive and useful tool available for the pharmaceutical companies during this drug development project.

This Directory has been published in September 2015 and will have a complete diffusion among all kinds of organizations interested in Clinical Research.

A questionnaire was distributed to 37 Early Stages Units in Spain and the network during Febreaury and July 2015 to collect data for this Directory.

The Directory is divided in two main sections, the first one offering a general view of the Units, and the second presenting each Unit with complete descriptions and individual facilities.

SUMMARY

The table below depicts the Early Stages Units included in this Directory (Regions are in alphabetical order; see map on page 4):

Early Stages Unit	Short name	Region
Unidad de Ensayos Clínicos Fase I y II (Hospital General. Hospitales U. Virgen Macarena - Virgen del Rocío)	MACA-ROCÍO	Andalucía
Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria	V. VICTORIA	Andalucía
Unidad de Investigación Clínica - Hospital Universitario Reina Sofía	R. SOFÍA	Andalucía
Unidad de Ensayos Clínicos - Hospital Universitario Virgen de las Nieves	V. NIEVES	Andalucía
Unidad de Ensayos Clínicos Valdecilla	VALDECILLA	Cantabria
CIM-Sant Pau (Centre d´Investigació del Medicament)	CIM-S. PAU	Cataluña
Programa de Desarrollo de Ensayos Clínicos. Instituto Catalán de Oncología	ICO	Cataluña
Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)	BELLVITGE	Cataluña
UPIC Unidad de Fase I - Hospital Universitari Germans Trias i Pujol	G. TRIAS	Cataluña
Unidad de Ensayos Clínicos Sant Joan de Déu	S. JOAN DEU	Cataluña
Unidad de Investigación Clínica del Institut Hospital del Mar d'Investigacions Mèdiques (IMIM)	IMIM	Cataluña
Unidad de Investigación de Nuevas Terapias. Inther Unit. Hospital ClInic de Barcelona	CLINIC	Cataluña
Unidad de Ensayos Clínicos Fase I de Oncología Médica del Hospital Vall D'Hebron	V. HEBRON	Cataluña
Unidad de Ensayos Clínicos de Alicante (UECA)	UEC ALICANTE	C. Valenciana
Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA	INCLIVA	C. Valenciana
Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia	HGU VALENCIA	C. Valenciana
UICAB- Instituto de Investigación Sanitaria La Fe	UICAB-LA FE	C. Valenciana
Unidad de Fase I Instituto Valenciano de Oncología IVO	IVO	C. Valenciana
CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz	CICAB	Extremadura

Early Stages Unit	Short name	Region
Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago	HCU SANTIAGO	Galicia
Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña	HU CORUÑA	Galicia
Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe	CICA GETAFE	Madrid
Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid	UAM	Madrid
Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla	G. ULLA	Madrid
Unidad de Ensayos Clínicos del Hospital Universitario de La Princesa UECHUP	LA PRINCESA	Madrid
Unidad de Estudios de Farmacología Clínica del Hospital Clínico San Carlos	CLÍNICO	Madrid
Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda	P. HIERRO	Madrid
Unidad de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda	ONCO-P.HIERRO	Madrid
Unidad de Estudios Clínicos en Fase Temprana en Oncología - UFTO. Hospital Universitario 12 de Octubre	HU 12 OCTUBRE	Madrid
Unidad de Ensayos Clínicos. Hospital Ramón y Cajal	R. Y CAJAL	Madrid
Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz	LA PAZ	Madrid
Unidad de Ensayos START Madrid - CIOCC. Hospital HM Universitario Sanchinarro	HM-START	Madrid
Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz	FJD-START	Madrid
Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón	G. MARAÑÓN	Madrid
Unidad de Investigación Clínica - Clínica Universidad de Navarra CUN	CU NAVARRA	Navarra
Unidad de Ensayos Clínicos IIS Bioaraba. Hospital Universitario de Araba	HU ARABA	País Vasco
Unidad de Terapias Avanzadas - Onkologikoa Donostia	ONKOLOGIKA	País Vasco
net GEICAM Grupo de Investigación	netGEICAM	Nacional

Location of Early Stages Units

Summary

Main conclusions derived from the present directory are:

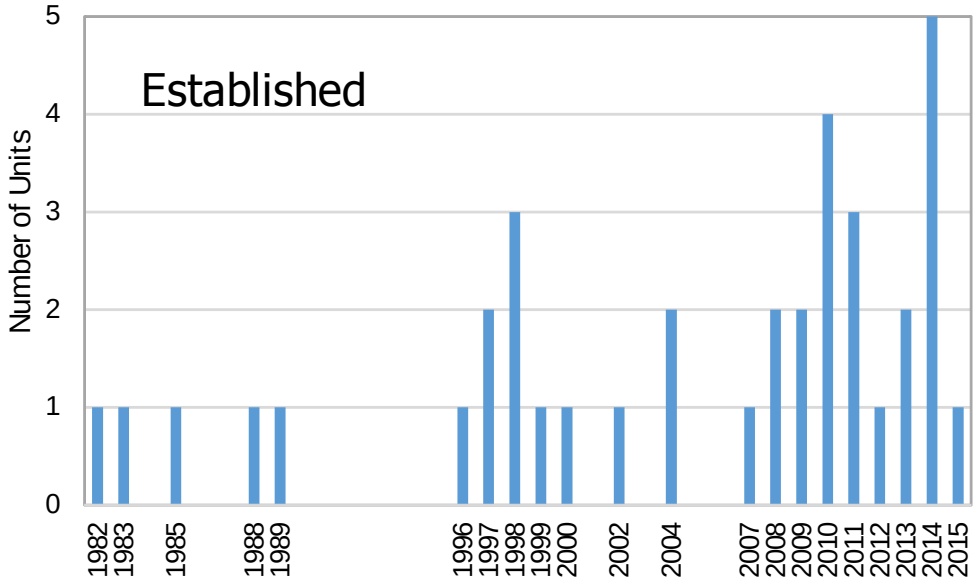
- Out of the 37 units included, 5 are **privately** owned, 30 belong to the national **public** healthcare system, most of them within a hospital structure, one **public** and **privately** owned and remaining one do not declare its condition.
- All units are devoted to **patients** and almost all units also to **healthy-volunteers studies**, only 13 units are exclusively devoted to **patients**. Only 4 units do not realize **oncology clinical trials**. Thirteen units perform studies on paediatric patients.
- The first Unit was found **in 1982** (the IMIM unit in Barcelona), and further units have been established through till **2015** (the Unit of Hospital Clínico Universitario de Santiago). In general, the first units established where located in Catalonia, followed by Madrid.
- The total **usable space** of units amounts to **15,144 square meters** (m^2), with an **average of 445 m^2 each**, although the size can range **from 25 m^2 to 2,778 m^2**.
- The total **number of beds** available in all the 37 Spanish Early Stages is **268**, with an **average of 7 beds per unit**. Units devoted to healthy-volunteers studies showed the higher average of beds per unit.
- The mean usable space (in m^2)/number of beds ratio was approximately of **56 m^2 per bed**, giving a preliminary idea about the availability in the Spanish units of enough space to carry out other study activities.
- There is a total of **684 Staff or personnel** working in the 37 Spanish units; 333 of which are permanent employees, 119 have specific-term contracts, and 232 are collaborators. **Each unit** would have an average **of 9 permanent employees**, **4 contracted employees**, **and 8 collaborators**.
- The **number of clinical trials** performed by the 37 units during the last 6 years (2009-2014) summed **2,818 studies**, 351 of them were linked to a PEI submission ("Producto En Investigación", equivalent to the IND). Each unit performed an **average of 76 clinical trials** (close to **13 per year**), corresponding 10 trials to PEI submissions (close to 2 per year).
- Regarding the **sponsorship** of clinical trials performed in the Spanish units, **local Spanish sponsors contracted 22% of the studies** and multinationals or sponsors from abroad contracted the remaining 78%.

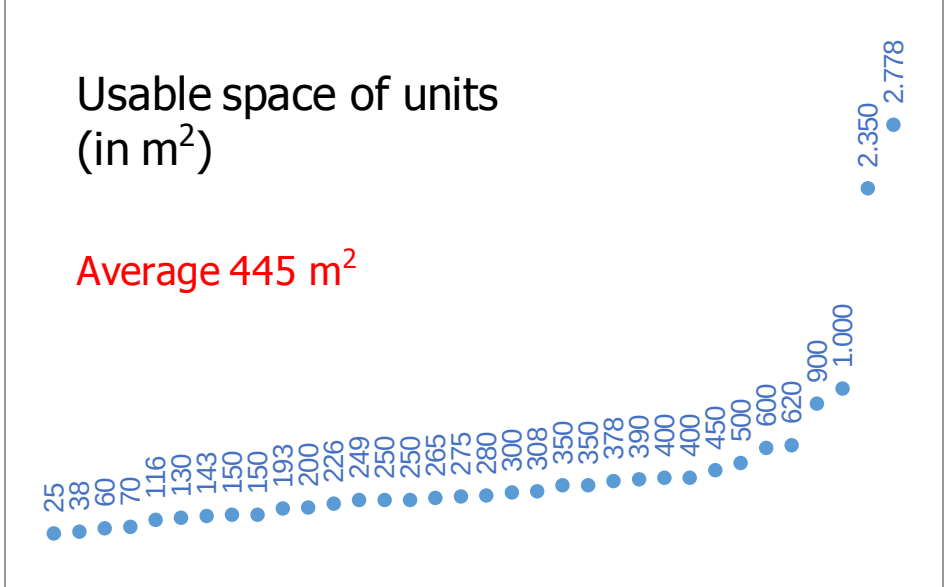
Summary

The figures and tables shown below summarize the main features of the units included in this directory. This information comes under the following **8 main topics**:

1. Ownership and affiliation
2. Accreditations and audits
3. Facilities
4. Staffing and resources
5. Services capabilities
6. Study participants
7. Pharmacodynamic and pharmacokinetic capabilities
8. Experience

Summary

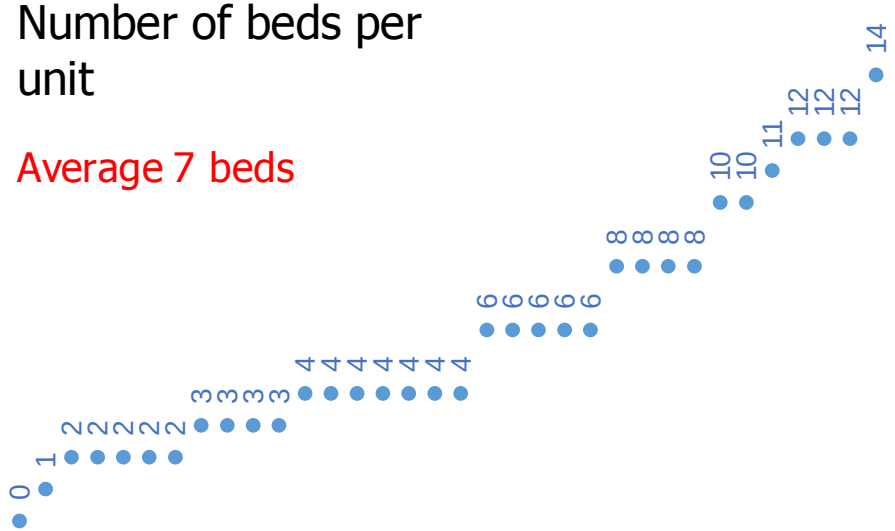

Established
Number of Units
0
1
2
3
4
5
1982
1983
1985
1988
1989
1996
1997
1998
1999
2000
2002
2004
2007
2008
2009
2010
2011
2012
2013
2014
2015


Usable space of units (in m2)
Average 445 m2
25
38
60
70
116
130
143
150
150
193
200
226
249
250
250
265
275
280
300
308
350
350
378
390
400
400
450
500
600
620
900
1.000
2.350
2.778

Summary

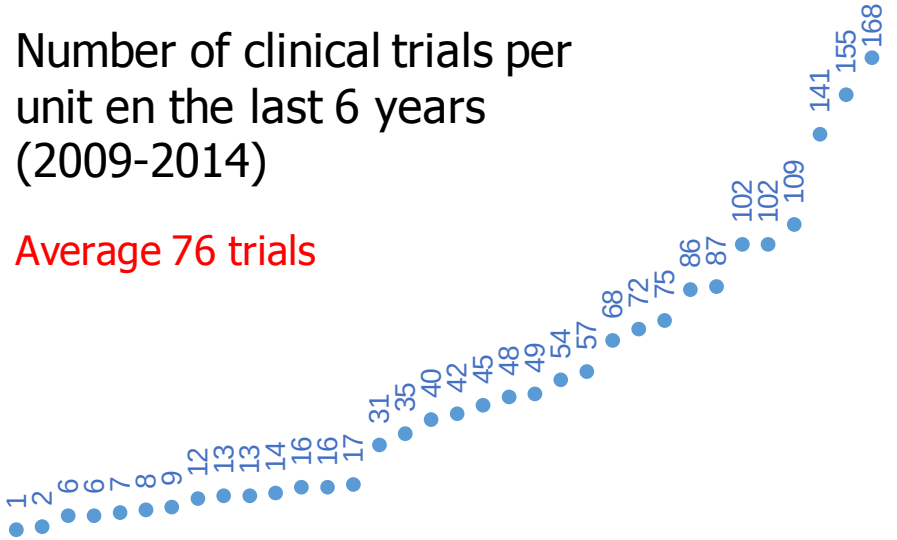
Number of beds per unit

Average 7 beds



Number of clinical trials per unit en the last 6 years (2009-2014)

Average 76 trials



Ownership, when established, and affiliated hospital

Early Stages Unit	Ownership	Established	Affiliated hospital
MACA-ROCÍO	Public	2004	Hospitales Universitarios Virgen del Rocío
V. VICTORIA	Public	2014	Hospitales Universitarios Regional y Virgen de la Victoria
R. SOFÍA	Public	2014	Hospital Universitario Reina Sofía
V. NIEVES	Public	2011	Hospital Universitario Virgen de las Nieves
VALDECILLA	Public	2014	Hospital Universitario Marqués de Valdecilla
CIM-S. PAU	Public	1983	Hospital de la Santa Creu i Sant Pau - Barcelona
ICO	Public	1998	Instituto Catalán de Oncología L`Hospitalet
BELLVITGE	Public	2000	Hospital Universitario de Bellvitge
G. TRIAS	Public	1985	Hospital Universitari Germans Trias i Pujol
S. JOAN DEU	Public	2012	Hospital Materno Infantil Sant Joan de Déu y Hospital Parc Sanitari Sant Joan de Déu
IMIM	Public	1982	Hospital del Mar
CLINIC	Public	2008	Hospital ClInic Barcelona
V. HEBRON	Public	1999	Hospital Universitario Vall d'Hebron
UEC ALICANTE	Public	2010	Hospital General Universitario de Alicante
INCLIVA	Public	2004	Servicio de Hematología y Oncología Médica (HCUV)
HGU VALENCIA	Public	2011	Consorcio Hospital General Universitario de Valencia
UICAB-LA FE	Public	2013	Hospital Universitari i Politècnic La Fe
IVO	-	2009	-
CICAB	Public	2007	Complejo Hospitalario Universitario de Badajoz. Hospital Universitario Infanta Cristina

Ownership, when established, and affiliated hospital

Early Stages Unit	Ownership	Established	Affiliated hospital
HCU SANTIAGO*	Public	2015	Hospital Clínico Universitario de Santiago
HU CORUÑA	Public	2010	Complejo Hospitalario Universitario A Coruña
CICA GETAFE	Public	2010	Hospital Universitario de Getafe
UAM	Public	1989	Hospital Universitario La Paz
G. ULLA	Public	2002	Hospital Central de la Defensa Gómez Ulla
LA PRINCESA	Public	1997	Hospital Universitario de La Princesa
CLÍNICO	Public	1998	Hospital Clínico San Carlos
P. HIERRO	Public	1998	Hospital Universitario Puerta de Hierro Majadahonda
ONCO-P.HIERRO	Public	2014	Hospital Universitario Puerta de Hierro Majadahonda
HU 12 OCTUBRE	Public	1996	Hospital Universitario 12 de Octubre
R. Y CAJAL	Public	2010	Hospital Ramón y Cajal
LA PAZ	Public	2009	Hospital Universitario La Paz
HM-START	Private	2008	Hospital HM Universitario Sanchinarro
FJD-START	Private	2014	Hospital Universitario Fundación Jiménez Díaz
G. MARAÑÓN	Public	2011	Hospital General Universitario Gregorio Marañón
CU NAVARRA	Private	1988	Clínica Universidad de Navarra
HU ARABA	Public - Private	1997	Hospital Universitario Araba (HUA)
ONKOLOGIKA	Private	2013	Fundación Onkologikoa

Accreditations and audits

Items collected in the table below are:

- **Accreditations**: number of accreditations obtained by the unit coming from the regions' administration (*comunidad autónoma*) o any other local, national or international organization during the last 3 years.
- **Audits by authorities**: number of audits carried out on the unit by national or international regulatory agencies during the last 3 years.
- **Audits by sponsors**: number of audits carried out on the unit by sponsors (private or public) during the last 3 years.
- **Internal audits per year**: number of internal audits carried out per year, including the general audits and those related to particular clinical trials.
- **SOPs**: availability of its own Standard Operating Procedures (SOPs).

Accreditations and audits

Early Stages Unit	Accreditations	Audits by authorities	Audits by sponsors	Internal audits (per year)	SOPs
MACA-ROCÍO	0	0	3	-	YES
V. VICTORIA	0	0	0	1	YES
R. SOFÍA	0	0	0	1	YES
V. NIEVES	1	0	18	6	YES
VALDECILLA	1	0	1	1	YES
CIM-S. PAU	1	1	SI	24	YES
ICO	0	0	0	0	YES
BELLVITGE	0	0	SI	1 or 2	YES
G. TRIAS	0	0	0	1	YES
S. JOAN DEU	0	0	5	3	YES
IMIM	0	0	2	1	YES
CLINIC	0	0	SI	4	YES
V. HEBRON	0	2	4 or 5	0	YES
UEC ALICANTE	1	0	2	1 general and 1 per trial	YES
INCLIVA	0	0	0	NA	YES
HGU VALENCIA	0	1	1	2	YES
UICAB-LA FE	0	0	1	1 general and 5 or 6 specific	YES
IVO	0	0	0	2 to 4	YES
CICAB	0	0	1	1	YES

Accreditations and audits

Early Stages Unit	Accreditations	Audits by authorities	Audits by sponsors	Internal audits (per year)	SOPs
HCU SANTIAGO*	0	0	1	2	YES
HU CORUÑA	0	0	0	0	YES
CICA GETAFE	1	0	0	0	YES
UAM	1	1	7	1 per trial	YES
G. ULLA	0	1	1	0	YES
LA PRINCESA	1	1	4	1 per trial	YES
CLÍNICO	0	1	1	3	YES
P. HIERRO	0	0	3	4	YES
ONCO-P.HIERRO	1	0	0	1	YES
HU 12 OCTUBRE	1	1	9	1	YES
R. Y CAJAL	2	0	0	1	YES
LA PAZ	1	0	5	0	YES
HM-START	1	0	3	2	YES
FJD-START	1	0	0	NA	YES
G. MARAÑÓN	1	0	0	3 or 4	YES
CU NAVARRA	1	1	1	Trial dependent	YES
HU ARABA	0	0	3	1 plus 6 per trial	YES
ONKOLOGIKA	0	0	0	NA	YES

Facilities

The table below summarizes information about:

- **Usable space:** the usable space of the unit in square meters.
- **Number of beds:** the number of beds available in the unit for clinical trial participants.
- **Simultaneous clinical trials:** the number of clinical trials that the unit can perform simultaneously.
- **Armchairs:** the number of armchairs suitable for volunteers/patients monitoring in the unit.
- **Resuscitation or emergency trolley:** availability in the unit of a crash or emergency trolley with equipment and medications needed for advanced life support and CPR (cardiopulmonary resuscitation).

Facilities

Early Stages Unit	Usable space (m^2)	Number of beds	Simultaneous Clinical trials	Armchairs	Emergency trolley
MACA-ROCÍO	226	10	12 to 15	2	YES
V. VICTORIA	275	4	12	4	YES
R. SOFÍA	2778	3	3	14	YES
V. NIEVES	60	6	-	12	YES
VALDECILLA	249	4	2	5	YES
CIM-S. PAU	620	26	2	4	YES
ICO	-	2 to 4	6 to 10	2 to 4	YES
BELLVITGE	500	10	2 to 3	0	YES
G. TRIAS	400	6	2	6	YES
S. JOAN DEU	150	4	3 to 4	4	YES
IMIM	280	12	2	12	YES
CLINIC	130	1	3 to 5	6	YES
V. HEBRON	1000	0	60	5	YES
UEC ALICANTE	116	8	2	2	YES
INCLIVA	378	2	15	5	YES
HGU VALENCIA	2350	4	3	8	YES
UICAB-LA FE	300	4	8	9	YES
IVO	25	2	3	4	YES
CICAB	390	9 to 12	4	4	YES

Facilities

Early Stages Unit	Usable space (m^2)	Number of beds	Simultaneous Clinical trials	Armchairs	Emergency trolley
HCU SANTIAGO*	-	4	6	16	YES
HU CORUÑA	-	16	6	20	YES
CICA GETAFE	38	2	2	4	YES
UAM	900	12	3	0	YES
G. ULLA	600	30	3	0	YES
LA PRINCESA	193	14	2	1	YES
CLÍNICO	350	8	It depends	6	YES
P. HIERRO	150	2	4	6	YES
ONCO-P.HIERRO	143	2	2	2	YES
HU 12 OCTUBRE	400	3	15	3	YES
R. Y CAJAL	200	3 to 4	4 to 5	3 to 4	YES
LA PAZ	450	8	-	0	YES
HM-START	250	6	30	6	YES
FJD-START	350	6	16	6	YES
G. MARAÑÓN	250	6	20	4	YES
CU NAVARRA	265	8	3 to 4	6	YES
HU ARABA	308	12	2 to 3	0	YES
ONKOLOGIKA	70	3	5 to 8	1 to 4	YES

Unit Staffing and Resources

The table below shows:

- **Permanent staff:** unit employees who work at the unit as their main activity and have a permanent-contract
- **Fixed-term or contracted staff:** unit employees who work at the unit as their main activity but have a fixed-term contract, such as internship or grant holders
- **Part-time collaborators:** unit employees who work at the unit as a secondary or temporary work activity. They are contracted temporarily for fixed activities in the unit, such as nurses from the affiliated hospital on specific clinical trials.

Staffing and Resources

Early Stages Unit	Permanent Staff	Contracted Staff	Collaborators
MACA-ROCÍO	5	1	1
V. VICTORIA	2	3	-
R. SOFÍA	7	-	20
V. NIEVES	3	1	-
VALDECILLA	6	5	-
CIM-S. PAU	20	-	1
ICO	5	2	6
BELLVITGE	2	2	-
G. TRIAS	5	1	5
S. JOAN DEU	8	1	4
IMIM	3	7	1
CLINIC	23	3	21
V. HEBRON	27	2	0
UEC ALICANTE	4	1	12
INCLIVA	13	-	-
HGU VALENCIA	6	4	15
UICAB-LA FE	18	-	3
IVO	3	-	1
CICAB	5	8	8

Staffing and Resources

Early Stages Unit	Permanent Staff	Contracted Staff	Collaborators
HCU SANTIAGO*	32	13	8
HU CORUÑA	9	9	-
CICA GETAFE	6	5	2
UAM	8	2	19
G. ULLA	2	2	20
LA PRINCESA	5	7	45
CLÍNICO	10	6	10
P. HIERRO	8	2	It depends
ONCO-P.HIERRO	20	3	1
HU 12 OCTUBRE	2	9	3
R. Y CAJAL	4	6	-
LA PAZ	7	6	15
HM-START	18	0	0
FJD-START	9	-	-
G. MARAÑÓN	12	8	-
CU NAVARRA	6	-	4
HU ARABA	8	-	5
ONKOLOGIKA	2	-	2

Services Capabilities

Tables below collect the following topics:

- **Central lab. (bioch.-hemat.):** availability of Central laboratory for safety analysis (biochemical and haematological parameters).
- **Bioanalytical Unit:** the unit has its own Bioanalytical Department.
- **Genotyping and Fenotyping:** availability of genotyping or fenotyping methods for study participants.
- **Data management:** Data Management Department availability.
- **Biometry or Statistical Dept.:** biometry or statistical department available.
- **Drug Accountability:** the Unit regularly uses drug accountability procedures, such as reception, preparation and dispensing forms.
- **Pharmacokinetics:** pharmacokinetic analysis available in the Unit.
- **Medical Writing:** accessibility to Medical Writing Department.
- **Quality Assurance:** the Unit can perform quality assurance activities.
- **Project Management:** available project management department in the Unit.
- **Drug storage and preparation area: a**vailability in the Unit of a specific area for drug storing and for the preparation of medications to carry out studies.
- **Archives:** the Unit has its own archives for study documentations.

Services Capabilities

Early Stages Unit	Central Lab. (bioch.-hemat.)	Bioanalysis department	Genotyping and Fenotyping	Data Management	Biometry or Statistical	Drug Accountability
MACA-ROCÍO	YES	YES	YES	YES	YES	YES
V. VICTORIA	YES	YES	YES	YES	YES	YES
R. SOFÍA	YES	YES	YES	YES	YES	YES
V. NIEVES	YES	NO	YES	YES	YES	YES
VALDECILLA	YES	YES	YES	YES	NO	YES
CIM-S. PAU	YES	NO	NO	YES	YES	YES
ICO	YES	YES	YES	YES	YES	YES
BELLVITGE	YES	NO	NO	NO	NO	YES
G. TRIAS	YES	NO	NO	NO	NO	YES
S. JOAN DEU	YES	NO	NO	YES	YES	YES
IMIM	YES	YES	YES	NO	YES	YES
CLINIC	YES	NO	-	NO	NO	YES
V. HEBRON	YES	YES	YES	NO	NO	YES
UEC ALICANTE	NO	NO	NO	YES	YES	YES
INCLIVA	YES	NO	NO	NO	NO	YES
HGU VALENCIA	YES	YES	YES	YES	YES	YES
UICAB-LA FE	YES	YES	YES	YES	YES	YES
IVO	YES	NO	NO	YES	NO	YES
CICAB	YES	YES	YES	YES	YES	YES

Services Capabilities (continued)

Early Stages Unit	Pharmacokinetic Analysis	Medical Writing	Quality Assurance	Project Management	Drug storage and preparation area	Own archives
MACA-ROCÍO	YES	NO	YES	-	YES	YES
V. VICTORIA	YES	NO	YES	YES	YES	YES
R. SOFÍA	NO	YES	YES	YES	YES	YES
V. NIEVES	YES	YES	YES	YES	YES	YES
VALDECILLA	YES	NO	YES	NO	YES	YES
CIM-S. PAU	YES	YES	YES	YES	YES	YES
ICO	YES	NO	YES	NO	YES	YES
BELLVITGE	YES	YES	YES	YES	YES	YES
G. TRIAS	NO	YES	YES	YES	YES	YES
S. JOAN DEU	NO	YES	NO	YES	YES	NO
IMIM	YES	YES	YES	NO	YES	YES
CLINIC	NO	NO	YES	NO	YES	YES
V. HEBRON	NO	NO	YES	YES	YES	YES
UEC ALICANTE	YES	YES	NO	YES	YES	YES
INCLIVA	NO	NO	YES	YES	NO	YES
HGU VALENCIA	YES	YES	YES	YES	YES	YES
UICAB-LA FE	YES	NO	YES	YES	YES	YES
IVO	NO	YES	YES	YES	YES	YES
CICAB	NO	YES	YES	NO	YES	YES

Services Capabilities

Early Stages Unit	Central Lab. (bioch.-hemat.)	Bioanalysis department	Genotyping and Fenotyping	Data Management	Biometry or Statistical	Drug Accountability
HCU SANTIAGO*	YES	NO	NO	NO	NO	YES
HU CORUÑA	YES	NO	YES	NO	NO	YES
CICA GETAFE	YES	YES	NO	YES	YES	YES
UAM	NO	NO	YES	YES	YES	YES
G. ULLA	NO	NO	NO	YES	YES	YES
LA PRINCESA	NO	NO	YES	YES	YES	YES
CLÍNICO	YES	YES	NO	YES	YES	YES
P. HIERRO	YES	NO	NO	NO	YES	YES
ONCO-P.HIERRO	YES	NO	NO	NO	NO	YES
HU 12 OCTUBRE	YES	YES	YES	YES	YES	YES
R. Y CAJAL	YES	NO	NO	YES	YES	YES
LA PAZ	YES	NO	YES	YES	YES	YES
HM-START	YES	-	NO	NO	NO	YES
FJD-START	YES	NO	YES	YES	NO	YES
G. MARAÑÓN	YES	YES	YES	YES	YES	YES
CU NAVARRA	YES	NO	NO	YES	YES	YES
HU ARABA	YES	NO	YES	YES	YES	YES
ONKOLOGIKA	-	NO	YES	NO	NO	YES

Services Capabilities (continued)

Early Stages Unit	Pharmacokinetic Analysis	Medical Writing	Quality Assurance	Project Management	Drug storage and preparation area	Own archives
HCU SANTIAGO*	NO	YES	YES	YES	YES	YES
HU CORUÑA	NO	NO	YES	NO	YES	YES
CICA GETAFE	NO	YES	NO	YES	YES	YES
UAM	YES	YES	YES	NO	NO	YES
G. ULLA	YES	YES	YES	NO	YES	YES
LA PRINCESA	YES	YES	YES	YES	YES	YES
CLÍNICO	YES	YES	YES	NO	YES	YES
P. HIERRO	YES	YES	YES	YES	YES	YES
ONCO-P.HIERRO	NO	NO	YES	NO	YES	YES
HU 12 OCTUBRE	NO	YES	YES	YES	YES	YES
R. Y CAJAL	NO	YES	YES	NO	YES	YES
LA PAZ	YES	YES	NO	YES	YES	YES
HM-START	NO	YES	YES	NO	YES	NO
FJD-START	NO	NO	NC	YES	YES	YES
G. MARAÑÓN	NO	YES	YES	YES	YES	YES
CU NAVARRA	YES	YES	YES	NO	YES	NO
HU ARABA	YES	YES	YES	YES	YES	YES
ONKOLOGIKA	NO	NO	-	YES	YES	YES

The Study Participants

Table below collects the following topics:

- **Healthy volunteers, patients**: these are the kind of participants the Unit includes in clinical trials.
- **Clinical Trials in Oncology:** the Unit has experience in different oncology diseases and age groups.
- **Surgery rooms for screening:** the number of available surgery rooms for subject screening.
- **Register of volunteers:** the Unit keeps paper or electronic database of volunteers.

Study Participants

			Clinical Trials in Oncology					
Early Stages Unit	**Healthy volunteers**	**Patients**	**Solid T.**	**Haematol. T.**	**Adults**	**Paediatrics**	**Rooms for screening**	**Register of volunteers**
MACA-ROCÍO	YES	YES	YES	YES	YES	YES	2	YES
V. VICTORIA	YES	YES	YES	YES	YES	YES	2	NO
R. SOFÍA	YES	YES	YES	YES	YES	YES	10	NO
V. NIEVES	YES	YES	YES	YES	YES	YES	2	NO
VALDECILLA	YES	YES	YES	NO	YES	NO	1	NO
CIM-S. PAU	YES	YES	NO	NO	NO	NO	4	YES
ICO	NO	YES	YES	YES	YES	NO	2	NO
BELLVITGE	YES	YES	NO	NO	NO	NO	YES	NO
G. TRIAS	YES	YES	YES	YES	YES	YES	3	YES
S. JOAN DEU	NO	YES	NO	NO	NO	**YES**	4	NC
IMIM	YES	YES	YES	YES	YES	NO	2	YES
CLINIC	NO	YES	YES	YES	YES	NO	2	NO
V. HEBRON	NO	YES	YES	YES	YES	NO	5	NO
UEC ALICANTE	YES	YES	NO	NO	NO	NO	1	NO
INCLIVA	NO	YES	YES	YES	YES	NO	2	NO
HGU VALENCIA	YES	YES	YES	YES	YES	YES	1	YES
UICAB-LA FE	YES	YES	YES	YES	YES	YES	1	NO
IVO	NO	YES	YES	NO	YES	NO	1	YES
CICAB	YES	YES	YES	YES	YES	YES	2	YES

Study Participants

			Clinical Trials in Oncology					
Early Stages Unit	**Healthy volunteers**	**Patients**	**Solid T.**	**Haematol. T.**	**Adults**	**Paediatrics**	**Rooms for screening**	**Register of volunteers**
HCU SANTIAGO*	NO	YES	YES	NO	YES	NO	12	-
HU CORUÑA	YES	YES	YES	NO	YES	NO	7	NO
CICA GETAFE	YES	YES	YES	YES	YES	NO	1	NO
UAM	YES	YES	YES	YES	YES	NO	1	YES
G. ULLA	YES	YES	YES	YES	YES	NO	2	YES
LA PRINCESA	YES	YES	YES	YES	YES	NO	3	YES
CLÍNICO	YES	YES	NO	NO	NO	NO	1	YES
P. HIERRO	YES	YES	NO	NO	YES	YES	1	NO
ONCO-P.HIERRO	NO	YES	YES	NO	YES	NO	2	NO
HU 12 OCTUBRE	NO	YES	YES	NO	YES	NO	3	Not apply
R. Y CAJAL	YES	YES	YES	YES	YES	NO	YES	YES
LA PAZ	YES	YES	YES	YES	YES	YES	1	NO
HM-START	NO	YES	YES	YES	YES	NO	4	NO
FJD-START	NO	YES	YES	YES	YES	NO	3	Not apply
G. MARAÑÓN	NO	YES	YES	NO	YES	NO	3	Not apply
CU NAVARRA	YES	YES	YES	YES	YES	YES	4	YES
HU ARABA	YES	YES	YES	YES	YES	YES	1	YES
ONKOLOGIKA	NO	YES	YES	NO	YES	NO	NO	NO

Pharmacodynamic / Pharmacokinetic Capabilities

The Table below depicts the Unit capabilities in terms of pharmacodynamic and pharmacokinetic assessments:

- **Digital blood pressure devices:** number of digital blood pressure measuring devices available.
- **Pulsioximetry devices:** number of pulsioximetry devices available.
- **12-leads ECG devices:** number of 12-leads ECG devices available.
- **QTc evaluation:** familiarity with evaluation of the QTc interval prolongation according to current rules.
- **CNS function testing:** availability for tests on assessing CNS drug effects in the Unit.
- **Poblational PK/PD modelling:** familiarity in poblational analysis and PK/PD modelling, including writing of clinical reports.
- **Electronic Data Capture capabilities:** familiarity with Electronic Data Capture –EDC applied to clinical trials

Pharmacodynamic / Pharmacokinetic Capabilities

Early Stages Unit	Digital BP devices	Pulsioximetry devices	12-leads ECG devices	QTc evaluation	CNS testing	Poblational PK/PD modelling	Electronic DC capab.
MACA-ROCÍO	10	10	2	YES	-	YES	-
V. VICTORIA	2	2	2	YES	-	NO	YES
R. SOFÍA	17	17	2	NO	NO	YES	YES
V. NIEVES	3	3	YES	NO	-	NO	NO
VALDECILLA	1	8	1	YES	-	NO	NO
CIM-S. PAU	5	1	5	YES	YES	YES	YES
ICO	YES	YES	YES	YES	-	NO	YES
BELLVITGE	3	2	2	NO	-	NO	YES
G. TRIAS	10	8	7	YES	-	NO	YES
S. JOAN DEU	2	2	2	-	NO	NO	YES
IMIM	8	8	4	YES	YES	NO	YES
CLINIC	6	2	1	NO	-	NO	YES
V. HEBRON	5	5	1	YES	YES	NO	YES
UEC ALICANTE	9	2	3	YES	NC	NO	YES
INCLIVA	6	8	4	YES	NO	NO	YES
HGU VALENCIA	2	2	1	NO	YES	YES	YES
UICAB-LA FE	2	1	1	YES	-	YES	NO
IVO	3	1	4	YES	-	NO	YES
CICAB	2	2	2	YES	YES	NO	YES

Pharmacodynamic / Pharmacokinetic Capabilities

Early Stages Unit	Digital BP devices	Pulsioximetry devices	12-leads ECG devices	QTc evaluation	CNS testing	Poblational PK/PD modelling	Electronic DC capab.
HCU SANTIAGO*	6	6	6	YES	-	NO	YES
HU CORUÑA	YES	YES	YES	YES	YES	NO	NO
CICA GETAFE	1	1	1	NO	YES	YES	YES
UAM	2	2	2	YES	YES	YES	YES
G. ULLA	3	2	2	YES	NO	YES	NO
LA PRINCESA	4	1	3	NO	YES	YES	YES
CLÍNICO	3	YES	2	NO	YES	YES	NO
P. HIERRO	4	2	2	YES	NO	NO	YES
ONCO-P.HIERRO	1	1	1	YES	NO	NO	YES
HU 12 OCTUBRE	2	3	2	YES	YES	NO	YES
R. Y CAJAL	6	6	1	YES	YES	YES	YES
LA PAZ	4	5	1	YES	NO	YES	YES
HM-START	1	1	2	YES	-	NO	YES
FJD-START	4	YES	YES	YES	-	NO	YES
G. MARAÑÓN	2	3	2	YES	-	NO	YES
CU NAVARRA	9	8	1+8 monitors	NO	YES	NO	NO
HU ARABA	3	3	3	YES	YES	NO	YES
ONKOLOGIKA	2	1	2	NO	NO	NO	YES

Experience (CTs: Clinical Trials)

Early Stages Unit	CTs in the last 6 years (09-14)	CTs linked to a PEI (IND)	CTs with Spanish sponsors	CTs with multinational sponsors	CTs published	Time to approval of CTs (days)
MACA-ROCÍO	87	87	8	79	87	-
V. VICTORIA	13	6	5	1	0	60
R. SOFÍA	1	-	-	-	-	60
V. NIEVES	12	-	1	10	-	-
VALDECILLA	6	0	1	-	0	30
CIM-S. PAU	57	5	53	4	1	105
ICO	102	30	-	91	>15	>60
BELLVITGE	45	0	0	8	1	60
G. TRIAS	6	2	3	2	-	90
S. JOAN DEU	155	1	0	155	-	-
IMIM	49	6	9	6	24	60
CLINIC	619	0	50	350	5 or 6	60
V. HEBRON	309	0	40	140	4 or 6	65
UEC ALICANTE	16	0	2	3	1	60
INCLIVA	31	14	1	32	15	90
HGU VALENCIA	35	0	2	-	0	45
UICAB-LA FE	9	0	1	8	0	60
IVO	8	8	2	3	1	30
CICAB	141	3	0	9	3	30

Experience (CTs: Clinical Trials)

Early Stages Unit	CTs in the last 6 years (09-14)	CTs linked to a PEI (IND)	CTs with Spanish sponsors	CTs with multinational sponsors	CTs published	Time to approval of CTs (days)
HCU SANTIAGO*	17	8	0	17	-	60
HU CORUÑA	40	0	0	40	1	30
CICA GETAFE	13	6	0	-	0	45 to 60
UAM	68	-	40	14	8	45
G. ULLA	7	0	0	7	0	30
LA PRINCESA	168	95	66	22	55	30
CLÍNICO	48	11	25	15	-	60
P. HIERRO	86	10	6	68	4	60
ONCO-P.HIERRO	184	0	1	3	0	80
HU 12 OCTUBRE	72	20	4	22	15	60
R. Y CAJAL	102	0	7	85	3	60
LA PAZ	54	0	15%	85%	11	60
HM-START	75	31	4	71	27	70
FJD-START	16	0	3	16	0	45 to 50
G. MARAÑÓN	14	2	0	11	-	60
CU NAVARRA	42	3	-	-	4	45
HU ARABA	109	1	30	6	0	60
ONKOLOGIKA	2	2	1	1	0	60

EARLY STAGES CLINICAL RESEARCH UNITS IN SPAIN

Andalusia	Unidad de Ensayos Clínicos Fase I y II (Hospital General.Hospitales U. Virgen Macarena -Virgen del Rocío)
Andalusia	Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria
Andalusia	Unidad de Investigación Clínica - Hospital Universitario Reina Sofía
Andalusia	Unidad de Ensayos Clínicos - Hospital Universitario Virgen de las Nieves
Cantabria	Unidad de Ensayos Clínicos Valdecilla
Catalonia	CIM-Sant Pau (Centre d´Investigació del Medicament)
Catalonia	Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología
Catalonia	Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)
Catalonia	UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol
Catalonia	Unidad de Ensayos Clínicos Sant Joan de Déu
Catalonia	Unidad de Investigación Clínica del Institut Hospital del Mar d'Investigacions Mèdiques (IMIM)
Catalonia	Unidad de Investigación de Nuevas Terapias. Inther Unit. Hospital Clínic de Barcelona
Catalonia	Unidad de Ensayos Clínicos Fase I de Oncología Médica - Hospital Vall D'Hebron
Valencia	Unidad de Ensayos Clínicos de Alicante (UECA)
Valencia	Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA
Valencia	Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia
Valencia	UICAB-Instituto de Investigación Sanitaria La Fe
Valencia	Unidad de Fase I Insittuto Valenciano de Oncología IVO
Extremadura	CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

EARLY STAGES CLINICAL RESEARCH UNITS IN SPAIN

Galicia	Unidad de Ensayos Cínicos - Hospital Clínico Universitario de Santiago
Galicia	Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña
Madrid	Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe
Madrid	Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid
Madrid	Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP
Madrid	Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla
Madrid	Unidad de Estudios de Farmacología Clínica del Hospital Clínico San Carlos
Madrid	Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda
Madrid	Unidad de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda
Madrid	Unidad de Estudios Clínicos en Fase Temprana en Oncología - UFTO. Hospital Universitario 12 de Octubre*
Madrid	Unidad de Ensayos Clínicos. Hospital Ramón y Cajal
Madrid	Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz
Madrid	Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro
Madrid	Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz
Madrid	Unidad de de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón
Navarre	Unidad de Investigación Clínica - Clínica Universitaria de Navarra CUN
Basque country	Unidad de Ensayos Clínicos IIS Bioaraba. Hospital Universitario de Araba
Basque country	Unidad de Terapias Avanzadas – Onkologikoa Donostia
National	net GEICAM Grupo de Investigación

*English version not available

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

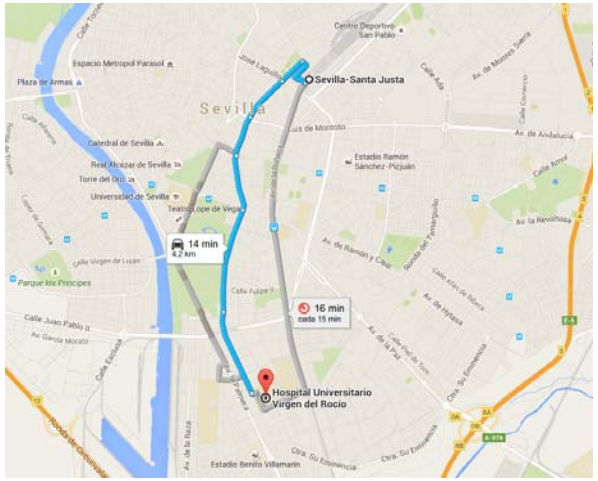
Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

General Information

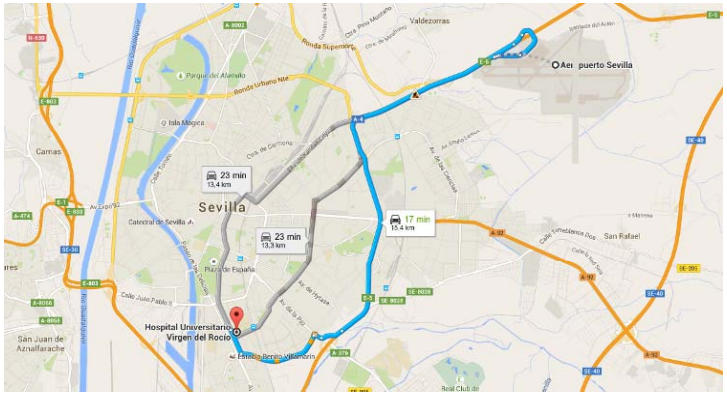
Who filled in this survey	Antonio Cervera Barajas
E-mail contact (Phone number)	uec.hvr.sspa@juntadeandalucia.es
Date of survey filling in	15 May 2015
Unit web address	
Formal name of the unit	Phase I-II Clinical Trial Unit
Postal address	Virgen del Rocío Hospital Universitary General Hospital Avda. Manuel Siurot s/n 41013 SEVILLE SPAIN

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Location



From Santa Justa train station



From San Pablo airport

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Ownership

Ownership	Public hospital
Established	2004
Linked hospital	Virgen del Rocío
Distance between linked hospital and Unit	Allocated in the same hospital
Linked Ethics Committee (CEIC)	CEIC Virgen del Rocío

Unit Manager

First and last names	Juan R. Castillo
Qualifications	MD PhD, full Professor
Medical specialty	Clinical Pharmacology
Manager since	2004
E-mail and phone	jcastillo@us.es 955013175

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Ownership

Short CV

Historial Académico

- Lcdo. En Medicina y Cirugía, en la Facultad de Medicina de Granada el 30-06-1975
- Doctor en Medicina y Cirugía por la F. De Medicina de Granada el 9-11-1978

Historial Profesional

- Situación actual y fecha de inicio: Funcionario a tiempo completo en la Universidad de Sevilla-SAS
  - Catedrático –Facultad de Medicina (Universidad de Sevilla)
  - Jefe de la Unidad Asistencial y Docente de Farmacología Clínica en HHUU Virgen del Rocío Sevilla desde 1989.
  - Coordinador del Centro Andaluz de Farmacovigilancia desde 1994 y Presidente del mismo Centro, según resolución de 5 de Noviembre de 2008 de la Secretaría General de Salud Pública y Participación de la Junta de Andalucía.
  - Responsable de la Unidad de Ensayos Clínicos Fase I y II desde su inicio en 2004

Resumen de Actividad científica

- Publicaciones libros y capítulos de libro: 21. Publicaciones nacionales: 94. Publicaciones internacionales: 50. Tesis Doctorales dirigidas: 13. Proyectos de investigación financiados: 19

Otros méritos

- Presidente del Comité Técnico Andaluz de Farmacovigilancia
- Miembro del Comité Autonómico de Ensayos Clínicos de Andalucía
- Miembro del Comité de Seguridad de Medicamentos de Uso Humano (Órgano colegiado de la Administración General del Estado), nombrado por la Ministra de Sanidad, Servicios sociales e Igualdad el día 11/05/2012 por un periodo de cuatro años.
- Miembro de la Red de Investigadores en Salud Pública dependiente de la Secretaría de Calidad, Innovación y Salud Pública de la Consejería de Igualdad, Salud y Políticas Sociales de la Junta de Andalucía.

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Accreditations and audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

No

Audits by regulatory agencies (last 3 years)

No

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **Yes**

Audits by sponsors (last 3 years)

Yes, 3 audits since 2014

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? Yes

Would you follow the sponsor SOPs if requested: In situations cosidered relevant to the clinical trial

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: None

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

There is a SOP regarding this procedures.

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

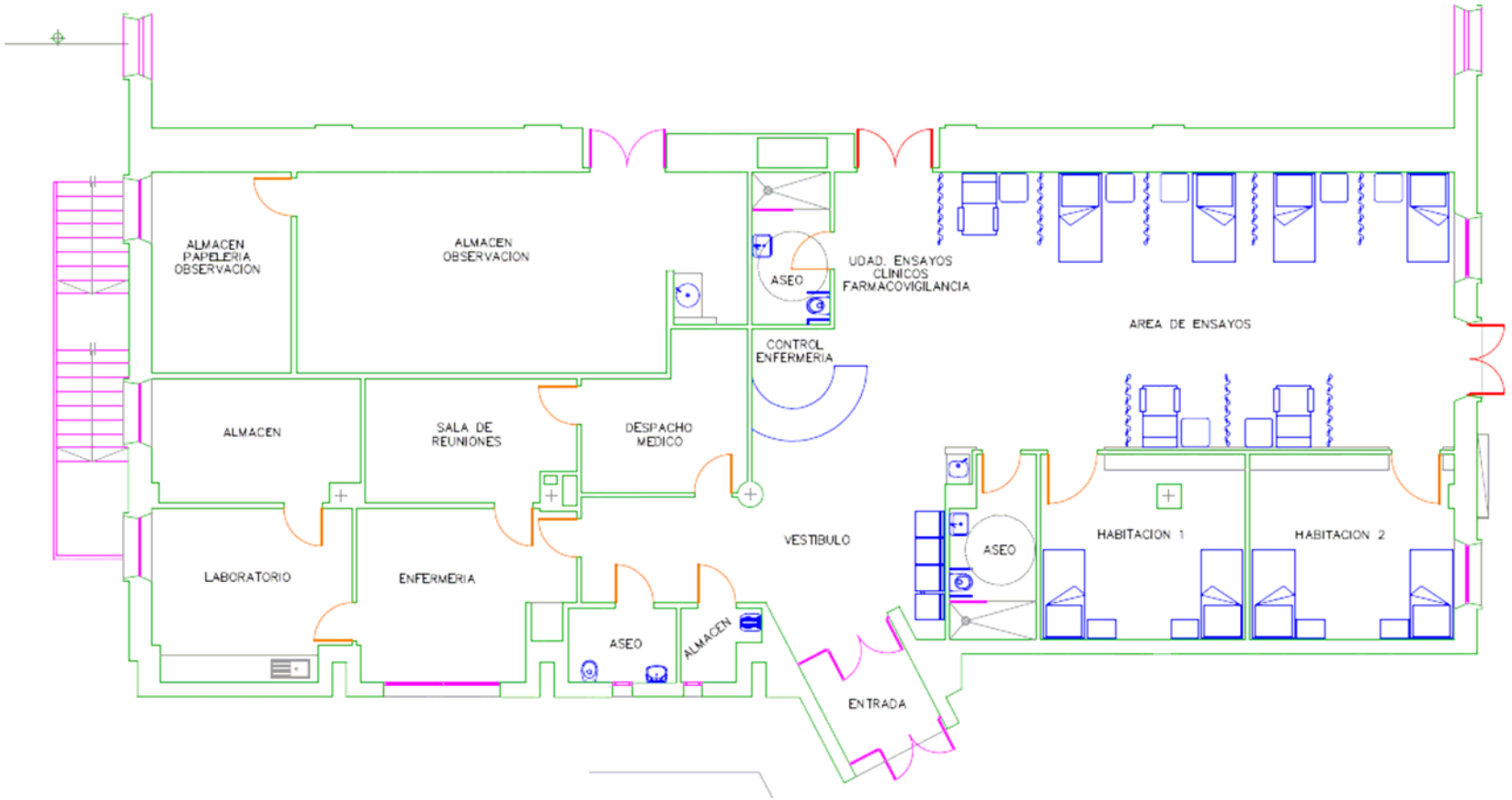
Facilities

Year of Unit building	1956	Last Unit reform	2014
Usable space	226.28	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	12-15	Number of beds	11
Beds distribution	2 rooms with 2 beds each and 1 ward with 7 armchairs for patients		
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	9	Number of armchairs suitable for subject monitoring	2
Owned kitchen	NO	Meals supervision by dietitian	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	No
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Critical Care Unit, Accident & Emergency Unit		
Distance and time to get the former services	AE is allocated just at the end of the Clinical Trial Unit		
Unit entrance/Exit door controlled	Yes, with a key	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Facilities

Unit distribution plan:



Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Staffing and Resources

Unit employees

Permanent staff 5 Fixed-term/contracted staff (internship, grant holders) 1 Part-time collaborators 1

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	1	
Nurse	2	
Monitor or CRA	5	
Pharmacist	3	
Biometry	1	
Data management	3	
Medical writing	2	
Pharmacokinetics		
Quality assurance		
Project Management	3	
Finance		
Recruitment		
IT (informatics)		
Other (specify): CTA, psychologist, etc	1 CTA+1 lab tecnician	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician **X** Nurse

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	Yes
The quality assurance activities are subcontracted by the Unit	We have our own Department
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	Yes
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Pharmaceutical **Preparation**: Pharmaceutical Department
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification	
Numeric and bard code. Identifique sticks.	
Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes
Number of centrifuges available	2
System for plasma/fluids samples storing	Yes
Fridges and freezers available in the Unit	2 freezers -20ºC and 1 freezer -80ºC
The Unit has its owned Bioanalytical Department	Yes. Biomedicine Institute of Seville (IBIS)
Availability of genotyping or fenotyping methods for participants	Yes

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Services Capabilities

Data Management and software used (describe)	Yes. Database
Biometry or Statistical Analysis and software used (describe)	Yes
Pharmacokinetic Analysis and software used (describe)	Yes
Medical Writing and skilled languages	Yes
Owned archives in the same Unit building (describe)	Yes

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Once the clinical trial is closed, all the documentation are sent to the main building of Archive Unit where are custodiated over 15 years.

The study files are digitized and converted in a CD or web format	Yes

Project management

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Study Participants

Kind of participants included in clinical trials performed in the Unit

X	Healthy volunteers	X	Patients
	Other populations		

If the Unit has experience in oncology, detail kind of tumour and age groups

X	Solid tumour	X	Haematological tumour	X	Adults		Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All kind of cancer

Recruiting methods for healthy volunteers

Web site and informative flyers.

Recruting methods for patients

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	Yes (2)
Do you keep a paper or electronic database of volunteers? (describe)	Yes
Have you implemented any measure for avoiding the over-volunteering? (describe)	Yes

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	Yes (11)	Pulsioximetry devices (number)	Yes (11)	12-leads ECG devices (number)	Yes (2)

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Yes
Availability in the Unit of tests for assessing CNS drug effects	No
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	Yes
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes

Experience in other kind of PD or PK evaluations not formerly collected

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Yes. In different clinical trials with food interactions.

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence			1	1	2	2
First single-dose administration in humans						
First multiple-dose administration in humans			1		1	
Drug interaction						
Food interaction					2	2
Special populations (Renal or liver impairment, elderly)	8	1	3	3	4	2
Proof of concept (Phase Ib or I/II)	7	6	9	9	8	11
Own research lines		2			1	1
Others (specificying)						

Number of trials linked to a PEI (IND) submission 2009 15 2010 9 2011 14 2012 13 2013 18 2014 18

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Biologicals drugs in different areas: medical oncology, haematology, nephrology and digestive. Inmunology in medical oncology.

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 8 Number of trials promoted by multinational companies 79

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials

Number of Early Stages trials performed in the Unit and published in the last 4 years

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

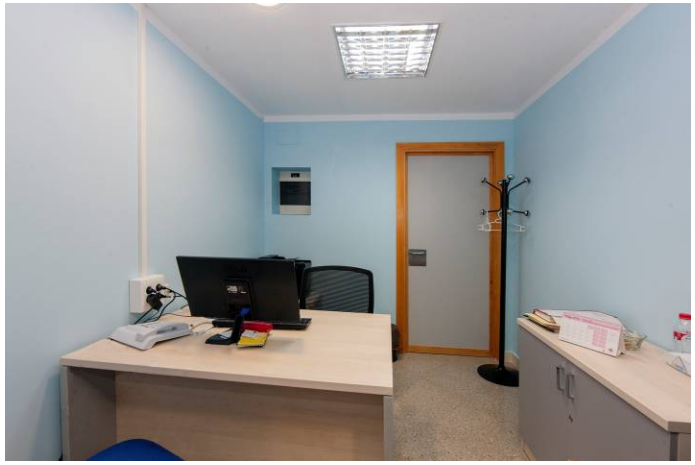
Annexes

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Annexes

Unidad de Ensayos Clínicos Fase I y II (Hospitales U. Virgen Macarena - Virgen del Rocío)

Annexes



Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

General Information

Who filled in this survey	Dr Antonio Pérez-Rielo
E-mail contact (Phone number)	perezrielo@gmail.com
Date of survey filling in	May, 4th, 2015
Unit web address	
Formal name of the unit	Phase I Unit for Regional and Virgen de la Victoria University Hospitals in Málaga (Spain)
Postal address	Virgen de la Victoria University Hospital. Campus de Teatinos s/n 29010-Málaga (Spain)

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Location

MÁLAGA (SPAIN)

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Ownership

Ownership	Andalusian Health Service (SAS)
Established	2014
Linked hospital	Virgen de la Victoria University Hospital
Distance between linked hospital and Unit	No distance
Linked Ethics Committee (CEIC)	Provincial de Málaga

Unit Manager

First and last names	Trigo-Pérez, José Manuel
Qualifications	MD
Medical specialty	Medical Oncology
Manager since	2014
E-mail and phone	E-mail: jmtrigo@seom.org Tel.: + 34 951032083

Short CV

Graduate in Medicine and Surgery at the University of Malaga (Spain) in 1990.
Specialist in Medical Oncology "Doce de Octubre" Hospital in Madrid (Spain) in 1996.
Fellow in the Deaprtment of Clinical Pharmacogy (assistant in the development of phase I trials) at the Royal Marsden Hospital in London (UK) from 1997 to 1999.
Medical Oncologist (assitant in the development of pahe I clinical trials according to ICH Guidelines / GCP) at the Vall d'Hebron Hospital in Barcelona (Spain) from 2000 to 2003.
Medical Oncologist (assisting in the development of clinical trials according to ICH Guidelines / GCP) at the University Hospital Virgen de la Victoria in Malaga (Spain) from 2003 to the present.
Since 2003, he has participated as principal investigator in over 60 clinical trials (according to ICH / GCP guidelines).
Since 2014 in charge of Phase I Trials Unit of Regional and Virgen de la Victoria University Hospitals in Malaga.

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Accreditations and audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

NO

Audits by regulatory agencies (last 3 years)

NO

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? YES

Audits by sponsors (last 3 years) NO

Do you follow your own Standard Operating Procedures (SOPs)? YES Do you supply with a SOP copy to a sponsor if requested? YES

Would you follow the sponsor SOPs if requested: YES

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: NO

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data: Accorfing to the Good Clinical Practice Guidelines

The documents are processed in accordance with the protocols and legal regulations of Clinical Trials. The paper documents are kept in the Archives of liabilities of the Clinical Hospital Documentation that has only access by authorized personnel.

All Databases in digital format has only authotized access by authorized pernonel; no data that would allow the identification of the patients will be provided.

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Facilities

Year of Unit building	1971	Last Unit reform	2014
Usable space	275 m^2	The Unit building is separate from the linked hospital	NO
Number of CTs the unit could perform simultanously	3	Number of beds	4
Beds distribution	Two bedrooms with two beds each one and a room with four recliners as a day hospital		
Beds distribution allows a complete and continuous visual control by nurses			YES
Number of bed with intensive or continuous monitoring	4	Number of armchairs suitable for subject monitoring	4
Owned kitchen	No	Meals supervision by dietitian	YES
Dining-room available for volunteers	YES	Individual lockers available for volunteers	YES
Relaxing room available for volunteers independent from the beds area			YES
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			YES
The emergency trolly has available suitable medications with immediate by controlled access			YES
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	YES		
Unit availability of an evacuation plan for volunteers in emergency situations			YES
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			YES
Volunteers/patients healthcare would be covered by the national or the regional health system if required			YES
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Urgency/Emergency Unit and Intensive care		
Distance and time to get the former services	This is a Unit attached to the Emergency Service of the Hospital		
Unit entrance/Exit door controlled	YES	Unit with Closed Circuit Television	NO
Availability of an alternate electrical generating set that automatically works in case of a general system failure			NO

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Facilities

Unit distribution plan:

The Unit has the following facilities:

- Waiting room
- Blood extraction room
- Two outpatient clinic facilities
- One toilet
- One room for stogare of materials and documentation
- Two rooms for hospitalization with two beds each
- One treatment room (day hospital) with 4 reclinable armchairs
- One refrigeration room witn two freezers (-20 and -80) and one fridge, and a conduct to send blood test directly to our hospital laboratory
- One room for cleaning supplies

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Staffing and Resources

Unit employees

Permanent staff 3 Fixed-term/contracted staff (internship, grant holders) 2 Part-time collaborators

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	1	
Nurse	1	
Monitor or CRA		
Pharmacist		
Biometry		
Data management		1
Medical writing		
Pharmacokinetics		1
Quality assurance		
Project Management		
Finance		
Recruitment		
IT (informatics)		
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

Physician **1** Nurse

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	YES
The quality assurance activities are subcontracted by the Unit	ENAC Certification
Availability of a specific area for drug storing and preparation of medications for the study	YES
The former area or room has restricted access by key or code	YES
Laminar flow chamber availability for preparation of parenteral treatments	YES
Perfusion pumps for intravenous treatment	YES
Who is the responsible for drug preparation and dispensing	**Dispensing:** Pharmacy Department **Preparation**: Pharmacy Department
Drug accountability procedures, such as reception, preparation and dispensing forms	Pharmacy Department
SOPs available for drug preparation and dispensing	YES
SOPs available for drawing and managing of biological fluids	YES

System or procedure used for samples identification

Barcode (identification is determined generally in kits according to the extraction times provided by the promotor/sponsor about the trial to performe. In independent tests, using a code assigned to it and request the extracted tubes are sent to the Central Laboratory of the Hospital

Availability of a specific area for blood samples managing	YES
The former area or room has restricted access by key or code	YES
Number of centrifuges available	1

System for plasma/fluids samples storing

There is one -20 freezer with alarm system, onother -80 freezer with alarm system, a refrigerator and racks for those who need room temperature.

Fridges and freezers available in the Unit	3

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Services Capabilities

The Unit has its owned Bioanalytical Department	YES. In the same hospital
Availability of genotyping or fenotyping methods for participants	YES. TacMan, Applied Biosistem 7500 Fast Real Time PCR, Circulating Tumor Cells (isoflux), multi-Array (Light) in Pathology Department
Data Management and software used (describe)	Not in the Unit. Yes in the hospital
Biometry or Statistical Analysis and software used (describe)	Not in the Unit. Yes in the hospital
Pharmacokinetic Analysis and software used (describe)	Yes, WinNonlin software
Medical Writing and skilled languages	NO medical writer. Skill in English and Spanish
Owned archives in the same Unit building (describe)	YES. Own files in Unit, which are accessed with a key. Hospital files itself where all the documentation is sent once the trial is over. Passive file with restricted access.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

All the information of a trial is locked. Only when a trial is finished, files are sent to the hospital until legal time is over and the documentation can be destroyed.

The study files are digitized and converted in a CD or web format	YES
Project management	YES

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Study Participants

Kind of participants included in clinical trials performed in the Unit

X Healthy volunteers X Patients

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour X Haematological tumour X Adults X Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All kind of tumors

Recruiting methods for healthy volunteers

Detection by the investigator or subinvestigators of candidates for a given clinical trial. We have not yet begun trials with healthy volunteers.

Recruting methods for patients

Following inclusion criteria and advertising in satellite centers asking them to send us patients candidates.

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	YES
Do you keep a paper or electronic database of volunteers? (describe)	NO
Have you implemented any measure for avoiding the over-volunteering? (describe)	NO

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	2	Pulsioximetry devices (number)	2	12-leads ECG devices (number)	2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	YES
Availability in the Unit of tests for assessing CNS drug effects	Not in the Unit, but they are in the Hospital
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	NO
Familiarity with Electronic Data Capture –EDC applied to clinical trials	YES
Experience in other kind of PD or PK evaluations not formerly collected	NO

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Usually, they are externalized to pharmaceutical industries and sponsors.

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						1
First multiple-dose administration in humans						4
Drug interaction						4
Food interaction						2
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)						4
Own research lines						
Others (specificying)						

Number of trials linked to a PEI (IND) submission	2009	2010	2011	2012	2013	2014	6

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Oncology, endocrinology

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 5 Number of trials promoted by multinational companies 1

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 0

Unidad de Fase I Hospitales Universitarios Regional y Virgen de la Victoria

Annexes

Brochure not available in English

Unidad de Investigación Clínica – Hospital Universitario Reina Sofía

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Unidad de Investigación Clínica - Hospital Universitario Reina Sofía

General Information

Who filled in this survey	**José López Miranda**
E-mail contact (Phone number)	jlopezmir@uco.es (0034 957 01 10 40)
Date of survey filling in	20th May 2015
Unit web address	http://www.imibic.org/
Formal name of the unit	Clinical Research Unit – Unidad de Investigación Clínica
Postal address	Hospital Universitario Reina Sofía / Instituto de Investigación Biomédica de Córdoba (IMIBIC) Edificio del Hospital Provincial, 1ª planta - ala izquierda Edificio de Investigación Clínica Avda. Menéndez Pidal, s/n 14004 CÓRDOBA (SPAIN)

Unidad de Investigación Clínica - Hospital Universitario Reina Sofía

Location

La Unidad está ubicada en dos edificios:
Edificio del Hospital Provincial, 1ª Planta con 400 m2: Inaugurado en 1969.
Edificio de Investigación Clínica, con 1.500 m2 en dos plantas: Inaugurado en 1976.

Unidad de Investigación Clínica - Hospital Universitario Reina Sofía

Ownership

Ownership	**Reina Sofía University Hospital / Córdoba Institute of Biomedical Research (IMIBIC in Spanish)**
Established	2014
Linked hospital	Reina Sofía University Hospital
Distance between linked hospital and Unit	The Unit is located in two different buildings within the Reina Sofía University Hospital Provincial Hospital Building, first floor Clinical Research Building
Linked Ethics Committee (CEIC)	Ethics Committee of Córdoba

Unit Manager

First and last names	José López Miranda
Qualifications	Medical Doctor
Medical specialty	Internal Medicine
Manager since	2015
E-mail and phone	jlopezmir@uco.es / 0034 957 01 10 40

Unidad de Investigación Clínica - Hospital Universitario Reina Sofía

Ownership

Short CV

Bachelor and doctor in Medicine by the University of Córdoba in 1986 and 1991, respectively. Dr. López Miranda is a full professor at the Department of Internal Medicine of the University of Córdoba. He is also Director of the Internal Medicine Management Unit of the Reina Sofía Hospital. Whitin the University, he is also Vice-Dean of Hospital Affairs and Director of the Faculty of Medicine.

On the other hand, he is Scientific Director of the Centre of Excellence Research Olive Oil and Health (CEAS in Spanish).

Dr. López Miranda is the principal investigador of the IMIBIC research group of Nutrigenomics and metabolic syndrome which is part of the Biomedical Research Networking Centre in Physiopathology of Obesity and Nutrition (CIBERobn), associate at the Carlos III Health Institute.

Dr. López Miranda has extensive experience in both, healthcare and research fields. Up to date, he has been principal investigator of 26 research projects and has also directed 34 doctoral theses. He is the author of 54 papers published in national journals, 236 papers published in high-impact international journals of the field of Clinical Nutrition, Nutrigenomics, Internal Medicine, Atherosclerosis and their clinical impact. He has published 25 book chapters and has contributed over 520 congress communications.

Unidad de Investigación Clínica - Hospital Universitario Reina Sofía

Accreditations and audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

No

Audits by regulatory agencies (last 3 years)

No

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? Yes

Audits by sponsors (last 3 years)

No

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? Yes

Would you follow the sponsor SOPs if requested: Yes, in these SOPs are acceptable and there are no conflict of interest.

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: The Unit performed an internal audit in 2014

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

The Unit has its own Standard Operating Procedures.

Trial subject's safety: it is specified in the clinical trials protocols. Continued monitoring of the subjects the period of time they remain hospitalised in the Unit.

Data safety: the documents are processed according to the protocol and current legal regulations on clinical trials matters. The data of personal nature is treated in fulfilment of that stipulated in the Spanish Organic Law 15/1999, of December 13, on the Protection of Data of a Personal Nature.

The paper documentation is stored in the file of the Unit in a locked cabinet and with restricted access to authorized staff.

The Unit has a centralised computerized system of the Hospital with personal access and following the Regulation.

Databases access, exclusively restricted to authorised personnel.

Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Facilities

Year of Unit building		Last Unit reform	2014

The Unit is located in two different buildings: Provincial Hospital Building, opened in 1969 and Clinical Research Building, opened in 1976

The Unit building is separate from the linked hospital	No
Usable space	Provincial Hospital Building:400 m², Clinical Research Building: 1.500 m² distributed across two floors of which 200 m² are specially conditioned for Paediatric use.

Number of CTs the unit could perform simultanously	3	Number of beds	3
Beds distribution	1 room with 2 single beds and 1 room with 1 bed		
Beds distribution allows a complete and continuous visual control by nurses			No
Number of bed with intensive or continuous monitoring	All of them	Number of armchairs suitable for subject monitoring	14
Owned kitchen	Yes	Meals supervision by dietitian	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes		
Unit availability of an evacuation plan for volunteers in emergency situations	061 emergency line and Emergency and ICU Services of the Hospital		
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes

Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Facilities

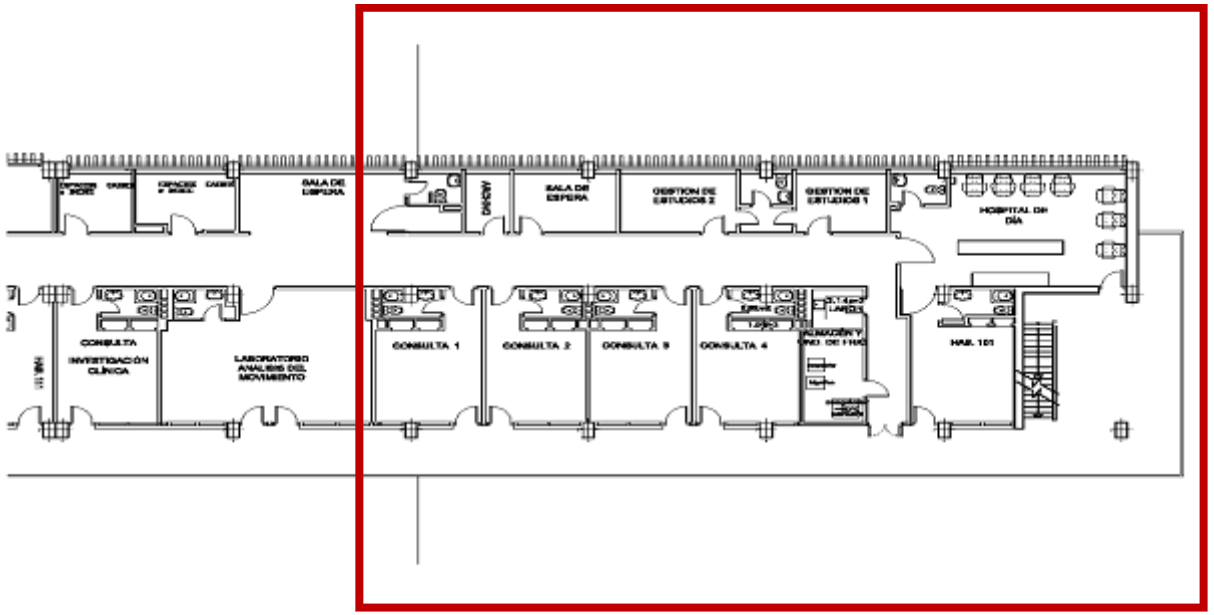
Volunteers/patients healthcare would be covered by the national or the regional health system if required	Yes		
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Yes		
Distance and time to get the former services	100 metres. In the event of emergency, the 061 service would arrive in less than 5 minutes		
Unit entrance/Exit door controlled	Yes, keys and Identity Card	Unit with Closed Circuit Television	Yes
Availability of an alternate electrical generating set that automatically works in case of a general system failure	Yes		

Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Facilities

Unit distribution plan:

The Unit situated in the Provincial Hospital (first floor) has 1 outpatient care, 1 room with 2 beds for hospitalised patients, 4 consulting rooms, 1 processing laboratory and storage of biological samples, 2 data manager offices (Data manager 1 and 2), 1 document archives and 1 waiting area for participants.

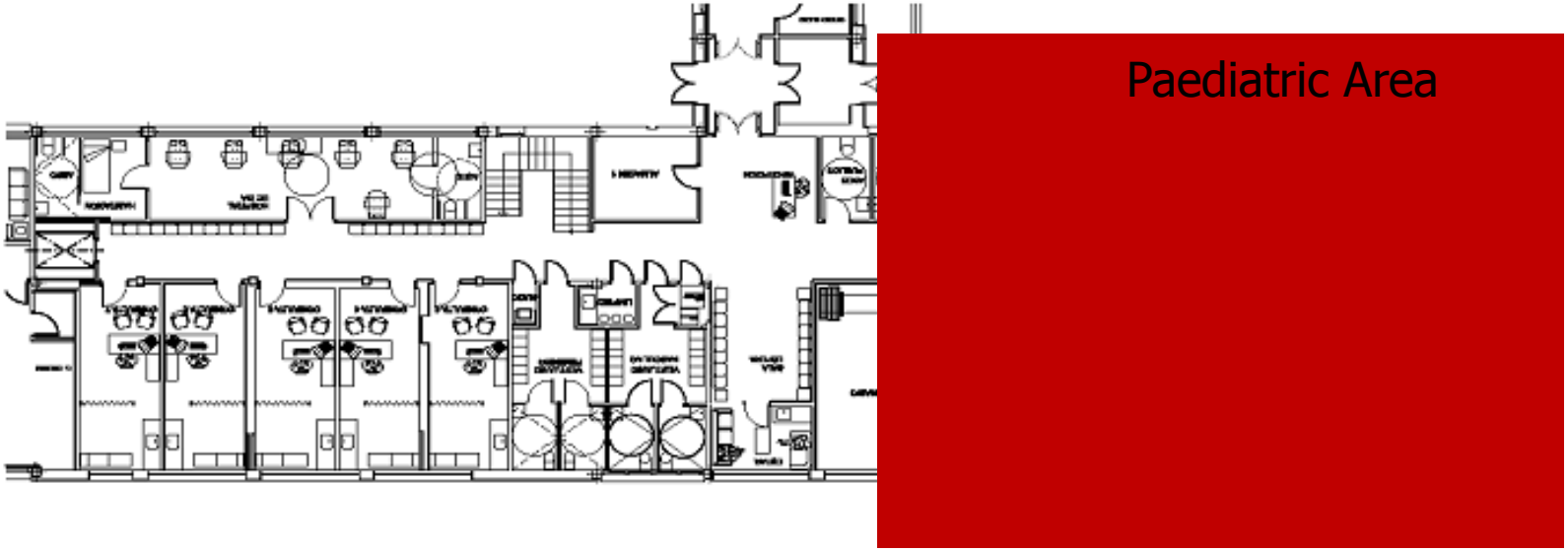


Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Facilities

Unit distribution plan:

The Unit situated in the Clinical Research building, level 0, has an Adult Area: 1 outpatient care, 1 room with 1 bed for hospitalised patients, 5 consulting rooms, 1 reception desk and 1 waiting area for participants with changing rooms. The Paediatric Area has 1 waiting room, 1 consulting room, 1 outpatient care, changing room, storeroom and multifunction room.

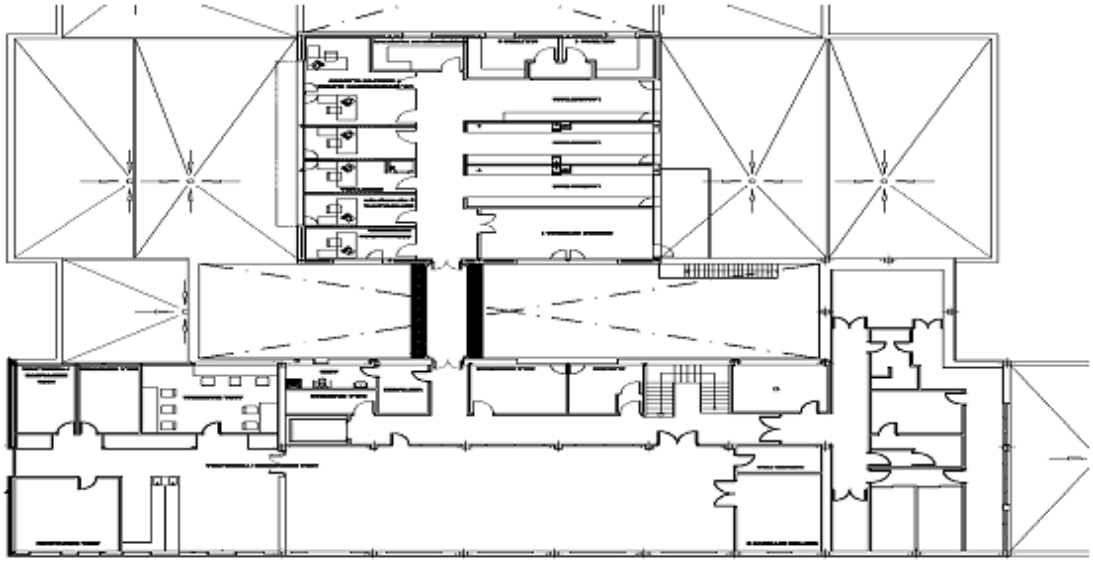


Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Facilities

Unit distribution plan:

There is in level 1, 1 processing laboratory and storage of biological samples, 2 data manager offices, 1 storeroom, 1 document archives and 1 clinical trials managers' office. The Hospital also has a biobank.



Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Staffing and Resources

Unit employees

Permanent staff 7 Fixed-term/contracted staff (internship, grant holders) Part-time collaborators 20

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	1	
Nurse	4	
Monitor or CRA	2	
Pharmacist	2	
Biometry		
Data management	8	
Medical writing	2	
Pharmacokinetics		
Quality assurance	1	
Project Management	1	
Finance	1	
Recruitment		
IT (informatics)	1	
Other (specify): CTA, psychologist, etc	2 Nursing assistant, 1 orderly	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician **X** Nurse

Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	Yes
The quality assurance activities are subcontracted by the Unit	No
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	Yes, in the pharmacy hospital.
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Pharmacist in the hospital **Preparation**: Pharmacist in the hospital
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes

System or procedure used for samples identification stickers with barcode and numbers sticking one of them to each bottle and the same sticker to a petition document.

Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes
Number of centrifuges available	6
System for plasma/fluids samples storing	Freezers in the unit
Fridges and freezers available in the Unit	2 refrigerators and 2 freezers

Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Services Capabilities

The Unit has its owned Bioanalytical Department	Yes, the techniques, infraestructures and equipments are the typicals of the UCAIB belonging to the IMIBIC
Availability of genotyping or fenotyping methods for participants	Yes
Data Management and software used (describe)	Red Cap
Biometry or Statistical Analysis and software used (describe)	SPSS
Pharmacokinetic Analysis and software used (describe)	No
Medical Writing and skilled languages	Spanish and English
Owned archives in the same Unit building (describe)	Yes, restricted access with ID card and cupboards with keys

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived The documentation is sent to file all documentation of the clinical trial being stored during the time stipulated by law

The study files are digitized and converted in a CD or web format	No
Project management	Yes

Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers Yes Patients Yes

Other populations Yes

If the Unit has experience in oncology, detail kind of tumour and age groups

Solid tumour Yes Haematological tumour Yes Adults Yes Paediatrics Yes

What kind of cancer (by organ) patients could be recruited by the Unit

This must be determined by the oncology department

Recruiting methods for healthy volunteers

This has been described in the SOP of the unit

Recruting methods for patients

In collaboration with the different services of the hospital through the main Principal Investigators of each Trial and electronic medical history

Do you have sugery rooms available for screening (separated from the in-house area)? (number) Current legislation will apply

Do you keep a paper or electronic database of volunteers? (describe)

No, we do not because the unit is very recent

Have you implemented any measure for avoiding the over-volunteering? (describe)

The measures dictated by the law

Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	Yes, 17	Pulsioximetry devices (number)	Yes,17	12-leads ECG devices (number)	Yes,2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	No
Availability in the Unit of tests for assessing CNS drug effects	No
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	No
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes
Experience in other kind of PD or PK evaluations not formerly collected	No

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

No

Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)						
Own research lines						
Others (specificying)						

Number of trials linked to a PEI (IND) submission	2009	2010	2011	2012	2013	2014

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies

Number of trials promoted by multinational companies

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60 days

Number of Early Stages trials performed in the Unit and published in the last 4 years

Unidad de Investigación Clínica - Complejo Hospitalario Reina Sofía

Anexos

Brochure not available in English

Unidad de Ensayos Clínicos - Hospital Universitario Virgen de las Nieves

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- Annexes

Unidad de Ensayos Clínicos - Hospital Universitario Virgen de las Nieves

General Information

Who filled in this survey	Dr. Martín García
E-mail contact (Phone number)	ensayosclinicos@hotmail.com
Date of survey filling in	June the 1st, 2015
Unit web address	
Formal name of the unit	Unidad de Ensayos Clínicos – Hospital Universitario Virgen de las Nieves - Granada
Postal address	Hospital Universitario Virgen de las Nieves 4ª planta izq. Hospital General. Unidad de Ensayos Clínicos Avda. Constitución, 100 18012 Granada

Unidad de Ensayos Clínicos - Hospital Universitario Virgen de las Nieves

Location

Unidad de Ensayos Clínicos - Hospital Universitario Virgen de las Nieves

Ownership

Ownership	Dr. Calleja Hernández
Established	Dr. Calleja Hernández
Linked hospital	http://www.hvn.es/
Distance between linked hospital and Unit	The Unit is in the Hospital
Linked Ethics Committee (CEIC)	http://www.hvn.es/invest_calid_docencia/investigacion/comisiones/comite_etico.php

Unit Manager	Dr. Martín García
First and last names	Agustín Martín-García
Qualifications	Master Degree in Chemistry
Medical specialty	Clinical Trials
Manager since	September 2009
E-mail and phone	agustin.martin.garcia.exts@juntadeandalucia.es / 622795953

Short CV

Master Degree in Chemistry 2002
University of Granada, Spain
Post-grade in Integrated Management System 2007
"Centro de Estudios Jurídicos" (CEJ- Granada) Spain
GCP training course 2010
"Agencia Española del Medicamento" AEMPS
Positions held in the last 5 years including current position:
Date From:
September 2009 Coordinator of UCICEC – CAIBER
"Hospital Universitario Virgen de las Nieves"
December 2012 Coordinator of Clinical Trial Unit
"Hospital Universitario Virgen de las Nieves"
Brief Summary of Relevant Clinical Research Experience:
I worked as a Data Manager for 4 months in Carlos Haya Hospital in 2006.
From September 2008 till June 2009, I worked in an investigation group in Granada's University.

Unidad de Ensayos Clínicos - Hospital Universitario Virgen de las Nieves

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

ACSA. Local accreditations of quality, every year

ISO. International accreditations of quality, every year

Audits by regulatory agencies (last 3 years)

We have audits by Sponsors and CROs every other month

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **NA**

Audits by sponsors (last 3 years)

In last 3 years we have 18 audits by sponsors

Do you follow your own Standard Operating Procedures (SOPs)?	yes	Do you supply with a SOP copy to a sponsor if requested?	no, we let the sponsor to see it, but copies are not supply
Would you follow the sponsor SOPs if requested:	no		

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: ACSA and ISO

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Yes, we follow the National and County law's. We work with numbers and we keep lock in a computer document or paper the relation between these numbers and names.

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Facilities

Year of Unit building	2005	Last Unit reform	2011
Usable space	120 m2	The Unit building is separate from the linked hospital	no, it's in the hospital
Number of CTs the unit could perform simultanously	Depends of the kind of trials.	Number of beds	6
Beds distribution	4 in individual room, and other 2 in one big room		
Beds distribution allows a complete and continuous visual control by nurses			no
Number of bed with intensive or continuous monitoring	6	Number of armchairs suitable for subject monitoring	12
Owned kitchen	yes	Meals supervision by dietitian	yes
Dining-room available for volunteers	yes	Individual lockers available for volunteers	yes
Relaxing room available for volunteers independent from the beds area			yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			yes
The emergency trolly has available suitable medications with immediate by controlled access			yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	yes		
Unit availability of an evacuation plan for volunteers in emergency situations			yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers			yes
Distance and time to get the former services			
Unit entrance/Exit door controlled	yes	Unit with Closed Circuit Television	no
Availability of an alternate electrical generating set that automatically works in case of a general system failure	no, hospital provide		

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Staffing and Resources

Unit employees

Permanent staff 4 Fixed-term/contracted staff (internship, grant holders) Part-time collaborators 13

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	Dr. Calleja Hernández	
Co-investigator (physician)	Dr. Martín García	
Nurse		María Isabel Hinojosa
Monitor or CRA	Dr. Martín García	Dr. Zafra Camacho
Pharmacist		Dr. Madrid Paredes, Dr. Hernández Magdalena, Dr. Vallejo
Biometry		
Data management		Coral García Vallecillos, Isabel Mérida, Sandra López, Isabel Rodríguez, Fátima López, Victor García, María Molina
Medical writing		
Pharmacokinetics	Dr. Cañadas Garre	Dr. Aguilera
Quality assurance	Dr. Aznarte Padial	
Project Management	Dr. Martín García	
Finance		
Recruitment		
IT (informatics)		
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician X Nurse

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Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	yes
The quality assurance activities are subcontracted by the Unit	yes
Availability of a specific area for drug storing and preparation of medications for the study	yes
The former area or room has restricted access by key or code	yes
Laminar flow chamber availability for preparation of parenteral treatments	yes
Perfusion pumps for intravenous treatment	yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Dr. Martín García **Preparation**: Dr. Hernández Magadalena, Dr. Vallejo, Dr. Madrid Paredes or Dr. Martín García
Drug accountability procedures, such as reception, preparation and dispensing forms	yes
SOPs available for drug preparation and dispensing	yes
SOPs available for drawing and managing of biological fluids	yes
System or procedure used for samples identification	
The system that supply the hospital	
Availability of a specific area for blood samples managing	yes
The former area or room has restricted access by key or code	yes
Number of centrifuges available	3
System for plasma/fluids samples storing	freezer and all temperature require are in the Unit, aldo restricted access by key
Fridges and freezers available in the Unit	yes
The Unit has its owned Bioanalytical Department	no, hospital provide
Availability of genotyping or fenotyping methods for participants	yes

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Services Capabilities

Data Management and software used (describe)

Depends of the CRO or sponsor, they provide its own software.

Biometry or Statistical Analysis and software used (describe)

R package and SPSS

Pharmacokinetic Analysis and software used (describe)

Pharmaclin Windows and PKS

Medical Writing and skilled languages

Owned archives in the same Unit building (describe) yes

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Right now, we use electronic system of documents, that's why we archive forever in electronic device

The study files are digitized and converted in a CD or web format Yes

Project management Yes

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Study Participants

Kind of participants included in clinical trials performed in the Unit

yes Healthy volunteers yes Patients depends of the trial

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

yes Solid tumour yes Haematological tumour yes Adults yes Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

all of them

Recruiting methods for healthy volunteers

by announcement

Recruting methods for patients

Depends of the trial

Do you have sugery rooms available for screening (separated from the in-house area)? (number) no

Do you keep a paper or electronic database of volunteers? (describe) yes

electronic database

Have you implemented any measure for avoiding the over-volunteering? (describe) yes

Depends of the Trials we decide the selection criteria

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Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	5	Pulsioximetry devices (number)	5	12-leads ECG devices (number)	2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	yes
Availability in the Unit of tests for assessing CNS drug effects	yes
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	yes
Familiarity with Electronic Data Capture –EDC applied to clinical trials	
Experience in other kind of PD or PK evaluations not formerly collected	no

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

no

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Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						
First multiple-dose administration in humans						1
Drug interaction	35	36	42	35	37	38
Food interaction						2
Special populations (Renal or liver impairment, elderly)	1	2	1	4	2	4
Proof of concept (Phase Ib or I/II)	1	1	0	1	2	2
Own research lines						
Others (specificying)						

Number of trials linked to a PEI (IND) submission 2009 0 2010 0 2011 0 2012 0 2013 0 2014 0

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

unknown

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies

Number of trials promoted by multinational companies

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials unknown

Number of Early Stages trials performed in the Unit and published in the last 4 years unknown

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Experience

References of clinical trials publications

Jiménez-Varo E, Cañadas-Garre M, Henriques CI, Pinheiro AM, Gutiérrez-Pimentel MJ, Calleja-Hernández MA.
Pharmacogenetics role in the safety of acenocoumarol therapy. Thromb Haemost. 2014 Jun 12;112(3). [Epubahead of print] PubMed PMID: 24919870.
FI: 6,094 Q1. TIPO DE PUBLICACIÓN: A

Manrique-Rodríguez S, Sánchez-Galindo AC, López-Herce J, Calleja-Hernández MA, Martínez Martínez F,
Iglesias- Peinado I, Carrillo-Álvarez A, Sanjurjo-Sáez M, Fernández-Llamazares CM. Implementing smart pump technology in a pediatric intensive care unit: a cost-effective approach. Int J Med Inform 2014; 83 (2): 99-105. FI:2.061 Q1 (Computer Science, Information Systems)
TIPO DE PUBLICACIÓN: A

Manrique-Rodríguez S, Sánchez-Galindo AC, López-Herce J, Calleja-Hernández MA, Iglesias-Peinado I, CarrilloÁlvarez
Á, Sanjurjo Sáez M, Fernández-Llamazares CM. “Risks in the implementation and use of smart pumps in a pediatric intensive care unit: application of the failure mode and effects analysis”. In J Technol Assess. 2014. Aceptado para su publicación. FI: 1,55 Q3 (HEALTH CARE SCIENCES & SERVICES)
TIPO DE PUBLICACIÓN: A

Martínez-Santana V, González-Sarmiento E, Calleja-Hernández M, Sánchez-Sánchez T. Comparison of drug survival rates for tumor necrosis factor antagonists in reumatoide artritis. Patient Prefer Adherente. 2013 Jul. 29;7:719-27. doi: 10.2147/PPA.S47453 FI :1.33 Q :2(MEDICINE, GENERAL & INTERNAL) TIPO DE PUBLICACIÓN: A

Heredia M, Tenías JM, Rocio R, Amparo F, Calleja MA, Valenzuela JC. Quality of life and predictive factors in patients undergoing assisted repreduction techniques. Eur J Obstet Gyn R B. 2013 Apr;167(2):176-80. doi:10.1016/j.ejogrb.2012.12.011. Epub 2013 Jan 21 FI: 1.84 Q:2 (OBSTETRICS & GYNECOLOGY)TIPO DE PUBLICACIÓN: A

Manrique-Rodríguez S, Sánchez-Galindo A, López-Herce J, Calleja-Hernández MA, Martínez-Martínez F,Iglesias-Peinado I, Carrillo-Álvarez Á, Sanjurjo-Sáez M, Fernández-Llamazares CM. Impact of implementing smart infusion pumps in a pediatric intensive care unit. Am J Health Syst Pharm. 2013; 70 (21): 1897-906. FI:1.984 Q3 (PHARMACOLOGY & PHARMACY) TIPO DE PUBLICACIÓN: A

Cortijo-Cascajares S, Nacle-López I, García-Escobar I, Aguilella-Vizcaíno MJ, Herreros-de-Tejada A, Cortés-Funes Castro H, Calleja-Hernández MÁ.
Effectiveness of oxaliplatin desensitization protocols. Clin Transl Oncol.2013 Mar;15(3):219-25. FI: 1.276 Q:4 (ONCOLOGY)
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Experience

References of clinical trials publications

Allende Bandrés MA, Arenere Mendoza M, Gutiérrez Nicolás F, Calleja Hernández MA, Ruiz La Iglesia F.Pharmacist-led medication reconciliation to reduce discrepancies in transitions of care in Spain. Int J Clin Pharm.2013 Jul 24. FI: 0.859. Q:4 (PHARMACOLOGY & PHARMACY)
TIPO DE PUBLICACIÓN: A

Cordero Cruz AM, Moreno Villares JM, Gomis Muñoz P, Valero Zanuy MA. [Pilot study of intravenous fluid therapy management in adult patients at a tertiary care hospital]. Nutr Hosp. 2012 May-Jun;27(3):943-7. doi:10.3305/nh.2012.27.3.5744. Impact Factor 2012: 1.305. Q:4 (NUTRITION & DIETETICS)
TIPO DE PUBLICACIÓN: A

Cecilia M. Fernández-Llamazares, M.A. Calleja, S. Manrique-Rodriguez, C. Pérez- Sánz, E. Durán-García, M.Sanjurjo-Saéz,. Impact of clinical pharmacist interventions in reducing paediatric prescribing errors. Arch Dis Child. 2012;97:564–568 FI: 3.051 Q1 (PEDIATRICS)
TIPO DE PUBLICACIÓN: A

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TIPO DE PUBLICACIÓN: A

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TIPO DE PUBLICACIÓN: A

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TIPO DE PUBLICACIÓN: A

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Experience

References of clinical trials publications

Heredia M, Tenías JM, Sanchez M, Fraga MD, Calleja MA, Valenzuela JC. Drug tolerability in assisted reproduction techniques: a longitudinal study. Syst Biol Reprod Med. 2012 Oct;58(5):245-54. doi:10.3109/19396368.2012.687036 FI: 1.847 Q3 (ANDROLOGY)
TIPO DE PUBLICACIÓN: A

Vargas-Rivas JE, Montes-Casas MM, Cancela-Diez B, Martínez-Martínez F, Sabater-Hernández D, Calleja-Hernández MA. Study of compliance with prescription information sheet of trastuzumab prescriptions in a tertiarylevel hospital. Farm Hosp. 2012 May;36(3):135-140.
TIPO DE PUBLICACIÓN: A

Martínez Santana V, Izquierdo Navarro M, Calleja Hernández MÁ, Sánchez Sánchez T, Sainz Gil M. Severe pancytopenia following etanercept administration in rheumatoid arthritis. Int J Rheum Dis. 2012 Aug;15(4):e78-9.FI: 1.650 Q:3 (RHEUMATOLOGY)
TIPO DE PUBLICACIÓN: A

Calleja MA, Vieites JM, Montero-Meterdez T, Torres MI, Faus MJ, Gil A, Suárez A. The antioxidant effect of caryophyllene protects rat liver from carbon tetrachloride-induced fibrosis by inhibiting hepatic stellate cell activation. Br J Nutr. 2012 May 1:1-8. FI:3.302 Q1 (NUTRITION & DIETETICS)
TIPO DE PUBLICACIÓN: A

Plaza-Plaza JC, Aguilera M, Cañadas-Garre M, Chemello C, González-Utrilla A, Faus Dader MJ, Calleja MA.Pharmacogenetic polymorphisms contributing to toxicity induced by methotrexate in the southern Spanish population with rheumatoid arthritis. OMICS. 2012 Nov;16(11):589-95. doi: 10.1089/omi.2011.0142. FI: 2.730. Q:2 ((GENETICS & HEREDITY)
TIPO DE PUBLICACIÓN: A

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TIPO DE PUBLICACIÓN: A

Aznarte Padial P, Perez Vicente S, Zarzuelo Zurita A, Calleja Hernández MA. [Monitoring of quality indicators of prescriptions after acute myocardial infarction] Rev Calid Asist. 2012 May-Jun;27(3):155-60. doi: 10.1016/j.cali.2011.09.009. Epub 2011 Dec 1.
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Experience

References of clinical trials publications

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López-Ruiz, A; Ibáñez-Gil, MA; Calleja-Hernández, MA; Faus-Dader, MJ; Martínez-Martínez, F; Arias-Mediano,JL; Pérez-Vicente, S. Study of the evolution of antidiabetic prescriptions in Spain during the years 2006-2007. O.F.I.L.21;3;11-120. TIPO DE PUBLICACIÓN: A

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Vargas-Rivas JE, Sabater-Hernández D, Calleja-Hernández MA, Faus MJ, Martínez-Martínez F. Role of the hospital pharmacy and therapeutics committee in detecting and regulating off-label drug use. Int J Clin Pharm. 2011 Oct;33(5):719-21 FI: 0.859. Q:4 (PHARMACOLOGY & PHARMACY)
TIPO DE PUBLICACIÓN: A

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Araque-Arroyo P, Ubago-Pérez R, Cancela-Diaz B, Fernández Feijóo MA, Hernádez Magdalena J, Calleja-Hernández MA. Controversies in the management of adjunvan breat cancer with taxanes: Review of the current literature. Cancer Treatment Reviews, Volume 37, Issue 2, April 2011, Pages 105-110 FI: 6.024. Q:1(ONCOLOGY). TIPO DE PUBLICACIÓN: A

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Experience

References of clinical trials publications

Olalla-Ramirez MN, Pérez-Vicente S, Muñoz-Castillo IM, Calleja-Hernández MA. Grado de adherencia al tratamiento antirretroviral para el virus de la inmunodeficiencia humana Pharmaceutical Care España 2010; 12(2): 53-60; ISSN: 1139-6202
TIPO DE PUBLICACIÓN: A

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Experience

References of clinical trials publications

Rojo Venegas K, Aguilera M, Cañadas Garre M, Eisman JA, García A, López JM, Llamas JM, Martínez JL,López-Mezquita B, Calleja MA. VDR gene polymorphisms on risk of osteoporotic hip fracture in an adult population spanish. ARS Pharmaceutica 2010 (51) 3; 193-201 FI: 0.134(SJR) Q3 (PHARMACEUTICAL SCIENCE) TIPO DE PUBLICACIÓN: A

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TIPO DE PUBLICACIÓN: A

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Experience

References of clinical trials publications

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Del Saz-Caracuel, Ana; López-Pastor, Antonio; Ubago-Pérez, Ruth; Criado-Daza, Maria; Aznarte-Padial, Pilar; Calleja-Hernández, Miguel Ángel. Efecto de la implantación de Diraya y nuevas tecnologías en la citación de pacientes en la consulta de Farmacia Hospitalaria. Revista Oficial de la Sociedad Andaluza de Farmacéuticos de Hospitales. 2009 Pág. 19
TIPO DE PUBLICACIÓN: A

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TIPO DE PUBLICACIÓN: A

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Unidad de Ensayos Clínicos - Hospital Universitario Virgen de las Nieves

Experience

References of clinical trials publications

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TIPO DE PUBLICACIÓN: CL

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TIPO DE PUBLICACIÓN: CL

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Unidad de Ensayos Clínicos - Hospital Universitario Virgen de las Nieves

Annexes

Unidad de Ensayos Clínicos Valdecilla

- General Informatin
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

Unidad de Ensayos Clínicos Valdecilla

General Information

Who filled in this survey	Mª BLANCA SANCHEZ SANTIAGO
E-mail contact (Phone number)	bsanchez@humv.es (+34 942204084)
Date of survey filling in	15.MAY.2015
Unit web address	http://www.idival.org/ES/APOYOALINVESTIGADOR/ENSAYOSCLINICOS/Paginas/Inicio.aspx
Formal name of the unit	CLINICAL TRIALS UNIT VALDECILLA
Postal address	UNIVERSITY HOSPITAL "Marqués De Valdecilla" PABELLÓN 15-2nd Floor AVD. VALDECILLA S/N 39008 SANTANDER. SPAIN

Unidad de Ensayos Clínicos Valdecilla

Location

CLINICAL TRIALS UNIT VALDECILLA. SANTANDER. CANTABRIA. SPAIN

Unidad de Ensayos Clínicos Valdecilla

Ownership

Ownership	Valdecilla Biomedical Research Institute (IDIVAL) and University Hospital "Marqués de Valdecilla".
Established	University Hospital "Marqués de Valdecilla"
Linked hospital	
Distance between linked hospital and Unit	The Unit is inside the Hospital
Linked Ethics Committee (CEIC)	Ethics Committee of Cantabria

Unit Manager

First and last names	BLANCA SANCHEZ SANTIAGO
Qualifications	MD, phD
Medical specialty	Clinical Pharmacology
Manager since	2013
E-mail and phone	bsanchez@humv.es (+34 942204084)

Short CV

Clinical pharmacology specialist, Doctor in Medicine and Master by King Juan Carlos University (Madrid) in Study and Treatment of Pain.
Professor of the Department of Physiology and Pharmacology, Faculty of Medicine, University of Cantabria, teaching in medicine and nursing
Secretary of the Ethics Committee of Cantabria from 2010 to 2013.
Numerous publications in the field of clinical pharmacology

Unidad de Ensayos Clínicos Valdecilla

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

ISO 9001: 2008 Certification, on February 2015.

Audits by regulatory agencies (last 3 years)

None

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **yes**

Audits by sponsors (last 3 years)

2

Do you follow your own Standard Operating Procedures (SOPs)? yes Do you supply with a SOP copy to a sponsor if requested? yes

Would you follow the sponsor SOPs if requested: Yes if they are not in conflict with Unit Procedures which habe been validates by ISO 9001:2008 audit.

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: One per year

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

The general procedures of the Unit include a specific procedure for information management. The Clinical Trials Management System (CTMS), an electronic tool in our Unit, is under controlled access by permission keys which are mandatory changed periodically; this system allows traceability of access and use.

The Unit has also access to the medical records of patients, as the Unit is included in the Hospital electronic information system that counts with the pertinent security systems.

Unidad de Ensayos Clínicos Valdecilla

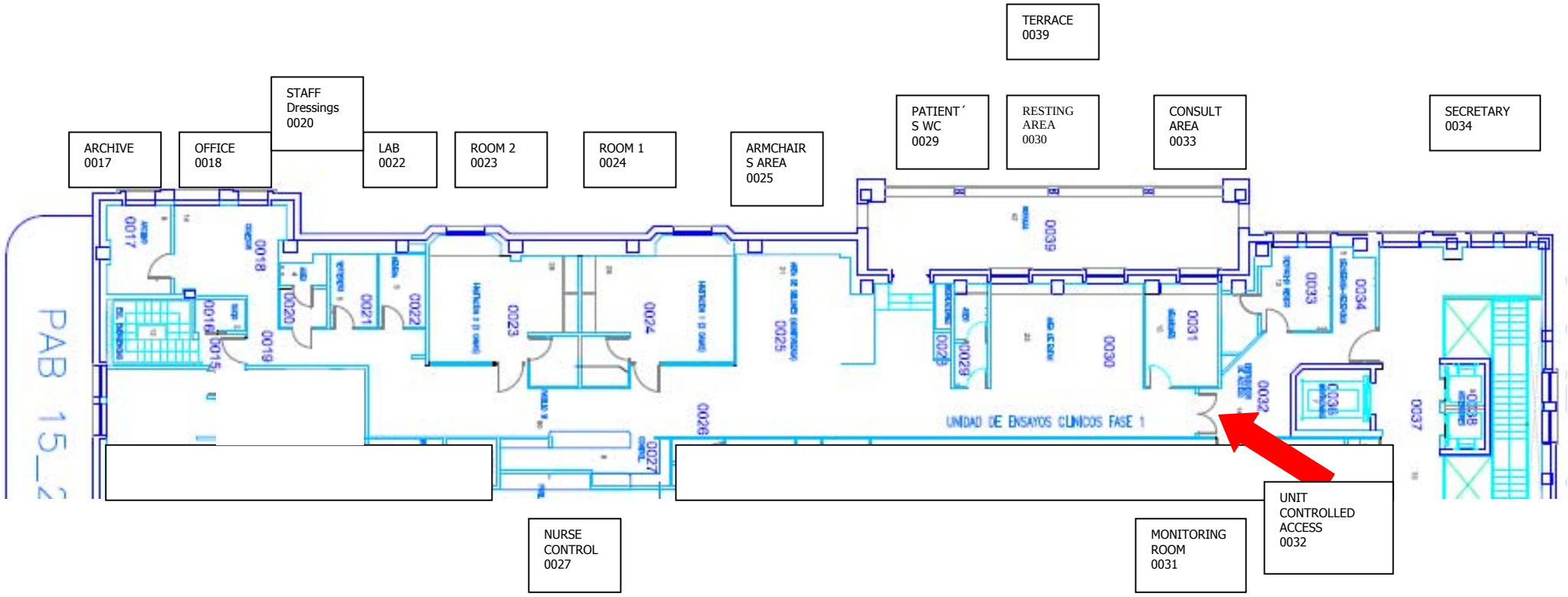
Facilities

Year of Unit building	2012	Last Unit reform	
Usable space	249 m2	The Unit building is separate from the linked hospital	NO
Number of CTs the unit could perform simultanously	2	Number of beds	4
Beds distribution	2 BEDS PER ROOM (TWO ROOMS,)		
Beds distribution allows a complete and continuous visual control by nurses			YES
Number of bed with intensive or continuous monitoring	4	Number of armchairs suitable for subject monitoring	5
Owned kitchen	YES	Meals supervision by dietitian	YES
Dining-room available for volunteers	YES	Individual lockers available for volunteers	YES
Relaxing room available for volunteers independent from the beds area			YES
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			YES
The emergency trolly has available suitable medications with immediate by controlled access			YES
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	YES		
Unit availability of an evacuation plan for volunteers in emergency situations			YES
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			YES
Volunteers/patients healthcare would be covered by the national or the regional health system if required			YES
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Emergency Service and Critical Care Service, both in the same hospital that the Unit, AND Cardiac arrest in hospital-telephone number (3)		
Distance and time to get the former services	The Unit is in the second floor of the building and Emergency and Critical Care services are in floor –1 in the same building. After calling the cardiac arrest telephone number, the time to in-site response will be less than 1 min.		
Unit entrance/Exit door controlled	YES, by an intercom	Unit with Closed Circuit Television	NO
Availability of an alternate electrical generating set that automatically works in case of a general system failure			YES

Unidad de Ensayos Clínicos Valdecilla

Facilities

Unit distribution plan:



Unidad de Ensayos Clínicos Valdecilla

Staffing and Resources

Unit employees

Permanent staff 7 Fixed-term/contracted staff (internship, grant holders) 4 Part-time collaborators 2

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1,2,3	
Co-investigator (physician)	1,2,3	10,11
Nurse	4,5	8
Monitor or CRA		9
Pharmacist	3	
Biometry		12
Data management	2,3	8,9,10,11
Medical writing	1,2,3	
Pharmacokinetics	2	
Quality assurance	3	
Project Management	1,2,3	
Finance	3	
Recruitment	5	8,10,11
IT (informatics)		13
Other (specify): LAB TECH	6,7	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician X Nurse

Unidad de Ensayos Clínicos Valdecilla

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	YES
The quality assurance activities are subcontracted by the Unit	NO
Availability of a specific area for drug storing and preparation of medications for the study	YES
The former area or room has restricted access by key or code	YES
Laminar flow chamber availability for preparation of parenteral treatments	YES
Perfusion pumps for intravenous treatment	YES
Who is the responsible for drug preparation and dispensing	**Dispensing:** If medications don´t need preparation in a laminar flow hood, when it arrives to the Pharmacy Service, the pharmacist makes a block dispensation to the Unit. Then the unit pharmacologist will dispense patient by patient in the trial. Medication in the Unit will be under temperature control and under controlled access. The Unit has a SOP for dispensing and administration. **Preparation**: If medications need to be prepared in a laminar flow hood, pharmacists in the Pharmacy Service (Clinical Trials Section) will be in charge of this issue.
Drug accountability procedures, such as reception, preparation and dispensing forms	The Unit has its own SOP and Logs
SOPs available for drug preparation and dispensing	YES
SOPs available for drawing and managing of biological fluids	YES
System or procedure used for samples identification	

Labelling samples in the point of care. Double check by nurse and physician, and traceability document that accompanies samples to the managing room.

Availability of a specific area for blood samples managing	YES
The former area or room has restricted access by key or code	YES
Number of centrifuges available	1 Refrigerated

Unidad de Ensayos Clínicos Valdecilla

Services Capabilities

Data Management and software used (describe)	CTMS-FUNDANET (Clinical Trials Management System)
Biometry or Statistical Analysis and software used (describe)	The Unit outsources this activity. Dr. LLorca. Chair of Preventive Medicine and Public Health Department of the University of Cantabria.
Pharmacokinetic Analysis and software used (describe)	Compartmental and Non-compartmental analysis. WinNonlin
Medical Writing and skilled languages	NO
Owned archives in the same Unit building (describe)	YES

A 10m2 archive in the Unit, with controlled access and with antifire measures. In this archive, files are kept during the clinical trial progress; when the trial ends, the unifie file will be sent to the General Archive (Section of clinical trials) in Liencres Hospital.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

It depends on the Promotor and legal requirements.

The study files are digitized and converted in a CD or web format	NO
Project management	YES
System for plasma/fluids samples storing	Under a central electronic temperature control system, using annually calibrated probes.
Fridges and freezers available in the Unit	4 Fridges and 2 Freezers (-20ºC, and –70ºC)
The Unit has its owned Bioanalytical Department	The Unit uses the Hospital Bioanalytical Department
Availability of genotyping or fenotyping methods for participants	NO

Unidad de Ensayos Clínicos Valdecilla

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers	X	Patients	X
Other populations			

If the Unit has experience in oncology, detail kind of tumour and age groups

Solid tumour	X	Haematological tumour		Adults	X	Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Breast, Lung, Prostate, Kidney, Colorectal, Skincancer (including Melanoma), osseous,…. The Oncology Service in University Hospital "Marqués de Valdecilla, is a national reference.

Recruiting methods for healthy volunteers

Through advertisements on the website of the Valdecilla Biomedical Research Institute and in newspapers.

Recruting methods for patients

We directly work with professionals in each service in our hospital. In each trial there is at least one investigator (principal or sub-intestigator) coming from the implicated Service; they directly recruit patients or they inform us and introduce us the patient.

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	YES / 1
Do you keep a paper or electronic database of volunteers? (describe)	In process at this moment.
Have you implemented any measure for avoiding the over-volunteering? (describe)	In process at this moment.

Unidad de Ensayos Clínicos Valdecilla

Pharmacodynamic / Pharmacokinetic Capabilities

Digital blood pressure devices (number)	1	Pulsioximetry devices(number):	8	12-leads ECG devices (number)	1

Also monitors in each bed and armchair (9)

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	YES
Availability in the Unit of tests for assessing CNS drug effects	NO
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	NO
Familiarity with Electronic Data Capture –EDC applied to clinical trials	YES
Experience in other kind of PD or PK evaluations not formerly collected	NO

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Unidad de Ensayos Clínicos Valdecilla

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						
First multiple-dose administration in humans						1
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						1
Proof of concept (Phase Ib or I/II)					4	4
Own research lines						1
Others (specificying): High complexity Phase III trials.					12	17

Number of trials linked to a PEI (IND) submission	2009	2010	2011	2012	2013	2014

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Monoclonal Antibodies, Anticoagulants, anti Hepatitis C virus drugs, vaccines, EPOs,

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 1 Number of trials promoted by multinational companies

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 30 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 1

Unidad de Ensayos Clínicos Valdecilla

Annexes

Brochure not available in English

CIM-Sant Pau (Centre d´Investigació del Medicament)

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

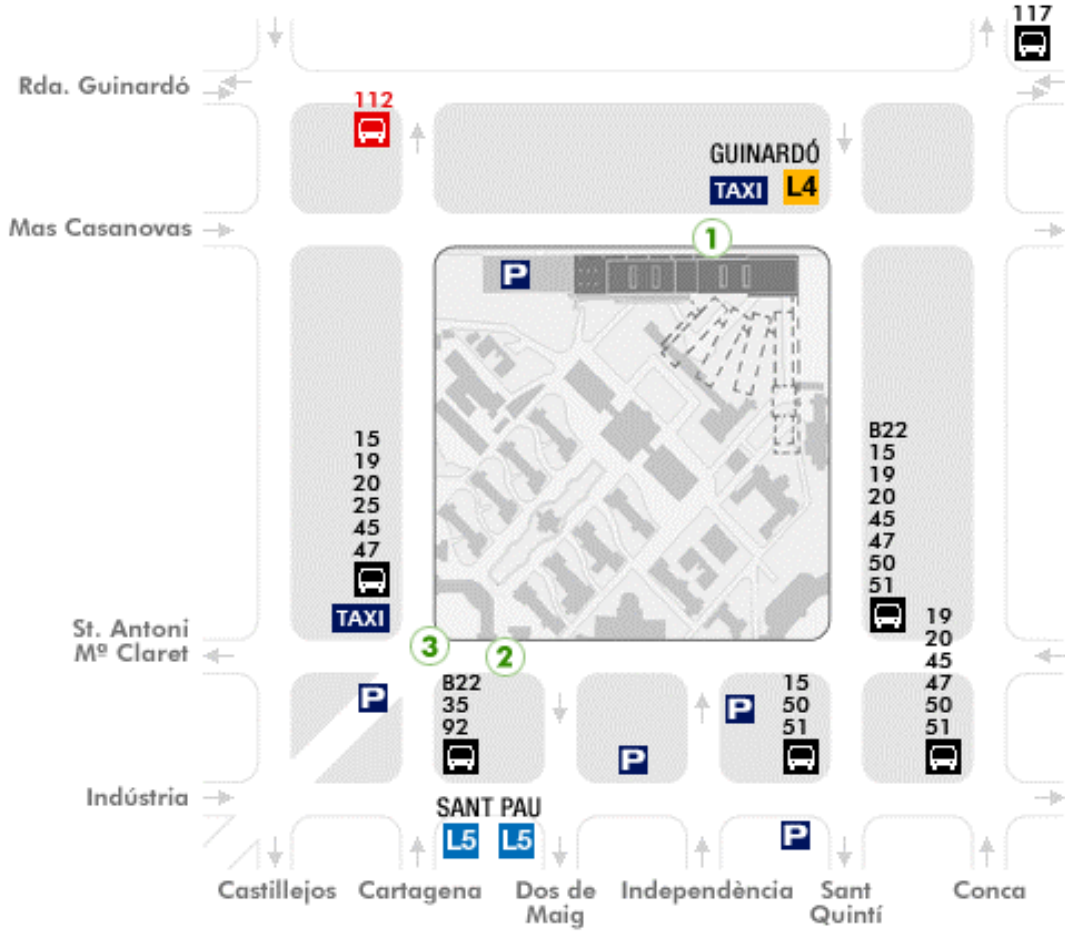
CIM-Sant Pau (Centre d´Investigació del Medicament)

General Information

Who filled in this survey	Jordi Virgili Arumi
E-mail contact (Phone number)	jvirgili@santpau.cat (935537868)
Date of survey filling in	February, 6th 2015
Unit web address	
Formal name of the unit	Drug Research Center. CIM Sant Pau
Postal address	Sant Antoni M. Claret, 167, Pab. 18

CIM-Sant Pau (Centre d´Investigació del Medicament)

Location Barcelona



1- Accés Nou Hospital | 2- Accés Urgències | 3- Accés

CIM-Sant Pau (Centre d´Investigació del Medicament)

Ownership

Ownership	Research Institute Hospital de Sant Pau
Established	1983
Linked hospital	Hospital de la Santa Creu I Sant Pau
Distance between linked hospital and Unit	Located in the health campus HSCSP
Linked Ethics Committee (CEIC)	CEIC Hospital de la Santa Creu I Sant Pau

Unit Manager

First and last names	Rosa Mª Antonijoan Arbòs
Qualifications	Physician
Medical specialty	Clinical Pharmacologyst
Manager since	January, 1st 2011
E-mail and phone	rantonijoana@santpau.cat

Short CV

Since 1989 develops her professional activity, teaching and research, in the Department of Clinical Pharmacology and Drug Research Center (CIM) at the Santa Creu I Sant Pau Hospital (HSCSP) in Barcelona as researcher of the Research Institute at Sant Pau Hospital.
In 2009, she became part of the hospital staff as associated doctor of the Clinical Pharmacology Service. From January 2011 she also is Director of CIM Sant Pau and the Platform for Clinical Trials of the Hospital, dependent of the Institute of Health Carlos III (UICEC Sant Pau), and director-in-charge of the Pharmacology Service
As associated doctor of the Clinical Pharmacology Service at HSCSP is responsible for the development and supervision of clinical trials (CT) carried out at the CIM, mainly Phase I CT in Healthy Volunteers to establish the drug effects in the early stages of development and Phase II CT in limited groups of patients in collaboration with several clinical services of HSCSP to establish more wide kinetic and conceptual information in relation to the study drugs
Her research activity is focuses on the effects of drugs in humans, both from a pharmacological and therapeutic perspective, in order to evaluate tolerability and pharmacokinetics, pharmacodynamics or bioequivalence between different formulations of drugs. An important part of her research is focused on the study of drugs acting on the central nervous system, evaluating different aspects of the motor and sensory-cognitive processing.
She has participated in over 120 clinical trials as principal investigator (PI) and more than 300 clinical trials sponsored by industry. In addition, she has participated in 11 projects of competitive funding (FIS Marató, etc.), being the PI in one of them (FIS 04 / 2268).

CIM-Sant Pau (Centre d´Investigació del Medicament)

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

Generalitat de Catalunya. Health Department. January 2008. Certificate of compliance with GCP

Audits by regulatory agencies (last 3 years) 1

Spanish Medicines Agency. December, 20th 2011

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? YES

Audits by sponsors (last 3 years) 6

Do you follow your own Standard Operating Procedures (SOPs)? YES Do you supply with a SOP copy to a sponsor if requested? YES

Would you follow the sponsor SOPs if requested: YES

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 2014 – 15 internal audits

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

During admission in the CIM, the participants remain in zones allowing continued visual supervision by specialized and trained personnel for the emergency situations management. There are acoustic alarms installed in beds and washrooms which the subject can activate at any time and none submission area allows the closing access by participants.
The CIM is inside the Hospital de la Santa Creu i Sant Pau and near to emergency department. The main emergency procedure in case of serious urgency situation consist in to transfer the subject to the emergency department (5 minutes). In the CIM, there are available SOPs with specific emergency procedures and emergency equipment (crash cart and medication).
All participants have an indentification card indicating his participation in the study and the telephone of the investigator to contact (24h) in any situation of emergency
The personal and medical data from the participants are managed in accordance with Law 15/1999 on Personal Data Protection, and its regulation (RD 1720/2007 of December 21st). Access to this information is restricted to authorized personnel of the CIM. In addition, all information of nature personal is coded in the study documentation.

CIM-Sant Pau (Centre d´Investigació del Medicament)

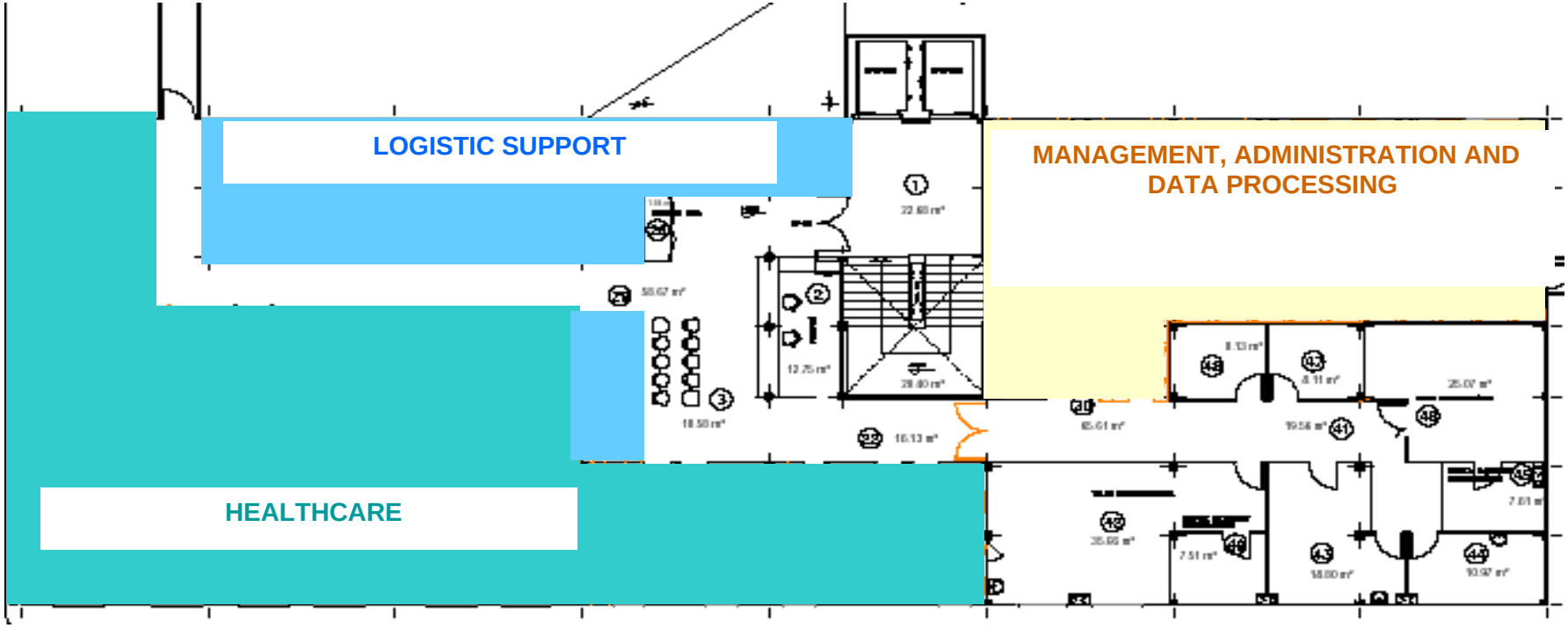
Facilities

Year of Unit building	1986	Last Unit reform	2006
Usable space	620 m^2	The Unit building is separate from the linked hospital	YES
Number of CTs the unit could perform simultanously	2	Number of beds	26
Beds distribution	24 beds in a room (distributed in 4 modules) and 2 independents single-bed rooms		
Beds distribution allows a complete and continuous visual control by nurses			YES
Number of bed with intensive or continuous monitoring	24	Number of armchairs suitable for subject monitoring	4
Owned kitchen	YES	Meals supervision by dietitian	YES
Dining-room available for volunteers	YES	Individual lockers available for volunteers	YES
Relaxing room available for volunteers independent from the beds area			YES
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			YES
The emergency trolly has available suitable medications with immediate by controlled access			YES
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)			YES
Unit availability of an evacuation plan for volunteers in emergency situations			YES
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			YES
Volunteers/patients healthcare would be covered by the national or the regional health system if required			YES
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Emergency Service of HSCSP		
Distance and time to get the former services	400 m and 5 min		
Unit entrance/Exit door controlled	YES	Unit with Closed Circuit Television	YES
Availability of an alternate electrical generating set that automatically works in case of a general system failure			NO

CIM-Sant Pau (Centre d´Investigació del Medicament)

Facilities

Unit distribution plan:



CIM-Sant Pau (Centre d´Investigació del Medicament)

Staffing and Resources

Unit employees

Permanent staff 20 Fixed-term/contracted staff (internship, grant holders) Part-time collaborators 1

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1, 2, 3, 6, 13	
Co-investigator (physician)	2, 3, 4, 5	
Nurse	7, 8, 9, 10	
Monitor or CRA	11, 12	
Pharmacist	6	22
Biometry	13	
Data management	14, 15	
Medical writing	1, 2, 3, 4, 5, 6	
Pharmacokinetics	6, 13	
Quality assurance	16	
Project Management	1, 2, 3, 4, 5, 6	
Finance	17	
Recruitment	7, 8, 9, 10	
IT (informatics)	18	
Other (specify): CTA, psychologist, etc	Lab. Technician (19), Psycologist (20), Secretary (21)	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

Physician Nurse **X**

CIM-Sant Pau (Centre d´Investigació del Medicament)

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	YES
The quality assurance activities are subcontracted by the Unit	NO, since we have a specific department.
Availability of a specific area for drug storing and preparation of medications for the study	YES
The former area or room has restricted access by key or code	YES
Laminar flow chamber availability for preparation of parenteral treatments	YES
Perfusion pumps for intravenous treatment	YES
Who is the responsible for drug preparation and dispensing	**Dispensing:** Dispensing is done by the own unit staff **Preparation**: The medication is prepared by the Pharmacy Service at Sant Pau Hospital
Drug accountability procedures, such as reception, preparation and dispensing forms	YES
SOPs available for drug preparation and dispensing	YES
SOPs available for drawing and managing of biological fluids	YES
System or procedure used for samples identification	codified Labels including study information and subject identification
Availability of a specific area for blood samples managing	YES
The former area or room has restricted access by key or code	YES
Number of centrifuges available	3
System for plasma/fluids samples storing	Freezers of -20 ºC or -80 ºC
Fridges and freezers available in the Unit	1 fridge, 3 freezers of -20ºC and 3 freezers of -80ºC
The Unit has its owned Bioanalytical Department	NO. We work with Anapharm, Echevarne, Kymos.
Availability of genotyping or fenotyping methods for participants	NO

CIM-Sant Pau (Centre d´Investigació del Medicament)

Services Capabilities

Data Management and software used (describe) YES

When paper CRFs are used, the data management is carried out by the DPM section of the CIM-Sant Pau for data entry in the database of the study. Data management is carried out according to the SOPs of the CIM-Sant Pau. Data entry is performed in duplicate way by two impartial trained operators using two independent computers (connected to the hospital network in order to facilitate the subsequent database comparisons and to ensure ongoing and long-term security of the data storage). Comparisons between both database and resolution of "queries" are carried out until no discrepancies are found in the comparisons. The software used is ACCESS (versio 2007).
When e-CRFs are used, CIM-Sant Pau collaborates with the company BIOCLEVER, in services for data collection (e-CRF) and data management by means the Clinsight software.

Biometry or Statistical Analysis and software used (describe) YES

Statistical analysis is realized by a statistician following the methodology specified in the Statistical Analysis Plan, approved by de principal investigator and the sponsor prior to obtain study results. The following software are regularly used: IBM-SPSS v. 22.0 and Win-Nonlin-Pro v. 2.0.

Pharmacokinetic Analysis and software used (describe) YES.

Included in the previous item

Medical Writing and skilled languages YES

Owned archives in the same Unit building (describe) YES

The CIM-Sant Pau have a specific area for temporal archive of study documentation. This area has access control and fire detector. The Investigator TMF remains filed in the CIM-Sant Pau up to the study close-up.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

After study close-up all study related documentationThen is sent to the central department of Management and Clinical Trials Documentation (AGDAC) of the hospital. Later, this documentation will be sent to the General Archive of the Hospital de la Santa Creu I Sant Pau. Study documentation will remain filed for 25 years after the end of the clinical trial a longer period, if required by the applicable regulatory requirements

The study files are digitized and converted in a CD or web format YES (only 90% of documentation)

Project management YES

CIM-Sant Pau (Centre d´Investigació del Medicament)

Study Participants

Kind of participants included in clinical trials performed in the Unit

X Healthy volunteers X Patients

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

Solid tumour Haematological tumour Adults Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Lung and breast

Recruiting methods for healthy volunteers

Own Data Base

Recruting methods for patients

Healthcare staff of the Hospital

Do you have sugery rooms available for screening (separated from the in-house area)? (number) YES. 4

Do you keep a paper or electronic database of volunteers? (describe) YES

The unit have an internal electronic database with more than 700 active healthy joung volunteers (demografics: age 18-45; nº females: 351; nº men: 380).

Have you implemented any measure for avoiding the over-volunteering? (describe) YES

Prior to the subject inclusion in a clinical study, it's verified that the subject has not taken part in any clinical trial during the previous months consulting database "Registro de Voluntarios Clínicos" managed by Generalitat de Catalunya and shared by Phase I Units of Barcelona.

CIM-Sant Pau (Centre d´Investigació del Medicament)

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	5	Pulsioximetry devices (number)	1	12-leads ECG devices (number)	3

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	YES. 1 Study
Availability in the Unit of tests for assessing CNS drug effects	YES. Psychomotor performance, , pupillometry, evoked potencials, polysomnography
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	YES. Nonmen
Familiarity with Electronic Data Capture –EDC applied to clinical trials	YES

Experience in other kind of PD or PK evaluations not formerly collected

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Viral loads

CIM-Sant Pau (Centre d´Investigació del Medicament)

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence	6	7	5	3	5	5
First-in human administration	1				2	1
First multiple-dose administration in humans					2	
Drug interaction		1		1		
Food interaction	1			1		
Special populations (Renal or liver impairment, elderly)	1 HIV	1 primary insomnia	1 primary insomnia	1 (diabetes) 1 (cardiacac insufficiency)		
Proof of concept (Phase Ib or I/II)		1			1	1
Own research lines				1		
Others (specificying)	3 (PK)		1 (efficacy) 1 (Nutrional supplements)	2 (PD) 1 (efficacy) 1 (Nutrional supplements)	1 (Nutrional supplements)	

Number of trials linked to a PEI (IND) submission | 2009 | 1 | 2010 | - | 2011 | - | 2012 | 1 | 2013 | 2 | 2014 | 1

CIM-Sant Pau (Centre d´Investigació del Medicament)

Experience

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Antihypertensives, antibiotics, hypoglycemic agents, diuretics, antidepressants, anticoagulants, antipsychotics, anti-inflammatory, asthma drugs, Anti-Parkinson's, Antivirals

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies	53	Number of trials promoted by multinational companies	4

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials: 105 days

Number of Early Stages trials performed in the Unit and published in the last 4 years: 1

References of clinical trials publications

Abadías M, Escriche M, Vaqué A, Sust M, Encina G. Safety, tolerability and pharmacokinetics of single and multiple doses of a novel sigma-1 receptor antagonist in three randomized phase I studies. Br J Clin Pharmacol 2013; 75 (1):103-17

CIM-Sant Pau (Centre d´Investigació del Medicament)

Annexes

Brochure not available in English

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

General Information

Who filled in this survey	Margarita García
E-mail contact (Phone number)	mgarciamartin@iconcologia.net
Date of survey filling in	22th May 2015
Unit web address	http://ico.gencat.cat/es
Formal name of the unit	Development Program of Early Clinical Trials and Adapted Medicine
Postal address	Institut Català d'Oncologia| Av. Gran Via de l'Hospitalet, 199-203 | 08908 L'Hospitalet de Llobregat | Barcelona, Spain

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Location

Map not available

L'Hospitalet de Llobregat , Barcelona, Spain

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Ownership

Ownership	Catalan Institute of Oncology
Established	
Linked hospital	Catalan Institute of Oncology L'Hospitalet
Distance between linked hospital and Unit	
Linked Ethics Committee (CEIC)	Ethics Committee: Hospital Universitario de Bellvitge

Unit Director

First and last names	Ramón Salazar
Qualifications	MD, PhD
Medical specialty	Medical oncology
Director since	2004
E-mail and phone	Tel: +34 93 2607744 Fax: +34 93 2607741 ramonsalazar@iconcologia.net

Short CV

Academic Degrees
• Bachelor of Medicine and Surgery University of Barcelona 1993
• Specialist in Medical Oncology, Hospital Sant Pau, 1998
• PhD. Autonomous University of Barcelona, 1999
• Master in Clinical Pharmacology at the University of Glasgow, 2000
Professional Experience
• Head of Medical Oncology (January 2015)
• Medical specialist and medical researcher and program coordinator for development of new drugs in the Units of GI tumors, gynecological and Phase I trials in the ICO
• Medical specialist oncology service at Vall d'Hebron (2002-2004)
• Medical attached to the medical oncology service at Sant Pau (2001-2002) Hospital
Research experience
• Principal Investigator in over 10 clinical trials in the Medical Oncology Service at the Hospital Vall d'Hebron
• post-doctoral scholarship awarded by the European Society of Medical Oncology, Beatson Oncology Centre (1999-2000). He participated as co-investigator in the development of Phase I clinical trials with new antitumor drugs.
• Principal Investigator in over 100 clinical trials in the Department of Medical Oncology at the Catalan Institute of Oncology L'Hospitalet

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

Audits by regulatory agencies (last 3 years)

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies?

Audits by sponsors (last 3 years)

Do you follow your own Standard Operating Procedures (SOPs)? yes Do you supply with a SOP copy to a sponsor if requested? yes

Would you follow the sponsor SOPs if requested: Yes, after assessing its viability

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial:

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Facilities

Year of Unit building	1980	Last Unit reform	2004
Usable space		The Unit building is separate from the linked hospital	
Number of CTs the unit could perform simultanously		Number of beds	2-4
Beds distribution			
Beds distribution allows a complete and continuous visual control by nurses			no
Number of bed with intensive or continuous monitoring	0	Number of armchairs suitable for subject monitoring	
Owned kitchen	no	Meals supervision by dietitian	yes
Dining-room available for volunteers	no	Individual lockers available for volunteers	yes
Relaxing room available for volunteers independent from the beds area			no
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			yes
The emergency trolly has available suitable medications with immediate by controlled access			yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	yes		
Unit availability of an evacuation plan for volunteers in emergency situations			yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	yes		
Distance and time to get the former services	3 minutes		
Unit entrance/Exit door controlled	no	Unit with Closed Circuit Television	no
Availability of an alternate electrical generating set that automatically works in case of a general system failure			yes

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Facilities

Unit distribution plan: Not available

Hospital services.
Team :
1. Personal care from inpatient and outpatient units specifically trained in the protocol: " Action Guidelines for cardiac arrest in the Hospital Duran i Reynals "
2. First Intervention Team at Catalan Institute of Oncology L'Hospitalet
3. Advanced Resuscitation Team at University Hospital Bellvite
4. Emergency Medical Equipment

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Staffing and Resources

Unit employees

Permanent staff 5 Fixed-term/contracted staff (internship, grant holders) 2 Part-time collaborators 6

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	2	2
Nurse	2	
Monitor or CRA		
Pharmacist	1	
Biometry		
Data management		
Medical writing		
Pharmacokinetics	1	
Quality assurance	1	
Project Management		
Finance	1	
Recruitment		
IT (informatics)		
Other (specify): CTA, psychologist, etc		1 Psycologist, 1 Palliative Care Specialist

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

Physician Nurse

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	Yes, UNE-EN ISO 15189
The quality assurance activities are subcontracted by the Unit	No
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	Yes
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Pharmacy **Preparation**: Pharmacy
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification	Yes
Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes
Number of centrifuges available	2
System for plasma/fluids samples storing	yes
Fridges and freezers available in the Unit	1
The Unit has its owned Bioanalytical Department	Yes, own translational laboratory
Availability of genotyping or fenotyping methods for participants	yes

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Services Capabilities

Data Management and software used (describe)	SQL server
Biometry or Statistical Analysis and software used (describe)	SAS
Pharmacokinetic Analysis and software used (describe)	WinNonlin®. Not compartimental
Medical Writing and skilled languages	English
Owned archives in the same Unit building (describe)	Yes, Room Restricted by personal code

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

All documents, minimum 15 years

The study files are digitized and converted in a CD or web format	no
Project management	CRO

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers Patients Cancer patients

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

yes Solid tumour yes Haematological tumour yes Adults no Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All tumours

Recruiting methods for healthy volunteers

Recruting methods for patients

Patients come from outpatient rooms of oncology and hematology from the centre and the health centre network

Do you have sugery rooms available for screening (separated from the in-house area)? (number) no

Do you keep a paper or electronic database of volunteers? (describe) no

Have you implemented any measure for avoiding the over-volunteering? (describe) no

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	yes	Pulsioximetry devices (number)	yes	12-leads ECG devices (number)	yes

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Yes,> 20 trials
Availability in the Unit of tests for assessing CNS drug effects	no
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	yes
Familiarity with Electronic Data Capture –EDC applied to clinical trials	yes
Experience in other kind of PD or PK evaluations not formerly collected	yes

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Barcelona University

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans	0	0	0	0	1	1
First multiple-dose administration in humans	5	4	4	4	4	3
Drug interaction						1
Food interaction						
Special populations (Renal or liver impairment, elderly)	2	1	0	0	1	1
Proof of concept (Phase Ib or I/II)					1	1
Own research lines	0	0	0	0	1	1
Others (specificying)	5	5	16	17	14	11

Number of trials linked to a PEI (IND) submission 2009 5 2010 4 2011 4 2012 5 2013 6 2014 6

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

oncolytic viruses, new drugs (TKI), other

Sponsor typology for Early Stages trials performed in the last 4 years (2003 to 2006)

Number of trials promoted by Spanish companies Number of trials promoted by multinational companies 90%

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials > 60 days

Number of Early Stages trials performed in the Unit and published in the last 4 years >15

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Experience

References of clinical trials publications

1. 2010 Vilar E, Grünwald V, Schöffski P, Singer H, **Salazar R**, Iglesias JL, Casado E, Cullel-Young M, Baselga J, Tabernero J. A phase I dose-escalating study of ES-285, a marine sphingolipid-derived compound, with repeat dose administration in patients with advanced solid tumors. *Investigational New Drugs.* 30 (1): 299 -305

2. 2011 **Salazar R**, Plummer R, Oaknin A, Robinson A, Pardo B, Soto-Matos A, Yovine A, Szyldergemajn S, Calvet AH. Phase I study of weekly plitidepsin as 1-hour infusion combined with carboplatin in patients with advanced solid tumors or lymphomas. *Investigational New Drugs.* 29: 1406-1413

3. 2011 Melichar B, Casado E, Bridgewater J, Bennouna J, Campone M, Vitek P, Delord JP, Cerman J, **Salazar R**, Dvorak J, Sguotti C, Urban P, Viraswami-Appanna K, Tan E, Tabernero J. Clinical activity of patupilone in patients with pretreated advanced/metastatic colon cancer; results of a phase I dose escalation trial*. British Journal of Cancer.* 105 (11): 1646-1653

4. 2011 Pardo B, **Salazar R**, Ciruelos E, Cortés-Funes H, García M, Majem M, Montes A, Cuadra C, Soto-Matos A, Lebedinsky C, Alfaro V, Paz-Ares L. Phase I and pharmacokinetic study of trabectedin 3-hour infusion every three weeks in patients with advanced cancer and alteration of hepatic function. *Medical Oncology*. 29 (3): 2240-2250

5. 2012 Massard C, **Salazar R**, Armand JP, Majem M, Deutsch E, García M, Oaknin A, Fernández-García EM, Soto A, Soria JC. Phase I dose-escalating study of ES-285 given as a three-hour intravenous infusion every three weeks in patients with advanced malignant solid tumors. *Investigational New Drugs* . 30 (6): 2318-2326

6. 2012 Vidal L, Magem M, Barlow C, Pardo B, Florez A, Montes A, Garcia M, Judson I, Lebedinsky C, Kaye SB, **Salazar R**. Phase I clinical and pharmacokinetic study of trabectedin and carboplatin in patients with advanced solid tumors. *Investigational New Drugs.* 30:616-628

7. 2012 Gómez-Martín C, **Salazar R**, Montagut C, Gil-Martín M, Nuñez JA, Puig M, Lin X, Khosravan R, Tursi JM, Lechuga MJ, Bellmunt J. A phase I, dose-finding study of sunitinib combined with cisplatin and 5-fluorouracil in patients with advanced gastric cancer. *Investigational New Drugs.* 31 (2): 390-398 2012

8. **Salazar R**; Cuadra C; Gil-Martín M; Vandermeeren A; Alfaro V; Coronado C. Complete and Sustained Objetive Response per RECIST to Irvalec (PM02734) in Undifferentiated Large Cell Esophageal Adenocarcinoma: A case report and a review of the literature. *Case Reports in Oncology.*5: 354-358

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Experience

Published trials

9. 2012 **Salazar R**; Jones RJ; .Daknin A; Crawford D; Cuadra C; Hopkins C; Gil M; Coronado C; .Soto-Matos A; Culell-Young M. A phase I and pharmacokinetic study of elisidepsin (PM02734) in patients with advanced solid tumors. *Cancer Chemotherapy and Pharmacolog* . 70 (5): 673-681

10. 2013 **Salazar R**; Cortés-Funes H; Casado E; Pardo B; López-Martín A; Cuadra C; Tabernero J; Coronado C; García M; Soto Matos-Pitas A, Miguel-Lillo B, Cullell-Young M, Iglesias Dios JL, Paz-Ares L. Phase I study of weekly kahalide F as prolonged infusion in patients with advanced solid tumors*. Cancer Chemother Pharmacol*. 72 (1): 75-83

11. 2014 **Salazar R**, Morales S, Gil-Martín M, Aguirre E, Oaknin A, Garcia M, Callies S, Wickremsinhe E, Benhadji K, Llombart A. Phase 1 dose escalation and pharmacokinetic evaluation of oral gemcitabine produg (LY2334737) in combination with docetaxel in patients with advanced solid tumors*. Cancer Chemotherapy Pharmacology* . 73 (6): 1205 -1215

12. 2014 **Salazar R**; Calles A; Gil M; Durán I; García M; Hidalgo M; Coronado C; Alfaro V; Siguero M; Fernández-Teruel C; Prados R; Calvo E. Phase I study of carboplatin in combination with PM00104 (Zalypsis®) in patients with advanced solid tumors. *Invest New Drugs* (in press)

Programa de Desarrollo de Nuevos Fármacos. Instituto Catalán de Oncología

Annexes

Brochure not available in English

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

General Information

Who filled in this survey	Marcela Manríquez Tapia
E-mail contact (Phone number)	mmanriquez@bellvitgehospital.cat (+34932607107)
Date of survey filling in	21/05/2015
Unit web address	N/A
Formal name of the unit	Unidad de Ensayos Clínicos (Hospital Universitari de Bellvitge)
Postal address	Gran Via de l'Hospitalet, 199. 08908 L'Hospitalet de Llobregat. Barcelona Location and directions: https://www.google.com/maps/d/viewer?mid=zmOmBLzEFycI.kqtKmr0SqDyU&msa=0

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

Ownership

Ownership	Public
Established	2000
Linked hospital	Bellvitge Hospital University
Distance between linked hospital and Unit	430mts
Linked Ethics Committee (CEIC)	CREC Bellvitge Hospital University

Unit Manager

First and last names	Marcela Manríquez Tapia
Qualifications	Doctor
Medical specialty	Clinical Pharmacology
Manager since	2009
E-mail and phone	mmanriquez@bellvitgehospital.cat (+34932607107)

Short CV

- Graduate in Medicine (1994)
- Specialist Qualification in Clinical Pharmacology (2000)
- Member of Sociedad Española de Farmacología Clínica
- Clinical pharmacologist Clinical Trials Unit 'Hospital Clínic de Barcelona' (2000 to 2006)
- Clinical pharmacologist Clinical Trials Unit 'Hospital Universitari de Bellvitge' (2006 to present)
- Member of CREC:
  * Corporació Sanitària Parc Taulí (2000 to present)
  * Hospital Universitari de Bellvitge (2006 to 2009)
  * Instituto de Microcirugía Ocular(2006 to present)
- Participation in several clinical trials of different phases (I, II, III)
- Drafting of clinical trial protocols and final reports
- Management and coordination of non-commercial clinical trial

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

Pending accreditation for 2015

Audits by regulatory agencies (last 3 years)

Not

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? Yes

Audits by sponsors (last 3 years) Yes, November 2013

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? Yes

Would you follow the sponsor SOPs if requested: Yes, If standards are met BPC

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 1-2

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Continuous supervision of patients who stay in the unit.
Confidentiality and data protection according Stated in Law 15/1999.
Camera monitoring all area of Unit.
Limited access to the Unit staff.
Restricted access to computers by means of passwords and manuals locked files.

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

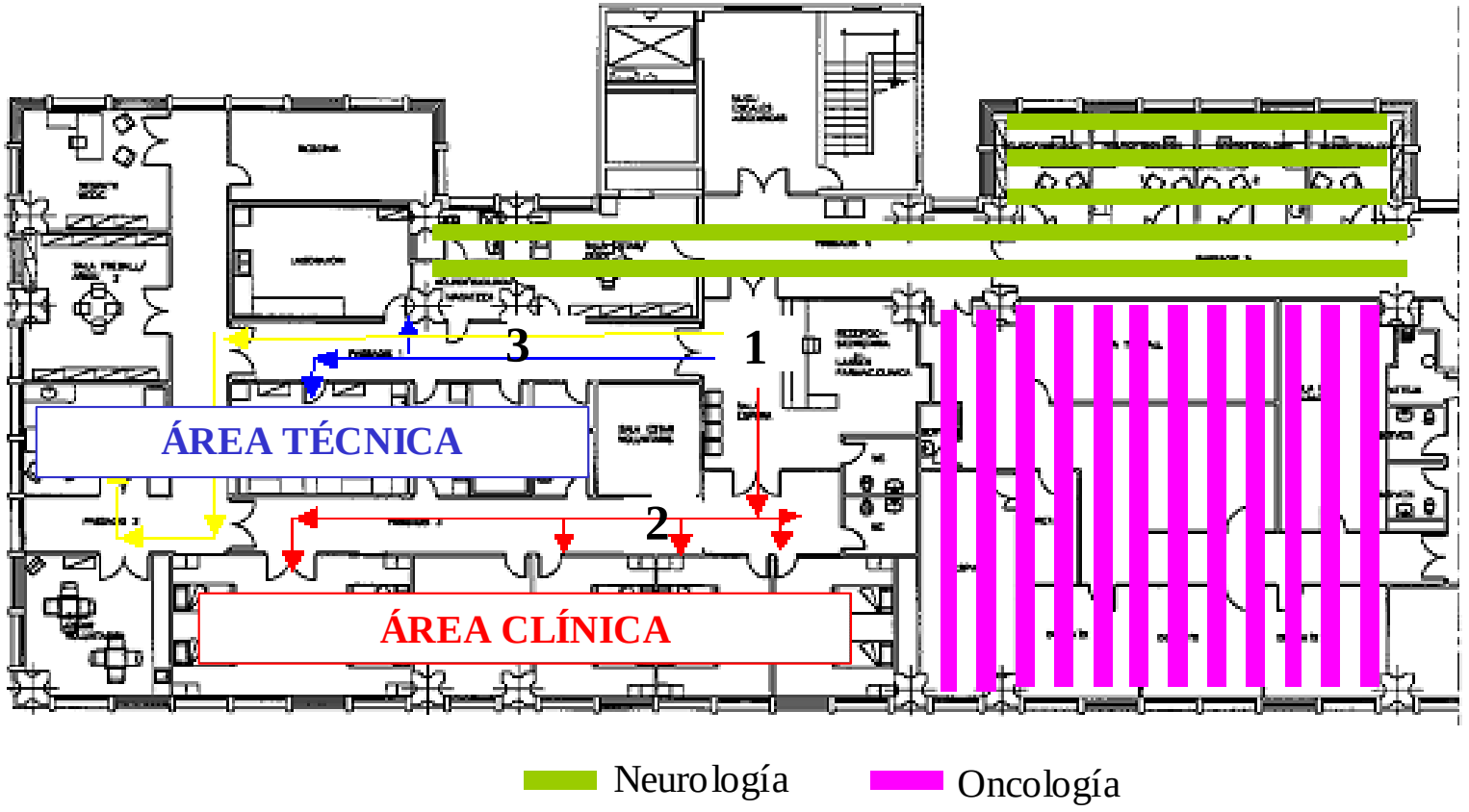
Facilities

Year of Unit building	1977	Last Unit reform	2007
Usable space	500m2	The Unit building is separate from the linked hospital	Yes
Number of CTs the unit could perform simultanously	2-3	Number of beds	10
Beds distribution	A room with four beds and three rooms with two beds each		
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	3	Number of armchairs suitable for subject monitoring	0
Owned kitchen	No	Meals supervision by dietitian	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	yes, both (Basic Life Support or/and Advanced LS)		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Direct connection with emergency equipment		
Distance and time to get the former services	Some meters and few minutes (<5 min usually)		
Unit entrance/Exit door controlled	Yes, by keys	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

Facilities

Unit distribution plan



Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

Staffing and Resources

Unit employees

Permanent staff 2 Fixed-term/contracted staff (internship, grant holders) 2 Part-time collaborators N/A

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	1	3
Nurse	2	4
Monitor or CRA		
Pharmacist		
Biometry		
Data management	1	
Medical writing	1	3
Pharmacokinetics		
Quality assurance	1	
Project Management	1	
Finance	1	
Recruitment	1.3	3
IT (informatics)		
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

x Physician x Nurse

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	UNE-EN ISO 15189: 2007
The quality assurance activities are subcontracted by the Unit	No
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	No
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Unit nurse **Preparation**: Unit nurse
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification	
Label of clinical trial with the requested specific data.	
Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes
Number of centrifuges available	Two centrifuges for samples refrigerated and not refrigerated
System for plasma/fluids samples storing	It depends on the type of sample and the sponsor instructions
Fridges and freezers available in the Unit	1 Fridge and 2 freezers
The Unit has its owned Bioanalytical Department	No
Availability of genotyping or fenotyping methods for participants	

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

Services Capabilities

Data Management and software used (describe)	No
Biometry or Statistical Analysis and software used (describe)	No
Pharmacokinetic Analysis and software used (describe)	No
Medical Writing and skilled languages	Yes

Owned archives in the same Unit building (describe)

Yes, four files locked in rooms restricted to unit personnel

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Master file and CRF non-electronic remain in the unit the time required by law

The study files are digitized and converted in a CD or web format	No
Project management	Yes

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers	Yes	Patients	Yes
Other populations	N/A		

If the Unit has experience in oncology, detail kind of tumour and age groups

Solid tumour		Haematological tumour	
Adults		Pediatrics	

What kind of cancer (by organ) patients could be recruited by the Unit

N/A

Recruiting methods for healthy volunteers

Specific posters previously approved by the CREC

Recruting methods for patients

Recruited by the clinical trial team doctor

Do you have sugery rooms available for screening (separated from the in-house area)? (number) Yes, a consulting room

Do you keep a paper or electronic database of volunteers? (describe)

No

Have you implemented any measure for avoiding the over-volunteering? (describe)

Yes, the database by healthy volunteers of health department of "Generalitat de Catalunya"

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

Pharmacodynamic / Pharmacokinetic Capabilities

Digital blood pressure devices (number)	3	Pulsioximetry devices (number)	2	12-leads ECG devices (number)	2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	No
Availability in the Unit of tests for assessing CNS drug effects	N/A
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	No
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes
Experience in other kind of PD or PK evaluations not formerly collected	N/A

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

N/A

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)	2					
Proof of concept (Phase Ib or I/II)	4	4	4	4	4	4
Own research lines						
Others (specificying)	2	3	3	4	4	3

Number of trials linked to a PEI (IND) submission | 2009 | 0 | 2010 | 0 | 2011 | 0 | 2012 | 0 | 2013 | 0 | 2014 | 0

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Antipsychotics, anti-platelet, anti-TNF, diverse monoclonal antibodies

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies - Number of trials promoted by multinational companies 8

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 1

Unidad de Ensayos Clínicos (Hospital Universitario de Bellvitge)

Annexes

Brochure not available in English

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

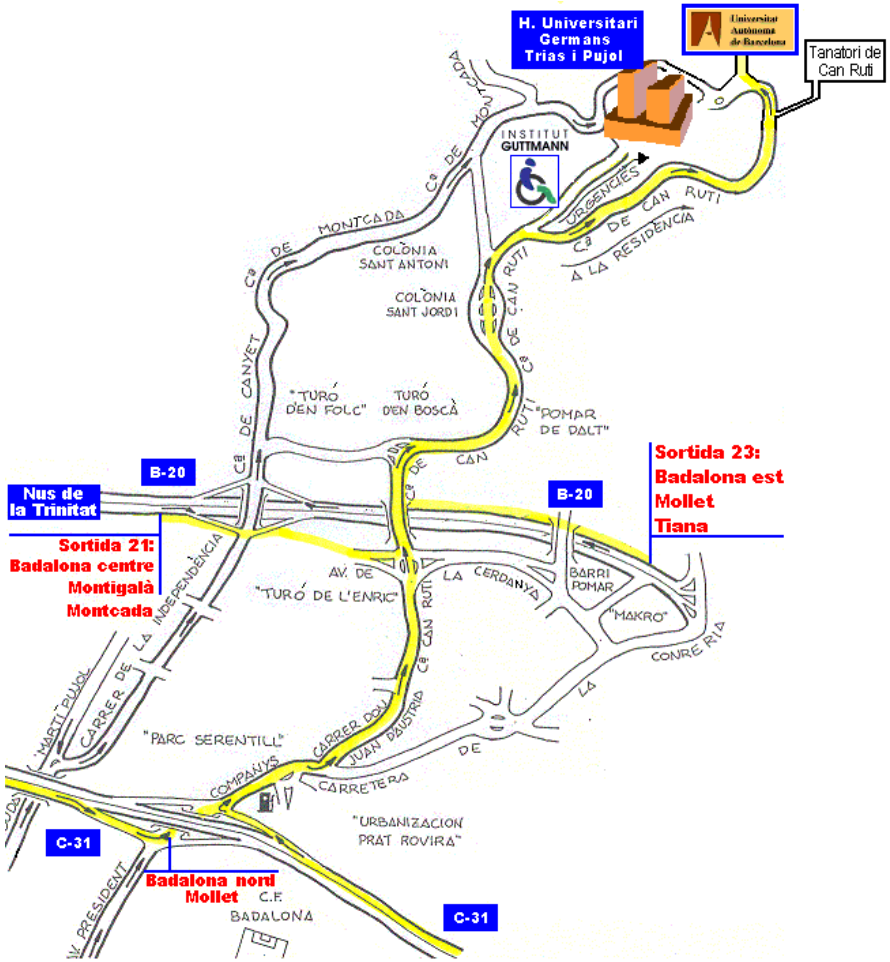
UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

General Information

Who filled in this survey	Ana Mª Barriocanal
E-mail contact (Phone number)	ambarriocanal@igtp.cat / abarrio.germanstrias@gencat.cat +34 93 497 84 88 / +34 93 497 84 92
Date of survey filling in	19/MAY/2015
Unit web address	-
Formal name of the unit	UPIC (Unidad Polivalente de Investigación Clínica) Clinical Research Unit (Phase I Unit)
Postal address	Hospital Germans Trias i Pujol. Carretera de Canyet s/n. Maternal building, 2nd floor. 08916 Badalona. Barcelona. Spain

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Location

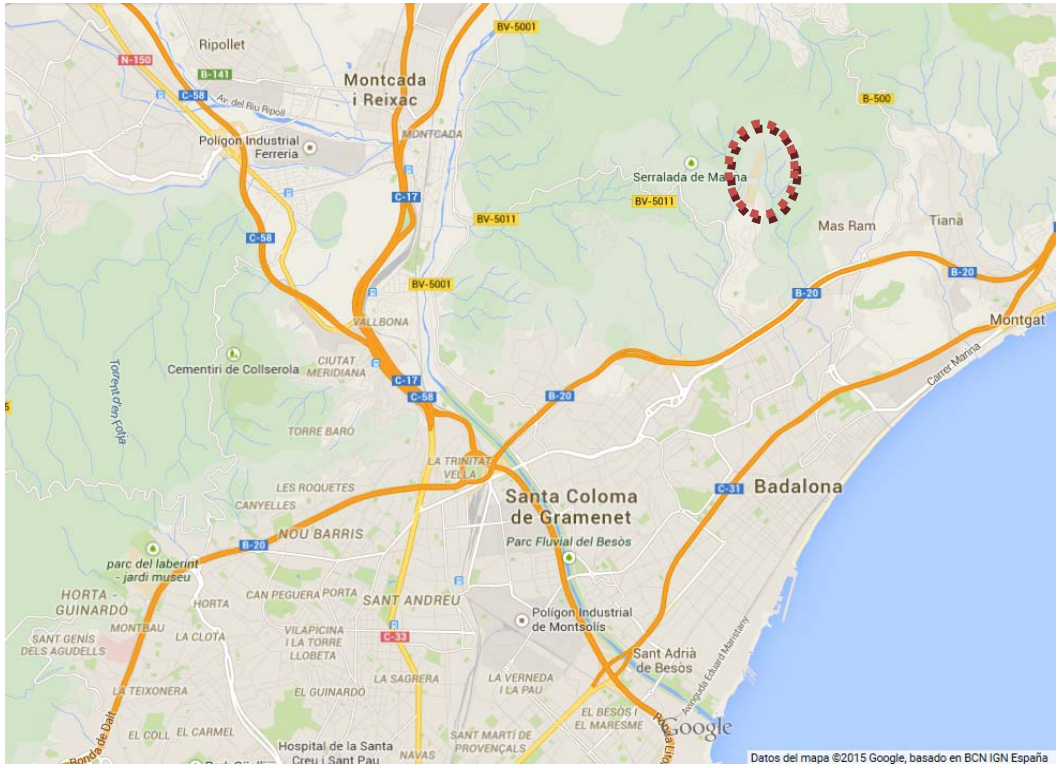


UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Location

https://www.google.es/maps/@41.4641343,2.2295363,13z:

On the map Campus Can Ruti location is marked with a red intermittent circle. It includes Hospital Universitario Germans Trias i Pujol, the Health Sciences Research Institute of the "Germans Trias i Pujol" Foundation (IGTP), the Cancer Preventive and Personalized Medicine Institute (IMPPC), the AIDS Investigation Institute (Irsi Caixa), the Catalan Oncology Institute (ICO), the Guttmann Institute, the Blood and Tissues Bank, the Barcelona Autonomous University docent unit and the Josep Carreras Foundation against Leukaemia.



UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Ownership

Ownership	Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol Hospital Universitari Germans Trias i Pujol
Established	
Linked hospital	Hospital Universitari Germans Trias i Pujol
Distance between linked hospital and Unit	Unit inside the hospital building
Linked Ethics Committee (CEIC)	CEIC Hospital Universitari Germans Trias i Pujol

Unit Manager

First and last names	Magí Farré Albaladejo
Qualifications	Physician
Medical specialty	Clinical Pharmacology
Manager since	2015
E-mail and phone	mfarre.germanstrias@igtp.cat +34 93 497 88 65

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Ownership

Short CV

Education
MD / Degree in Medicine (Universidad Autónoma de Barcelona, 1978)
PhD / Doctor in Medicine (Universidad Autónoma de Barcelona, 1990)
Clinical Pharmacology specialist MIR (Hospital Clínic, 1984)
Master in Pharmacoepidemiology (Universidad Autónoma de Barcelona, 1993)
Diploma in Pharmaceutical Medicine (Universidad Autónoma de Barcelona, 1997)
Diploma in Bioethics and Quality of Life (Universidad de Barcelona, 2002)
Diploma in Medical Ethics (Organización Médica Colegial e Instituto Universitario de Investigación Ortega y Gasset, 2012)

Professional experience
Head of Unit, Cliinical Pharmacology Unit, Hospital Universitari Germans Trias i Pujol. Badalona. Institut Català de la Salut (ICS), (2015-act)
Professor of Pharmacology, Departamento Farmacología, Terapéutica y Toxicología, Universidad Autónoma de Barcelona (2008-actualidad)
Professional experience (cont.)
Senior Consultant-3, HUman Pharmacology Unit, Institut Hospital del Mar d'Investigacions Mèdiques (IMIM, Parc de Salut MAR) (1986-2015)
Mentor Clinical Pharmacology residents (1988 – act)
Chairman Human Research Ethical Committee CEIC-PSMAR (2001-2015)

Research
Principal investigator or subinvestigator in 196 clinical trials with medicines, non-prescription drugs, drugs of abuse and nutraceutics
Director de 17 Doctoral Thesis
Publications: 249 original manuscripts in international journals, 534 manuscripts in total

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

No. During 2015 first semester it's planned to apply for Phase I Unit acreditation to Catalonia's Generalitat (government) Health Department.

Audits by regulatory agencies (last 3 years)

No.

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **Yes**

Audits by sponsors (last 3 years)

No audit has been performed at the Unit, however several Pharmacy industry sponsor evaluation pre-shight visits have been performed in order to assess the unit as site for Phase II to IV clinical trials.

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? No

Would you follow the sponsor SOPs if requested: Yes if they are feasible with the unit conditions.

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: Unit internal audit one per year

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

UPIC is integrated as a functional unit in the hospital organigram. The computerized clinical history is used as a tool for daily activity, matching the hospital requirements on confidentiality and data protection for volunteers/patients treated on it. Furthermore there is a unit specific SOP in data protection.

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Facilities

Year of Unit building	1982 the hospital building. 2010 the specific unit (UPIC)	Last Unit reform	--
Usable space	400 m^2	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	2 Phase I	Number of beds	6
Beds distribution	1 hospitalization with 6 beds		
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	6	Number of armchairs suitable for subject monitoring	6
Owned kitchen	No	Meals supervision by dietitian	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Advanced LS		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Emergency, Intensive Care Unit and Coronary Unit at the hospital. The emergency care is immediate because the unit is integrated into the hospital.		
Distance and time to get the former services	Between one and two plants in the same hospital (about 5 to 10 minutes)		
Unit entrance/Exit door controlled	Entrance controled by the administrative staff of the unit	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

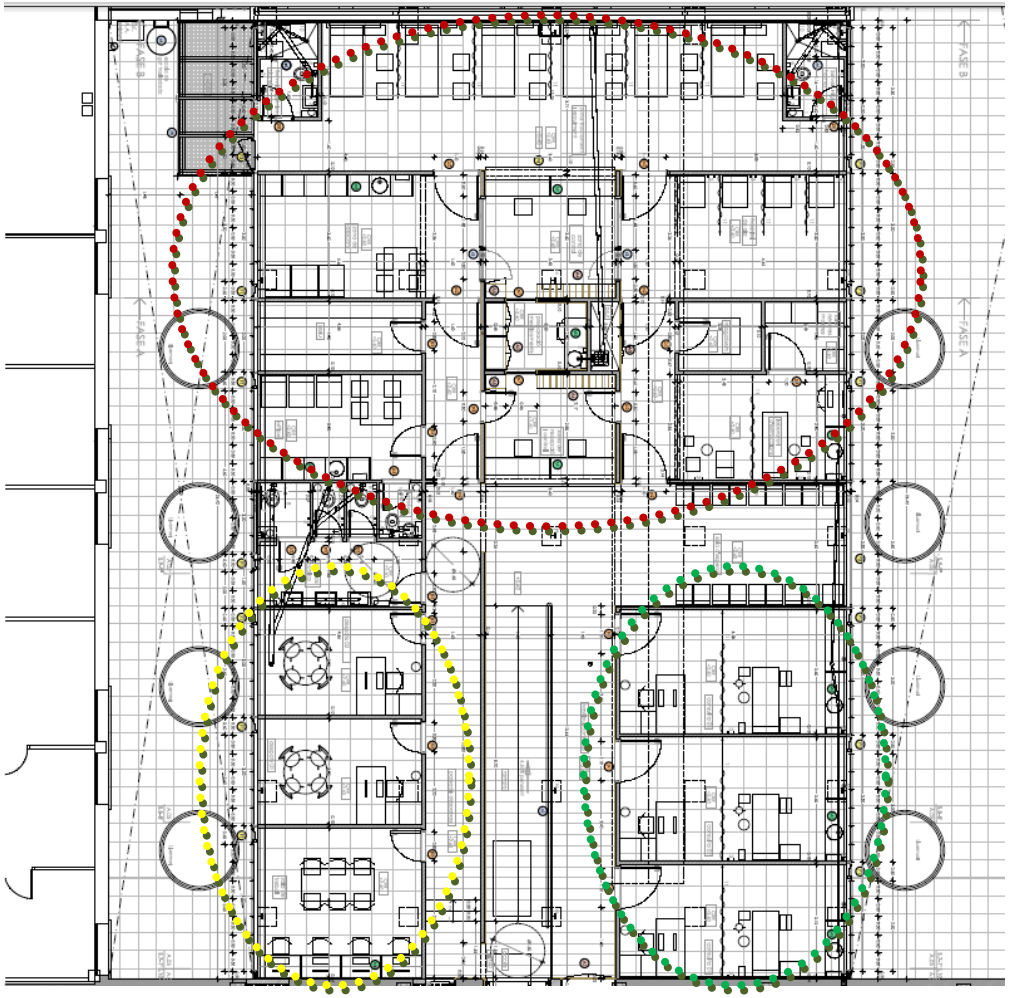
UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Facilities

Unit distribution plan

Colour code:

- Intermittent red line: Bed zone and Day hospitalization area, nurse control, ongoing studies file area, administration area, rest for volunteers area and sample management and frozen zone.
- Intermittent green line: Outpatient office shared with clinical trials in Phases II, III and IV.
- Intermittent yellow line: Medical offices without medical care to volunteers, and clinical trial monitoring area.



UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Staffing and Resources

Unit employees

Permanent staff 5 Fixed-term/contracted staff (internship, grant holders) 1 Part-time collaborators 5

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	4	
Co-investigator (physician)	1	1
Nurse	3	
Monitor or CRA		1
Pharmacist		
Biometry		
Data management		
Medical writing		
Pharmacokinetics		
Quality assurance		
Project Management		
Finance		
Recruitment		
IT (informatics)		
Other (specify): CTA, psychologist, etc	1 CTA	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician **X** Nurse

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	Yes
The quality assurance activities are subcontracted by the Unit	Yes
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	No
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Hospital Pharmacy **Preparation**: depending on the study design: Hospital Pharmacy / Nurse **Administration:** specialized nurse under research team supervision
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification	
Stickers computer generated. Covered with transparent plastic adhesive to prevent data loss during freezing	
Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	No
Number of centrifuges available	1 refrigerated, 1 not refrigerated
System for plasma/fluids samples storing	-27ºC and -80ºC Freezers(the last one located in the Health Sciences Research Institute of the "Germans Trias i Pujol" Foundation (IGTP) building, 200 meters away from the hospital)
Fridges and freezers available in the Unit	2 fridges, 2 freezers (-20ºC)

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Services Capabilities

The Unit has its owned Bioanalytical Department	No. Subcontracting companies if needed and depending on budget
Availability of genotyping or fenotyping methods for participants	No. Subcontracting to IGTP Foundation or specific companies
Data Management and software used (describe)	No. Subcontracted depending on the project.
Biometry or Statistical Analysis and software used (describe)	No. Subcontracted depending on the project.
Pharmacokinetic Analysis and software used (describe)	No. Subcontracted depending on the project.
Medical Writing and skilled languages	Yes. English, French, Spanish.
Owned archives in the same Unit building (describe)	Yes

Ongoing studies Trial Master File at the UPIC unit.

Hospital historic archive for the sponsor closed studies.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Full Trials doccuments are sent to the archives and are kept for 15 years.

The study files are digitized and converted in a CD or web format	No
Project management	Yes

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Study Participants

Kind of participants included in clinical trials performed in the Unit

X Healthy volunteers X Patients

X Other populations Pediatrics

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour X Haematological tumour X Adults Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Oncology studies at site are managed from Catalan Institut of Oncology (ICO).

Recruiting methods for healthy volunteers

Advertisements distributed throughout the hospital and the School of Medicine Docent Unit of Universitat Autònoma de Barcelona. Also through receipt of voluntary requests to participate in Phase I clinical trials.

Recruting methods for patients

Through contacts with specialists doctors in the hospital, according to the study.

Do you have sugery rooms available for screening (separated from the in-house area)? (number) Yes (3)

Do you keep a paper or electronic database of volunteers? (describe) Yes

Electronic database with following information: name, age, sex, nationality, date of contact with the unit for inclusion in the database, personal identification code in national health system (CIP), contact information data (phone, e-mail, address), previous participation in clinical trials and unit in which participation was performed.

Have you implemented any measure for avoiding the over-volunteering? (describe) Yes

Interrogation about other projects participation. Acces to the Clinical Trials Volunteers Registry of the Catalonia Generalitat

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	Yes (10)	Pulsioximetry devices (number)	Yes (8)	12-leads ECG devices (number)	Yes (7)

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	No
Availability in the Unit of tests for assessing CNS drug effects	No
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	No
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes
Experience in other kind of PD or PK evaluations not formerly collected	No

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

No

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						1
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)			1			1
Own research lines			1			1
Others (specificying) Pharmacokinetics				1		

Number of trials linked to a PEI (IND) submission | 2009 | 2010 | 2011 | 2012 | 2013 | 2 | 2014 |

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Vaccines, probiotics, antipsychotics, antidiabetic

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 3 Number of trials promoted by multinational companies 2

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 90 days

Number of Early Stages trials performed in the Unit and published in the last 4 years -

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Experience

References of clinical trials publications

- Arellano AL, Barriocanal A, Valderrama A, Sanz Y, Vilaplana C, Cardona PJ, Montané E. Preliminary safety results of a double-blind, randomized, placebo-controlled, Clínical trial with the probiotic Nyaditum resae in adults with or without latent tuberculosis infection. Poster en el XXVII congreso de la Sociedad Española de Farmacología Clínica. Sevilla. 2014.
- Montané E, Barriocanal AM, Arellano AL, Valderrama A, Sanz Y, Cardona P, Vilaplana C, Cardona PJ. Clínical trial with the food supplement Nyaditum resae®: a new tool to reduce the risk of developing active tuberculosis. Poster (PD-1027-01) en la 45th Union World Conference on Lung Health. Barcelona. 2014.
- Montané E, Barriocanal AM, Arellano AL, Valderrama A, Sanz Y, Cardona P, Vilaplana C, Cardona PJ. Double-Blind, randomized, masked, placebo-controlled Clínical Trial of the heat-killed probiotic Nyaditum resae® to reduce the risk of active tuberculosis. Original envíado para su publicación.

UPIC Unidad de Fase I – Hospital Universitari Germans Trias i Pujol

Annexes

Brochure not available in English

Unidad de Ensayos Clínicos Sant Joan de Déu

Unidad de de Ensayos Clínicos Sant Joan de Déu

General Information

Who filled in this survey	Joana Claverol Torres
E-mail contact (Phone number)	jclaverol@fsjd.org
Date of survey filling in	May 6, 2015
Unit web address	http://www.fsjd.org/es
Formal name of the unit	Clinical Trials Unit, Sant Joan de Déu
Postal address	Hospital Sant Joan de Déu Outpatient Facilities Building Floor 0 Psg. Sant Joan de Déu num 2 08950 Esplugues de Llobregat, Barcelona Spain

Unidad de de Ensayos Clínicos Sant Joan de Déu

Location

Hospital Sant Joan de Déu - Barcelona
Passeig Sant Joan de Déu, 2
08950 Esplugues de Llobregat
Barcelona

Unidad de de Ensayos Clínicos Sant Joan de Déu

Ownership

Ownership	Sant Joan de Déu Research Foundation
Established	2012
Linked hospital	Hospital Materno Infantil Sant Joan de Déu and Hospital Parc Sanitari Sant Joan de Déu
Distance between linked hospital and Unit	Within the same pediatric- maternity hospital . 10 km from the Parc Sanitari Hospital
Linked Ethics Committee (CEIC)	CEIC Fundació Sant Joan de Déu

Unit Manager

First and last names	Joana Claverol Torres
Qualifications	Biology D.
Medical specialty	Clinical Research
Manager since	2012
E-mail and phone	jclaverol@fsjd.org +34 610 58 14 29

Short CV

Academic history:
- 1999 Degree in Biological Sciences Autonomous University of Barcelona
- 1999 Master of monitoring clinical trials Universitat de Barcelona
- 2002 Master in Pharmaceutical Marketing Universitat Pompeu Fabra, Barcelona

Professional history and research:
- April 2012-present: Clinical Reserach Unit Manager, Fundació Sant Joan de Deu
- November 2011-April 2012: Regional-Osteoporosis Medical Liaison Amgen SA
- November 2010 - November 2011 International Manager of Regional Medical Officers, Amgen HQ (Zug, Switzerland)
- March 2004-October 2010 Amgen SA Regional Medical Liaison, Nephrology and General Medicine.
- January 2002-March 2004 Pfizer SA, Project Manager, Cardiovascular area
- January 2000-January 2002 Pfizer SA CRA Cardiovascular Clinical Trials
- November 1999-January 2000 Parke Davis S. A CRA Cardiovascular Clinical Trials

Unidad de de Ensayos Clínicos Sant Joan de Déu

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

None

Audits by regulatory agencies (last 3 years)

None

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? Yes

Audits by sponsors (last 3 years)

4 audits in 2014 and 3 in 2013

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? Yes

Would you follow the sponsor SOPs if requested: Yes if they do not conflict with the procedures of the unit

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 3

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Unit SOPs are followed, the Guidelines for Good Clinical Practice, the RD 223/2004 of clinical trials and the Law on Data Confidentiality Protection .Annually an internal audit on compliance with the Data Confidentiality is performed.

Access to confidential information is restricted and locked. Access to clinical patient data is restricted to center staff that has permissions and access code, and monitors who have access to reading data on paper. All other information is encrypted and anonymized according to the trial sponsor requirements.

We follow an internal SOPs describing the retention policy documents (according to ICH), and documentation is stored for 15 years in an external archive facility that fulfils all applicable regulations.

Unidad de de Ensayos Clínicos Sant Joan de Déu

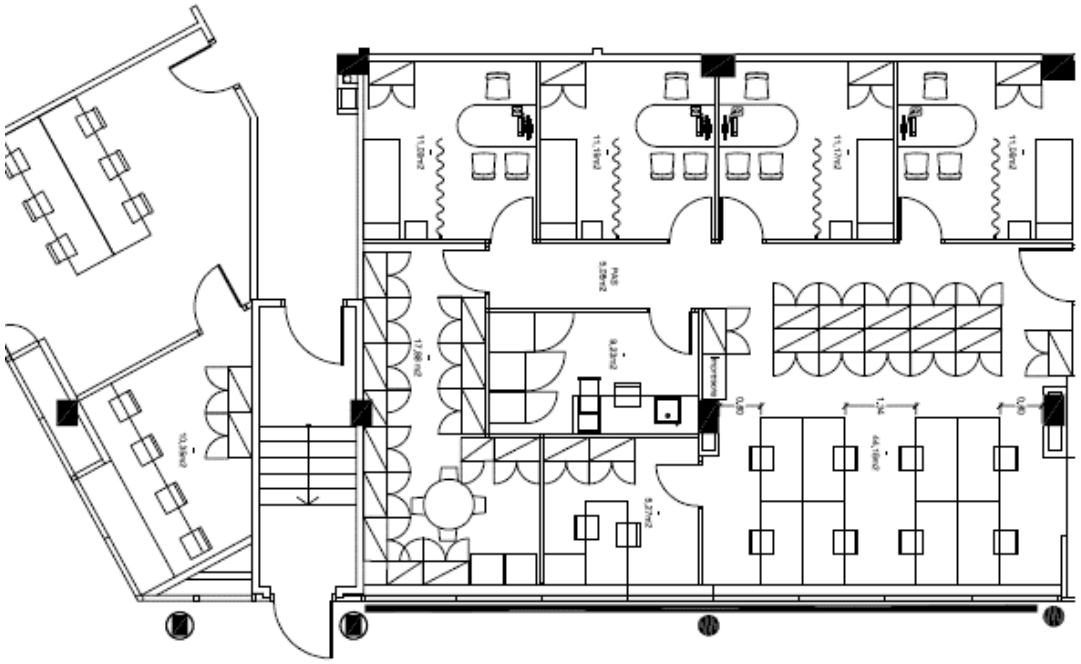
Facilities

Year of Unit building	2012	Last Unit reform	2015
Usable space	150 m^2	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	3-4 ph1	Number of beds	4
Beds distribution	Single rooms in the unit, and single or double rooms in the hospital		
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	All beds	Number of armchairs suitable for subject monitoring	4
Owned kitchen	Hospital	Meals supervision by dietitian	yes
Dining-room available for volunteers	na	Individual lockers available for volunteers	na
Relaxing room available for volunteers independent from the beds area			na
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			yes
The emergency trolly has available suitable medications with immediate by controlled access			yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes		
Unit availability of an evacuation plan for volunteers in emergency situations			yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Yes, ICU and emergency department of the hospital		
Distance and time to get the former services	In the same building		
Unit entrance/Exit door controlled	Doors are blocked electronically and can only be accessed by authorized personnel with a specific badge	Unit with Closed Circuit Television	no
Availability of an alternate electrical generating set that automatically works in case of a general system failure	No, is the one of the Hospital		

Unidad de de Ensayos Clínicos Sant Joan de Déu

Facilities

Unit distribution plan



Unidad de de Ensayos Clínicos Sant Joan de Déu

Staffing and Resources

Unit employees

Permanent staff 8 Fixed-term/contracted staff (internship, grant holders) 1 Part-time collaborators 4

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator *		
Co-investigator (physician)		
Nurse	3,4,5,6,7	
Monitor or CRA		
Pharmacist	9,10	
Biometry	8	
Data management	8	
Medical writing		
Pharmacokinetics		
Quality assurance		
Project Management	11	
Finance	12	
Recruitment		
IT (informatics)		
Other (specify): CTA, psychologist, etc	2	
Other (specify): Clinical Trials Unit Manager	1	

* The Principal Investigators are Hospital staff. Currently there are 41 IPs with active clinical trials conducted in the clinical trials unit

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

x Physician **x** Nurse

Unidad de de Ensayos Clínicos Sant Joan de Déu

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	Yes, the Hospital Lab
The quality assurance activities are subcontracted by the Unit	Data protection confidentiality
Availability of a specific area for drug storing and preparation of medications for the study	yes
The former area or room has restricted access by key or code	yes
Laminar flow chamber availability for preparation of parenteral treatments	No,we use chambers from the pharmacy service
Perfusion pumps for intravenous treatment	yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** research nurses **Preparation**: clinical trials pharmacist
Drug accountability procedures, such as reception, preparation and dispensing forms	yes
SOPs available for drug preparation and dispensing	yes
SOPs available for drawing and managing of biological fluids	yes

System or procedure used for samples identification

Labels provided by the sponsor in the study kits and local lab labels if required. There is an SOP that describes how to identify all biological samples stored in the research unit freezer, with code assignment system.

Availability of a specific area for blood samples managing	yes
The former area or room has restricted access by key or code	yes
Number of centrifuges available	1
System for plasma/fluids samples storing	Freezer (-80º and -20º)
Fridges and freezers available in the Unit	1 fridge, 2 freezers
The Unit has its owned Bioanalytical Department	No, we use the Hospital Department

Unidad de de Ensayos Clínicos Sant Joan de Déu

Services Capabilities

Availability of genotyping or fenotyping methods for participants	Yes, hospital genetic lab
Data Management and software used (describe)	Yes, there is a statistician that provides support to the investigator initiated trials
Biometry or Statistical Analysis and software used (describe)	SPSS, access, excel
Pharmacokinetic Analysis and software used (describe)	Performed in the Hospital lab
Medical Writing and skilled languages	No, we contract CRO services
Owned archives in the same Unit building (describe)	No, external facility that fulfils all the security regulations

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

The ISF, CRFs and all the essential documents as described in our SOPs and ICH. We agree with the sponor the archiving period (usually 15 years)

The study files are digitized and converted in a CD or web format	No
Project management	Yes

Unidad de de Ensayos Clínicos Sant Joan de Déu

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers No Patients Yes

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

Solid tumour Haematological tumour Adults yes Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All pediatric tumours

Recruiting methods for healthy volunteers

NA

Recruting methods for patients

Patients from outpatient, inpatient and patients referred from other centers in Spain and other countries

Do you have sugery rooms available for screening (separated from the in-house area)? (number) Yes, 4

Do you keep a paper or electronic database of volunteers? (describe) NA

Have you implemented any measure for avoiding the over-volunteering? (describe) NA

Unidad de de Ensayos Clínicos Sant Joan de Déu

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	2	Pulsioximetry devices (number)	2	12-leads ECG devices (number)	2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	-
Availability in the Unit of tests for assessing CNS drug effects	-
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	No, performed by the sponsors
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes
Experience in other kind of PD or PK evaluations not formerly collected	-

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Unidad de de Ensayos Clínicos Sant Joan de Déu

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)	2	2	2	4	5	10
Own research lines	2	4	5	2	2	1
Others (specificying) Pediatirc trials (from phase II_III)	26	10	17	18	21	22

Number of trials linked to a PEI (IND) submission | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 1

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Pediatric investigation plans (PIPs) and own pediatric trials in the following specialties: Anesthesia, Cardiology, Surgery, Dermatology, Endocrinology, Gastroenterology, Hematology, Immunology, Microbiology, Nephrology, Neonates,Neurology, Ophthalmology, Oncology, Pneumology, infectious diseases, Rheumatology, Rehabilitation, Palliative Psychiatry, ICU. Adults: Gynecology and obstetrics, pneumology, psychiatry and cardiolgy

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 0 Number of trials promoted by multinational companies all

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60 days

Number of Early Stages trials performed in the Unit and published in the last 4 years Published by the sponsors

Unidad de de Ensayos Clínicos Sant Joan de Déu

Annexes

Brochure not available in English

Unidad de Investigación Clínica del Institut Hospital del Mar d'Investigacions Mèdiques

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

General Information

Who filled in this survey	Rafael de la Torre
E-mail contact (Phone number)	rtorre@imim.es
Date of survey filling in	06 May 2015
Unit web address	www.imim.es
Formal name of the unit	Unidad de Investigación Clínica. Institut Hospital del Mar d'Investigacions Mèdiques. Parc de Salut Mar.
Postal address	Doctor Aiguader 88, second floor, PRBB building 08003 Barcelona

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Location

For additional information about access and public transportation: www.imim.es

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Ownership

Ownership	Hospital del Mar Medical Research Institute
Established	1982
Linked hospital	Hospital del Mar
Distance between linked hospital and Unit	100 m
Linked Ethics Committee (CEIC)	CEIC Parc de Salut Mar

Unit Manager

First and last names	Rafael de la Torre
Qualifications	Pharm.D., Ph.D
Medical specialty	Pharmacist
Manager since	Less than one year
E-mail and phone	rtorre@imim.es 933160484

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Ownership

Short CV

Consultant 3, Parc de Salut Mar
Graduate (1979) and Doctor of Pharmacy (1985), University of Barcelona
Post-doctoral studies Department of Clinical Pharmacology. Royal Postgraduate Medical School. Hammersmith Hospital, London, UK.
Specialist in Pharmaceutical Analysis and Drug Monitoring (MINECO, 2003)
Toxicology Professor Pompeu Fabra University (credited as Professor ANECA)
Coordinator of the Human Pharmacology and Clinical Neurosciences Research Group
Director of the Neurosciences Research Program in IMIM
More than 300 international indexed scientific publications related to pharmacology. Index H = 45.

Principal investigator in the past 5 years of the following clinical trials:

- Multicentric, longitudinal study without treatment to assess neurocognitive tests and functional scales to determine cognitive and functional variations in individuals with DS. F.HOFFMAN-LA ROCHE LTD (2012-2013).
- Multicenter, randomized, double-blind, placebo-controlled, Phase 2 trial to assess the efficacy, safety and tolerability of RO5186582 in adults and adolescents with Down syndrome (CLEMATIS) (2014-present)
- Estrogen Receptors beta (ER-B) as therapeutic target for the improvement of cognitive performance in Fragile-X. FRAXA Research Foundation (2012-2103).
- Collaboration agreement between Jérome Lejeune Foundation and Fundació Institut Mar d'Investigacions Mèdiques: "Normalization of Dyrk1A function as therapeutic approach to improve cognitive performance in Down syndrome mental retardation: Epigallocatechin gallate (EGCG) as therapeutic tool". FONDATION JÉRÔME LEJEUNE. (2011-2014).
- Normalization of Dyrk1A and APP function to improve cognitive performance and slow the progression of AD in patients with SD: epigallocatechin gallate as a therapeutic tool. FIS/ISCIII PI11/00744

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

No. Renovation of accreditation will be asked to Generalitat de Catalunya

Audits by regulatory agencies (last 3 years)

No

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies?

Audits by sponsors (last 3 years)

Yes (2013,2014)

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? No

Would you follow the sponsor SOPs if requested: If is a requirement for a specific study

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 1 each year

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

There is an agreement with Hospital del Mar for specialized care.

There is a specific SOP of the unit of data protection.

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

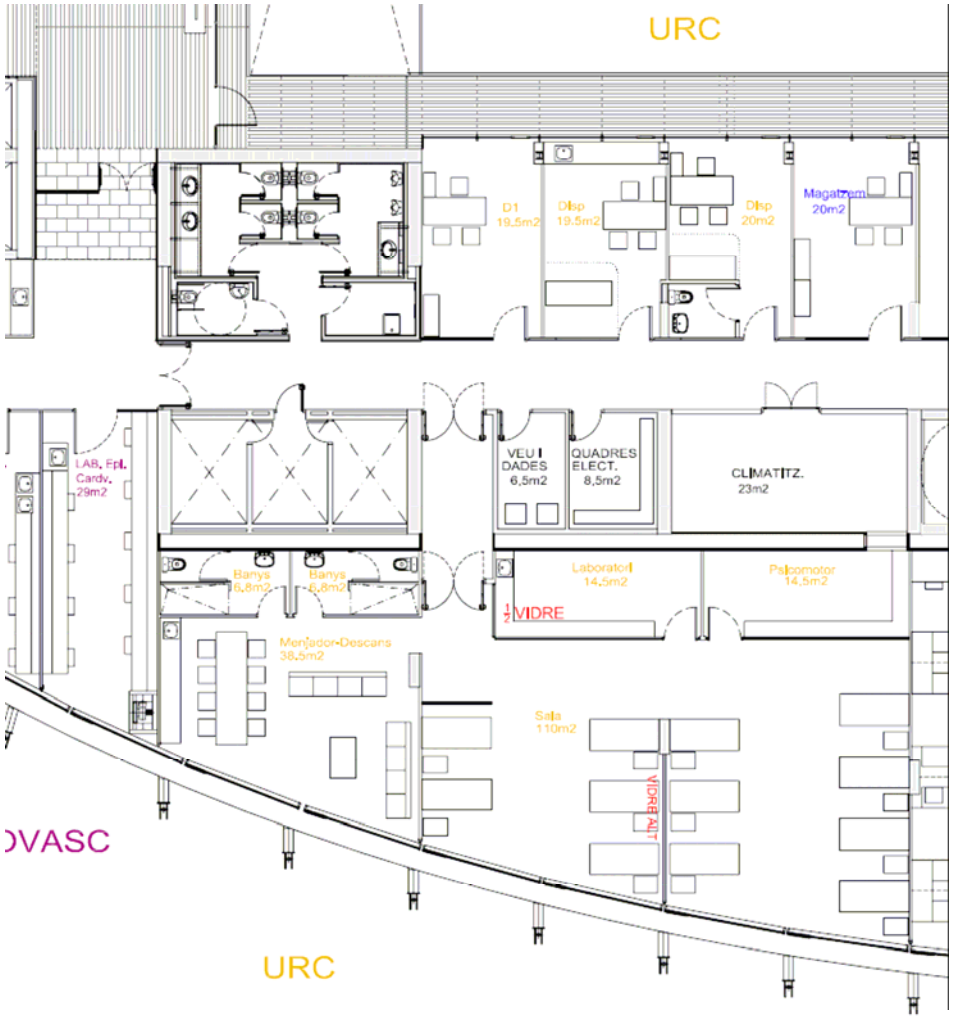
Facilities

Year of Unit building	2005	Last Unit reform	
Usable space	280	The Unit building is separate from the linked hospital	Yes
Number of CTs the unit could perform simultanously	2	Number of beds	12
Beds distribution	1 room with 8 beds and 1 room with 4 beds		
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	8	Number of armchairs suitable for subject monitoring	12
Owned kitchen	No	Meals supervision by dietitian	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Advanced LS		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Emergency, Intensive Care Unit, Coronary Unit		
Distance and time to get the former services	300 m /5-10 minutes		
Unit entrance/Exit door controlled	Yes	Unit with Closed Circuit Television	Yes
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Facilities

Unit distribution plan



Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Staffing and Resources

Unit employees

Permanent staff 3 Fixed-term/contracted staff (internship, grant holders) 7 Part-time collaborators 1

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	1
Co-investigator (physician)		3
Nurse	2	3
Monitor or CRA		1
Pharmacist		
Biometry		
Data management		
Medical writing		
Pharmacokinetics		
Quality assurance		
Project Management		
Finance		
Recruitment		1
IT (informatics)		
Other (specify): CTA, psychologist, etc		3

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician X Nurse

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	Reference Laboratory Catalunya (also responsible for emergency laboratory of Hospital del Mar) UNE -EN ISO 15189
The quality assurance activities are subcontracted by the Unit	No, an specific department exists
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	No
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Hospital del Mar pharmacy **Preparation**: Nurses
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification	
Self-adhesive labels with plastic coating	
Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	No
Number of centrifuges available	2
System for plasma/fluids samples storing	-20ºC Freezer . If necessary, samples are moved to freezer room -40ºC or -80ºC which is 20 meters away

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Services Capabilities

Fridges and freezers available in the Unit	2 fridges, 1 freezer
The Unit has its owned Bioanalytical Department	Yes
Availability of genotyping or fenotyping methods for participants	In the laboratory analysis of the Human Pharmacology and Clinical Neurosciences Research Group
Data Management and software used (describe)	No, subcontracted depending on study and sponsor
Biometry or Statistical Analysis and software used (describe)	Yes, SPSS, SAS.
Pharmacokinetic Analysis and software used (describe)	Excel adapted software
Medical Writing and skilled languages	Yes, in IMIM
Owned archives in the same Unit building (describe)	Yes

Room 20 m^2. Access Control wrench and locked in closets.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Source data, Case report forms (CRF), Investigator's Brochure. 15 years

The study files are digitized and converted in a CD or web format	No
Project management	No. Subcontracted depending on sponsor.

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers	Yes	Patients	Yes
Other populations	Children, Individuals with mental disabilities and genetic diseases (eg Down syndrome , Fragile X , Williams , and others)		

If the Unit has experience in oncology, detail kind of tumour and age groups

Solid tumour	Yes	Haematological tumour	Yes	Adults	Yes	Pediatrics	Yes

What kind of cancer (by organ) patients could be recruited by the Unit

Breast , urologic , lung, ovary

Recruiting methods for healthy volunteers

Own database

Recruting methods for patients

Contact with responsible of medical assistance of the patient

Do you have sugery rooms available for screening (separated from the in-house area)? (number) Yes, 2

Do you keep a paper or electronic database of volunteers? (describe)

Yes, it includes the following information: name, age , weight, height , gender , toxic and dietary habits, health card number

Have you implemented any measure for avoiding the over-volunteering? (describe)

Database of volunteers from Generalitat de Catalunya

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	Yes	Pulsioximetry devices (number)	8	12-leads ECG devices (number)	4
Familiarity with evaluation of the QTc interval prolongation accordingly with current rules				Yes	
Availability in the Unit of tests for assessing CNS drug effects				Yes. CANTAB computerized system and several tests of psychomotor performance in laptops.	
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports				No	
Familiarity with Electronic Data Capture –EDC applied to clinical trials				Yes (3 studies each year)	
Experience in other kind of PD or PK evaluations not formerly collected				Yes, PK programs based in Excel implemented in computers	

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Yes, following sponsor instructions

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence	1	1	1	1		
First single-dose administration in humans				1	1	
First multiple-dose administration in humans						
Drug interaction						1
Food interaction						
Special populations (Renal or liver impairment, elderly)				2	3	1
Proof of concept (Phase Ib or I/II)				2	1	1
Own research lines	4	4	5	5	5	5
Others (specificying)	2	1			1	

Number of trials linked to a PEI (IND) submission | 2009 | 2 | 2010 | 1 | 2011 | 0 | 2012 | 1 | 2013 | 2 | 2014 | 0

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Painkillers, antipsychotics , antidepressants, anxiolytics , antineoplastics , Radiopharmaceuticals (PET / SPECT) , psychostimulants, sedatives , Glucocorticoids , anabolic , Nutraceuticals (flavonols, isoflavones)

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 9 Number of trials promoted by multinational companies 6

Median time for approval by the Ethics Committee and the Spanish Agency for the E. S. trials 20 d Ethics Committee 60 d Spanish Agency

Number of Early Stages trials performed in the Unit and published in the last 4 years 24

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Experience

References of clinical trials publications

Ó Mathúna B, Farré M, Rostami-Hodjegan A, Yang J, Cuyàs E, Torrens M, Pardo R, Abanades S, Maluf S, Tucker GT, de la Torre R. The consequences of 3,4-methylenedioxymethamphetamine (MDMA, Ecstasy) induced CYP2D6 inhibition in humans. J Clin Psychopharmacol. 2008;28:523-9.

Fonseca F, Marti-Almor J, Pastor A, Cladellas M, Farré M, de la Torre R, Torrens M. Prevalence of long QTc interval in methadone maintenance patients. Drug Alcohol Depend. 2009;99:327-32.

Catafau AM, Suarez M, Bullich S, Llop J, Nucci G, Gunn RN, Brittain C, Laruelle M, and Barcelona Clinical Imaging in Psychiatry Group (..., Farré M, ...). Within-subject Comparison of Striatal D2 Receptor Occupancy measurements using [123I]IBZM SPECT and [11C]Raclopride PET. NeuroImage 2009; 46:447–458.

Marchei E, Farré M, Pellegrini M, García-Algar O, Vall O, Pacifici R, Pichini S. Pharmacokinetics of methylphenidate in oral fluid and sweat of a pediatric subject. Forensic Sci Int. 2010;196:59–63.

Marchei E, Farré M, Pardo R, Garcia-Algar O, Pellegrini M, Pacifici R, Pichini S. Correlation between methylphenidate and ritalinic acid concentrations in oral fluid and plasma. Clin Chem. 2010 Apr;56(4):585-92.

Ortuño J, Covas MI, Farré M, Pujadas-Bastardes M, Fitó M, Khymenets O, Andrés-Lacueva C, Roset PN, Joglar J, Lamuela RM, de la Torre R. Matrix effects on the bioavailability of resveratrol in humans. Food Chem. 2010:133:479-85.

Catafau AM, Searle GE, Bullich S, Gunn RN, Rabiner EA, Herance R, Radua J, Farré M, Laruelle M. Imaging cortical dopamine D1 receptors using [11C]NNC112 and ketanserin blockade of the 5-HT 2A receptors. J Cereb Blood Flow Metab. 2010;30:985-93.

Torrado JJ, Blanco M, Farré M, Roset P,García-Arieta A. Rationale and conditions for the requirement of chiral bioanalytical methods in bioequivalence studies. Eur J Clin Pharmacol. 2010;66:599-604.

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Experience

References of clinical trials publications

Marchei E, Farré M, Pardo R, Garcia-Algar O, Pellegrini M, Pacifici R, Pichini S. Usefulness of sweat testing for the detection of methylphenidate after fast and extended release drug administration: a pilot study. Ther Drug Monit. 2010;32:508-11.
Khymenets O, Farré M, Pujadas M, Ortiz E, Joglar J, Covas MI, de la Torre R. Direct analysis of glucuronidated metabolites of main olive oil phenols in human urine after dietary consumption of virgin olive oil. Food Chem. 2011; 126: 306-14.

Bullich S, Slifstein M, Passchier J, Murthy NV, Kegeles LS, Kim JH , Xu X, Gunn RR, Herance R, Gispert JD, Gutiérrez A, Farré M, Laruelle M, Catafau AM. Biodistribution and Radiation Dosimetry of the Glycine Transporter-1 Ligand 11C-GSK931145 Determined from Primate and Human Whole-Body PET. Mol Imaging Biol. 2011;13:776-84.

Catafau AM, Bullich S, Nucci G, Burgess C, Gray F, Merlo-Pich E, on behalf of the Barcelona Clinical Imaging in Psychiatry Group (… Farré M, …). Contribution of SPECT Measurements of D2 and 5-HT2A Occupancy to the Clinical Development of the Antipsychotic SB-773812. J Nucl Med. 2011;52:526–34.

Gunn RN, Murthy V, Catafau AM, Searle G, Bullich S, Slifstein M, Ouellet D, Zamuner S, Herance R, Salinas C, Pardo-Lozano R, Rabiner EA, Farre M, Laruelle M. Translational Characterization of [11C]GSK931145, a PET Ligand for the Glycine Transporter Type 1 (GlyT-1). Synapse. 2011;65:1319-32.

Matabosch M, Pozo OJ, Pérez-Mañá C, Farré M, Marcos J, Segura J, Ventura R. Identification of budesonide metabolites in human urine after oral administration. Anal Bioanal Chem. 2012; 404:325-40.

Pardo-Lozano R, Farré M, Yubero-Lahoz S, O'Mathúna B, Torrens M, Mustata C, Pérez-Mañá C, Langohr K, Cuyàs E, Carbó M, de la Torre R. Clinical Pharmacology of 3,4-Methylenedioxymethamphetamine (MDMA, "Ecstasy"): the Influence of Gender and Genetics (CYP2D6, COMT, 5-HTT). PLoS ONE 2012; 7(10):e4 75 99.

Krause K, Giménez-Arnau A, Martinez-Escala E, Farré-Albadalejo M, Abajian M, Church MC, Maurer M. Platelet-activating factor (PAF) induces wheal and flare skin reactions independent of mast cell degranulation. Allergy. 2013;68:256-8.

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Experience

References of clinical trials publications

Peiró AM, Farré M, Roset PN, Carbó M, Pujadas M, Torrens M, Camí J, de la Torre R. Human Pharmacology of 3,4-methylenedioxymethamphetamine (MDMA, ecstasy) after repeated doses taken 2 hours apart. Psychopharmacol (Berlin). 2013;225:883-93.

Marchei E, Papaseit E, Garcia-Algar O, Bilbao A, Farré M, Pacifici R, Pichini S. Sweat Testing for the Detection of Atomoxetine from paediatric patients with Attention Deficit/Hyperactivity Disorder: Application to Clinical Practice. Drug Test Anal. 2013;5:191-5.

Papaseit E, Marchei E, Farré M, Garcia-Algar O, Pacifici R, Pichini S. Concentrations of atomoxetine and its metabolites in plasma and oral fluid from paediatric patients with Attention Deficit/Hyperactivity Disorder. Drug Test Anal. 2013;5:446-52.
Matabosch X, Pozo OJ, Monfort N, Pérez-Mañá C, Farré M, Marcos J, Segura J, Ventura R. Urinary profile of methylprednisolone and its metabolites after oral and topical administrations. J Steroid Biochem Mol Biol. 2013;138C:214-221.

Giménez M, Ortiz H, Soriano-Mas C, López-Solà M, Farré M, Deus J, Martín-Santos R, Fernandes S, Fina P, Bani M, Zancan S, Pujol J, Merlo-Pich E. Functional effects of chronic paroxetine versus placebo on the fear, stress and anxiety brain circuit in Social Anxiety Disorder: Initial validation of an imaging protocol for drug discovery. Eur Neuropsychopharmacol. 2014;24:105-16.

Matabosch X, Pozo OJ, Papaseit E, Farré M, Marcos J, Segura J, Ventura R. Detection and characterization of triamcinolone acetonide metabolites in human urine by liquid chromatography/tandem mass spectrometry after intramuscular administration. Rapid Commun. Mass Spectrom. 2014;28:1828-39.

Farré M, Pérez-Mañá C, Papaseit E, Menoyo E, Pérez M, Martin S, Bullich S, Rojas S, Herance JR, Trampal C, Labeaga L, Valiente R. Bilastine vs. Hydroxyzine: Occupation of Brain Histamine H1 Receptors Evaluated by Positron Emission Tomography in Healthy Volunteers. Br J Clin Pharmacol. 2014:78:970-80.

Pérez-Mañá C, Farré M, Rodríguez-Morató J, Papaseit E, Pujadas-Bastardes M, Fitó M, Robledo P, Covas MI, Cheynier V, Meudec E, Escudier JL, de la Torre R. Moderate consumption of wine, through both its phenolic compounds and alcohol content, promotes hydroxytyrosol endogenous generation in humans. A randomized controlled trial. Mol Nutr Food Res. 2015 Feb 24. doi: 10.1002/mnfr.201400842. [Epub ahead of print].

Unidad de Investigación Clínica del Institut Hospital del Mar - IMIM

Annexes

Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

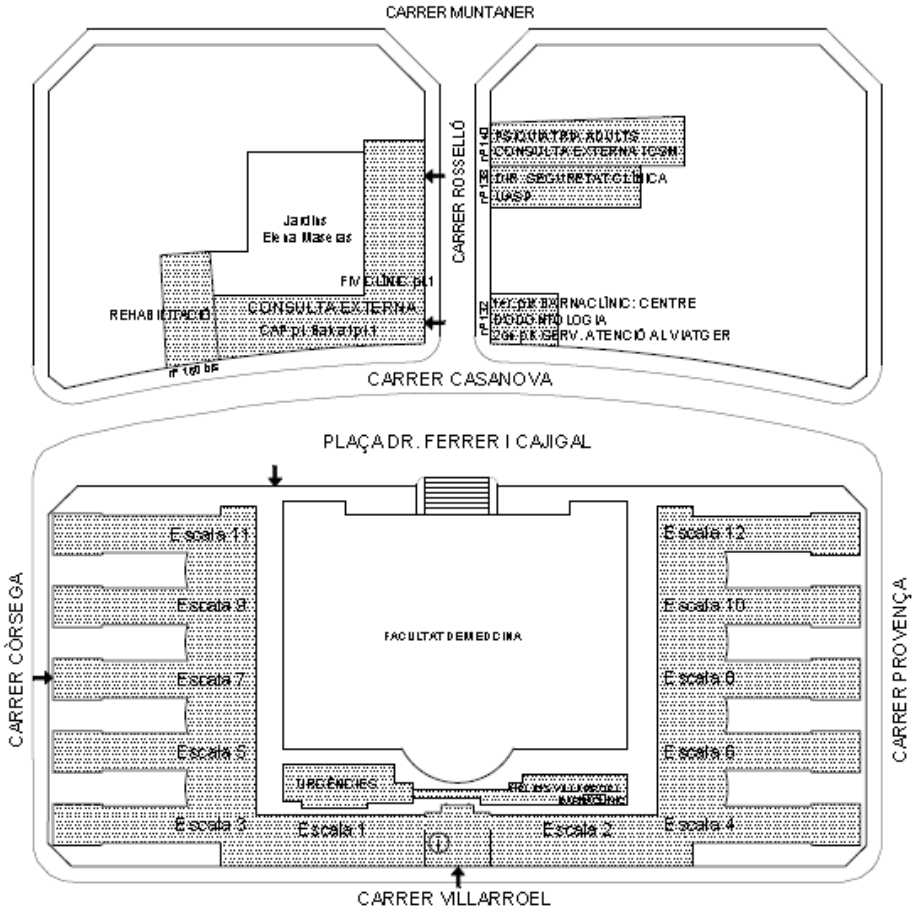
Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

General Information

Who filled in this survey	Laura Vidal
E-mail contact (Phone number)	lvidal@clinic.ub.es
Date of survey filling in	16.01.2015
Unit web address	In process
Formal name of the unit	Investigational Therapy Unit
Postal address	Hospital Clínic de Barcelona Villarroel, 170 street - 08036 Barcelona 3rd floor, 2nd block

Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

Location



Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

Ownership

Ownership	Fundació Clinic per a la Recerca Biomèdica
Established	2008
Linked hospital	Hospital Clínic of Barcelona
Distance between linked hospital and Unit	Same place
Linked Ethics Committee (CEIC)	CEIC Hospital Clínic of Barcelona

Unit Manager

First and last names	Laura Vidal
Qualifications	Doctor
Medical specialty	Oncology
Manager since	2010
E-mail and phone	lvidal@clinic.ub.es

Short CV

Dr Laura Vidal finished his training in Medical Oncology in 2003. She moved to London where she did a fellowship in Clinical Pharmacology at the Royal Marsden Hospital. Her major research was in development therapeutics, particularly in the area of phase I clinical trials for what she was honoured with several awards by the American Society of Clinical Oncology and the American Association of Cancer Research. Particularly, her interest focuses in the development of relevant biological markers which can be predictive of antitumoral benefit for the novel molecular targeted agents. In addition, her subspecialized disease site of expertise is in gynaecologist malignancies. In 2007, she completed a fellowship in the Drug Development Unit at the Princess Margaret Hospital, Toronto, where was involved participating in phase II international clinical trials of newer molecular targeted agents for gynaecological tumors. She was awarded in 2008 with the Novartis Young Canadian Investigator Award for her work on identifying the value to use different preclinical models to determine a safe starting dose for new molecular agents. She is now working as a consultant at the Hospital Clinic, Barcelona in the section of gynecology oncology and coordinating the Clinical trials Unit for Hemato-oncology diseases.

Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

No but there is the intention to apply for the accreditation of the Generalitat de Catalunya health department this year 2015

Audits by regulatory agencies (last 3 years)

No

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **Yes**

Audits by sponsors (last 3 years)

Several. The last one was on 2014.

Do you follow your own Standard Operating Procedures (SOPs)? yes Do you supply with a SOP copy to a sponsor if requested? yes

Would you follow the sponsor SOPs if requested: yes

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 4

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Follow up our Standard Operating Procedures (SOPs)

Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

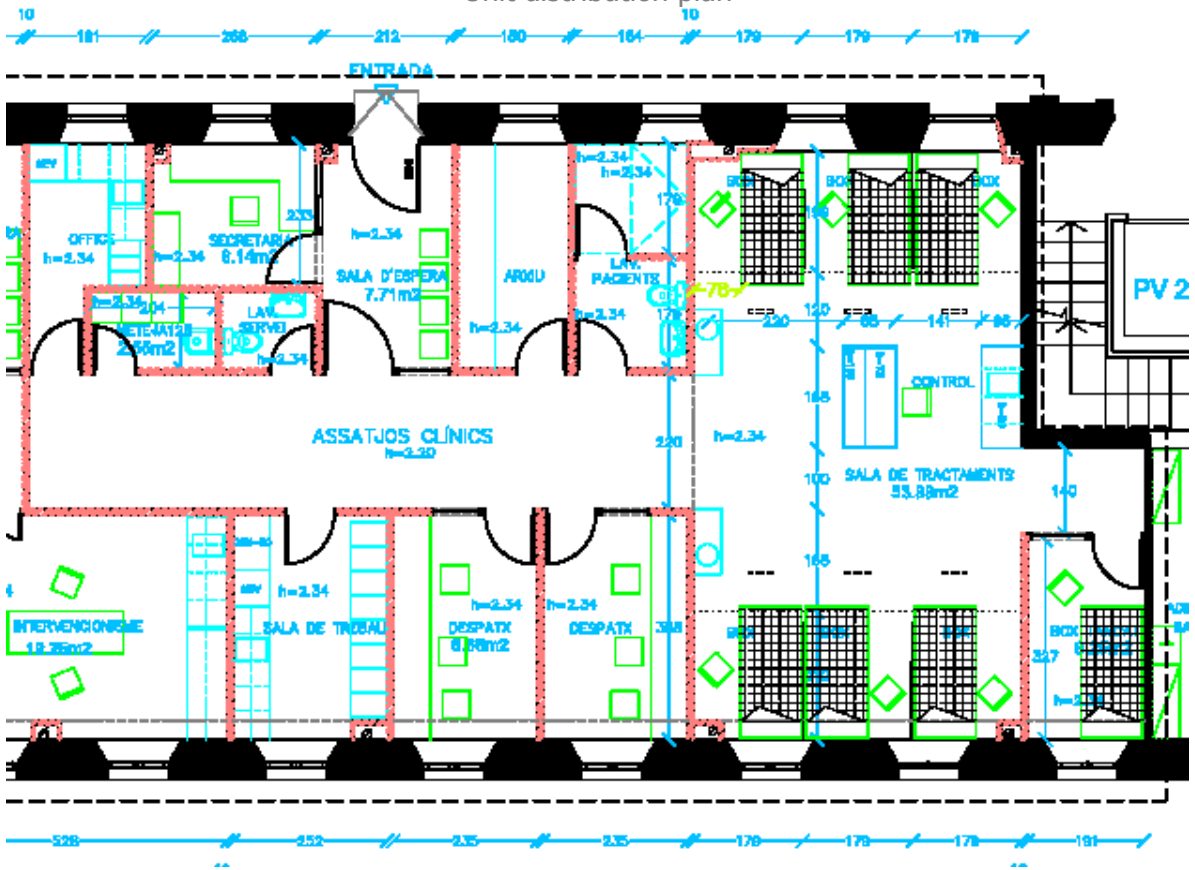
Facilities

Year of Unit building	1906	Last Unit reform	2008
Usable space	130M^2	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	3-5	Number of beds	1
Beds distribution	One room with one bed		
Beds distribution allows a complete and continuous visual control by nurses			yes
Number of bed with intensive or continuous monitoring	1	Number of armchairs suitable for subject monitoring	6
Owned kitchen	yes	Meals supervision by dietitian	yes
Dining-room available for volunteers	NA	Individual lockers available for volunteers	NA
Relaxing room available for volunteers independent from the beds area			NA
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	yes		
Unit availability of an evacuation plan for volunteers in emergency situations			yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	30m^2		
Distance and time to get the former services	Same building and same floor		
Unit entrance/Exit door controlled	no	Unit with Closed Circuit Television	no
Availability of an alternate electrical generating set that automatically works in case of a general system failure			yes

Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

Facilities

Unit distribution plan



Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

Staffing and Resources

Unit employees

Permanent staff _ Fixed-term/contracted staff (internship, grant holders) _ Part-time collaborators _

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	20	_
Co-investigator (physician)	5	_
Nurse	4	2
Monitor or CRA	_	1
Pharmacist	_	_
Biometry	_	3
Data management	9	_
Medical writing	_	_
Pharmacokinetics	_	_
Quality assurance	1	_
Project Management	_	_
Finance	1	_
Recruitment	IP	_
IT (informatics)	0	0
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

x Physician **x** Nurse

Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	yes
The quality assurance activities are subcontracted by the Unit	No, specific quality department
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	Yes
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Pharmacy **Preparation**: Pharmacy
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	yes

System or procedure used for samples identification : Trial code, patient number (SAP number), date and time

Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	No
Number of centrifuges available	2
System for plasma/fluids samples storing	Yes
Fridges and freezers available in the Unit	2 freezer and 1 Fridge
The Unit has its owned Bioanalytical Department	No
Availability of genotyping or fenotyping methods for participants	NA

Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

Services Capabilities

Data Management and software used (describe)	No. The same Hospital.
Biometry or Statistical Analysis and software used (describe)	No. The same Hospital.
Pharmacokinetic Analysis and software used (describe)	No. The same Hospital.
Medical Writing and skilled languages	No
Owned archives in the same Unit building (describe)	Yes

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

15 years

The study files are digitized and converted in a CD or web format	No
Project management	No

Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers	x Patients
Other populations	

If the Unit has experience in oncology, detail kind of tumour and age groups

x Solid tumour	x Haematological tumour	x Adults	Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Every kind of Cancer

Recruiting methods for healthy volunteers

NA

Recruting methods for patients

Same patients that have been seeing by the PI-specialist doctor for each patology

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	Yes (2)
Do you keep a paper or electronic database of volunteers? (describe)	NA
Have you implemented any measure for avoiding the over-volunteering? (describe)	NA

Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	Yes (6)	Pulsioximetry devices (number)	Yes (2)	12-leads ECG devices (number)	Yes. 1

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	No
Availability in the Unit of tests for assessing CNS drug effects	
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	No
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes
Experience in other kind of PD or PK evaluations not formerly collected	
Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted	

Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence	0	0	0	0	0	0
First single-dose administration in humans	0	0	0	0	0	0
First multiple-dose administration in humans	0	0	0	0	0	0
Drug interaction	0	0	0	0	0	0
Food interaction	NA	NA	NA	NA	NA	NA
Special populations (Renal or liver impairment, elderly)	NA	NA	NA	NA	NA	NA
Proof of concept (Phase Ib or I/II)	92	102	116	112	103	94
Own research lines	0	0	0	0	0	0
Others (specificying)						

Number of trials linked to a PEI (IND) submission 2009 0 2010 0 2011 0 2012 0 2013 0 2014 0

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

New biological treatments against of extracellular, intracellular and immunotherapy cell-signalling pathways,

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 50 Number of trials promoted by multinational companies 350

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60

Number of Early Stages trials performed in the Unit and published in the last 4 years 5-6

Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

Annexes

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Rojo F, Gracia E, Villena N, Cruz T, Corominas JM, Corradino I, Cedeño M, Campas C, Bellosillo B, Rovira A, Marsoni S, Gascón P, et al. Pharmacodynamic trial of nimotuzumab, an anti-epidermal growth factor receptor monoclonal antibody, in unresectable squamous cell carcinoma of the head and neck: a SENDO Foundation study. Clin Cancer Res 16: 2474-2482, 2010

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Unidad de Investigación de Nuevas Terapias; Inther Unit. Hospital Clínic de Barcelona

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Dose-escalation of the First in Human Phase I/Ib study of ABTL0812, a novel antitumor drug inhibiting the Akt/mTOR pathway in patients with advanced solid tumors. Enviado a ASCO 2015.

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

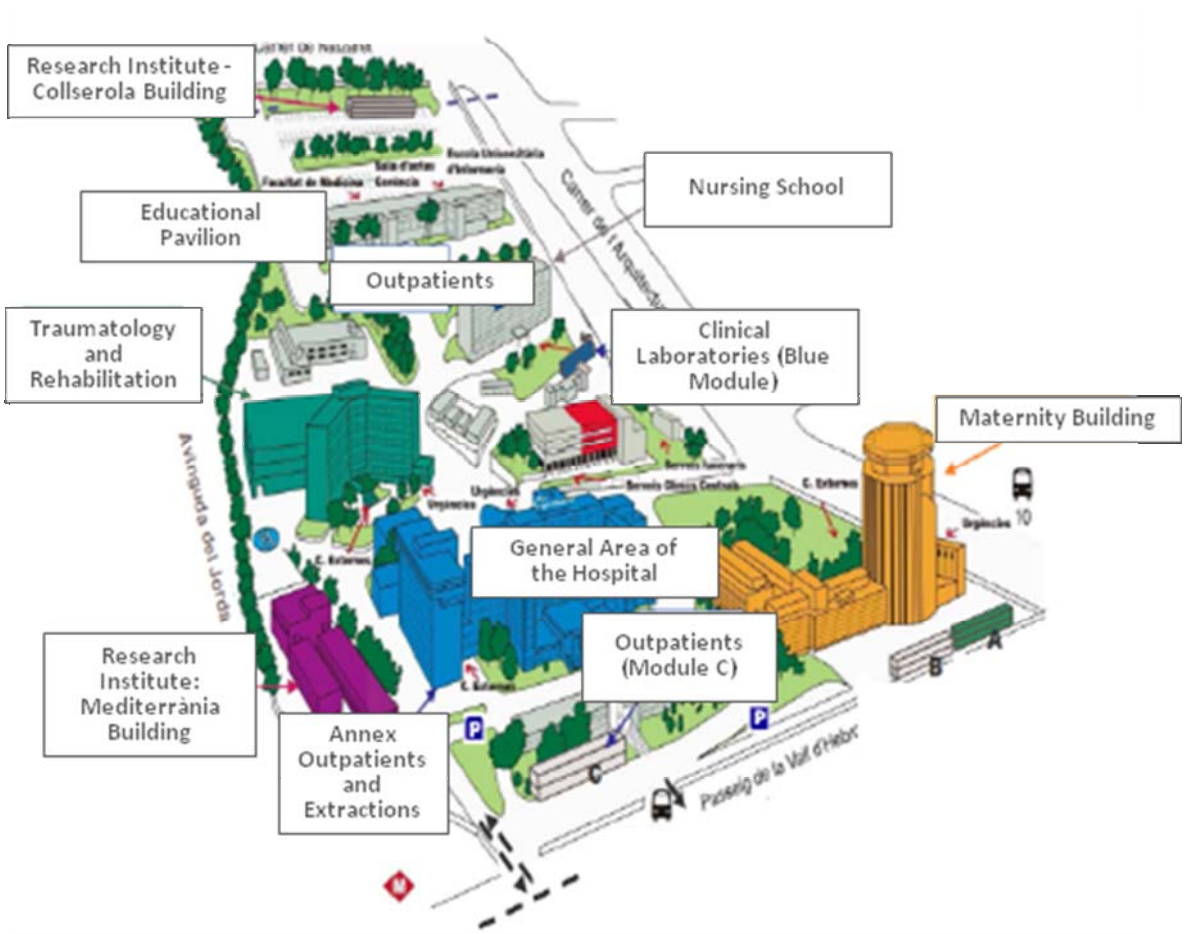
General Information

Who filled in this survey	Gemma Sala
E-mail contact (Phone number)	gsala@vhio.net
Date of survey filling in	25/02/2015
Unit web address	http://www.vhio.net/clinical-trials/en_research_unit_molecular_therapy_cancer.php
Formal name of the unit	UITM (Unitat de Terapia Molecular-La Caixa)/ RESEARCH UNIT FOR MOLECULAR THERAPY OF CANCER "LA CAIXA"
Postal address	Hospital Vall d'Hebron Servei d'Oncologia Ed.General pl.baixa P.Vall Hebron 119-129 08035 Barcelona

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Location

UITM: located in the General Area of the Hospital



Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Ownership

Ownership	RESEARCH UNIT FOR MOLECULAR THERAPY OF CANCER "LA CAIXA" VHIO
Established	
Linked hospital	Hospital Val lHebron
Distance between linked hospital and Unit	In the hospital
Linked Ethics Committee (CEIC)	www.vhir.org

Unit Manager

First and last names	Jordi Rodon
Qualifications	Oncología
Medical specialty	oncology
Manager since	2010
E-mail and phone	jrodon@vhio.net

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Ownership

Short CV

Licensed physician

2000 -Barcelona Medical License # 35,823
2010- Clinical Head of the Molecular Therapies Research Unit (Phase I Program) at the Valld´HebronUniversity Hospital. Barcelona, Spain

Education

1994-2000 School of Medicine - Universitat Autònoma de Barcelona. Barcelona, Spain.

1999 Internship at the Body Scanner of the Radiology Department. Vall d'Hebron University Hospital. Barcelona, Spain.
1997/98/99 Several internships at the Internal Medicine Department. Vall d'Hebron University Hospital. Barcelona, Spain.

Certificates

2000-Degree in Medicine and Surgery. Universitat Autònoma de Barcelona. Barcelona, Spain.
2005-Board Certified in Medical Oncology. Spanish Board of Medical Oncology.Hospital, Barcelona, Spain.
2010- Clinical Head of the Molecular Therapies Research Unit (Phase I Program) at the Valld´HebronUniversity Hospital. Barcelona, Spain

Postdoctoral Training

2000-2001 Board examination (Spanish National MIR exam -Medical Internal Resident-). Preparation July 2000 – March 2001. Examination passed in March 2001 with a 312 ranking number (above 95 percentile).
2001-2005 Residency in Medical Oncology. Institut Català d'Oncologia. Hospital Univeritari de Bellvitge. Barcelona, Spain.
2004- Gradute education: Completed the first 2 years of the graduate program in Experimental Medicine at the Universitat de Barcelona. Barcelona, Spain.
2008 Master in Science degree (Diploma Estudios Avanzados/Suficiencia investigadora) by the Universitat de Barcelona. Barcelona, Spain.
2004-2007 ECFMG Certification: October 2005. USMLE Exams (US Medical Licence Exam): Step 1, December 2004; Step 2 CK, February 2005; Step 2 CS May 2005. Step 3. October 2007.
2005-2007 Advanced Oncology Drug Development Fellowship Program: Clinical research fellow at The Institute for Drug Development, Cancer Therapy and Research Center, and the University of Texas Health Science Center. San Antonio, Texas, USA.
2007-2008 Senior Clinical Research Fellow, Investigational Cancer Therapeutics, U.T. MD Anderson, Houston, Texas, USA.
2007-2008 Internship at the Kleberg Center for Molecular Markers (Director: Gordon B. Mills, M.D., Ph.D.) at MD Anderson Cancer Center. Houston, Texas, USA.

Positions and Appointments

2008- Attending physician. Member of the Phase I Unit and the CentralNervous System tumors program at the Vall d´Hebron University

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

no

Audits by regulatory agencies (last 3 years)

Yes (FDA) 2012,2015

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **no**

Audits by sponsors (last 3 years) yes

Do you follow your own Standard Operating Procedures (SOPs)?	yes	Do you supply with a SOP copy to a sponsor if requested?	No (partially only)
Would you follow the sponsor SOPs if requested:	yes		

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 4-5 per year

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

We work under the spanish and local laws that guarantee patient's safety and confidentiality of patients that participate in a trial in Vall Hebron . Medical reports are protected in the electronic chart of the hospital that is validated. All the staff involved in clinical trials are also keeping this confidentiality following the SOPs and GCPs

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

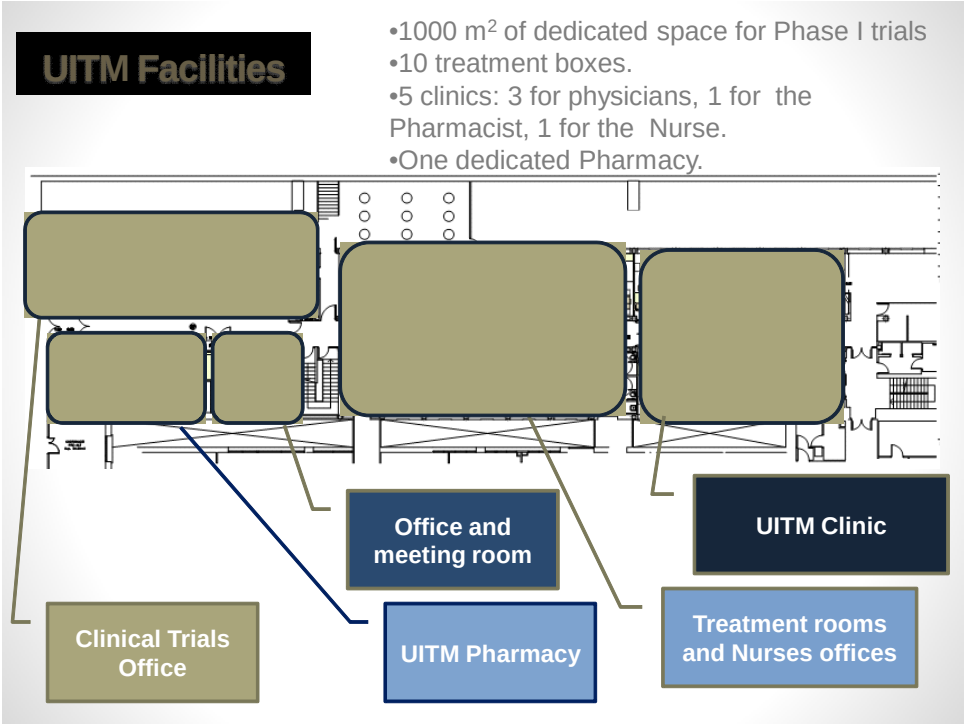
Facilities

Year of Unit building	1956	Last Unit reform	2010
Usable space	1000m2	The Unit building is separate from the linked hospital	no
Number of CTs the unit could perform simultanously	60	Number of beds	0 (10 treatment chairs)
Beds distribution	NA		
Beds distribution allows a complete and continuous visual control by nurses	NA		
Number of bed with intensive or continuous monitoring		Number of armchairs suitable for subject monitoring	10
Owned kitchen		Meals supervision by dietitian	
Dining-room available for volunteers		Individual lockers available for volunteers	
Relaxing room available for volunteers independent from the beds area			
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			yes
The emergency trolly has available suitable medications with immediate by controlled access			yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)		yes	
Unit availability of an evacuation plan for volunteers in emergency situations		yes	
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required		Unit is inside the hospital	
Volunteers/patients healthcare would be covered by the national or the regional health system if required		yes	
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers		Same hospital	
Distance and time to get the former services		0	
Unit entrance/Exit door controlled	yes	Unit with Closed Circuit Television	no
Availability of an alternate electrical generating set that automatically works in case of a general system failure			yes

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Facilities

Unit distribution plan:



Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Staffing and Resources

Unit employees

Permanent staff 27 Fixed-term/contracted staff (internship, grant holders) 2 Part-time collaborators

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	2	0
Co-investigator (physician)	4	2
Nurse	3	
Monitor or CRA	0	
Pharmacist	2	
Biometry		
Data management	5	
Medical writing		
Pharmacokinetics		
Quality assurance	1	
Project Management	1	
Finance	1	
Recruitment		
IT (informatics)	1	
Other (specify): CTA, psychologist, etc	7 study coordinators	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

Physician Nurse

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	yes
The quality assurance activities are subcontracted by the Unit	no
Availability of a specific area for drug storing and preparation of medications for the study	yes
The former area or room has restricted access by key or code	yes
Laminar flow chamber availability for preparation of parenteral treatments	yes
Perfusion pumps for intravenous treatment	yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Pharmacy (Laura Maños) **Preparation**: Pharmacy (Mª Josep Carreras)
Drug accountability procedures, such as reception, preparation and dispensing forms	yes
SOPs available for drug preparation and dispensing	yes
SOPs available for drawing and managing of biological fluids	yes
System or procedure used for samples identification	logs and stickers
Availability of a specific area for blood samples managing	yes
The former area or room has restricted access by key or code	no
Number of centrifuges available	4
System for plasma/fluids samples storing	yes
Fridges and freezers available in the Unit	3
The Unit has its owned Bioanalytical Department	yes
Availability of genotyping or fenotyping methods for participants	yes

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Services Capabilities

Data Management and software used (describe)	no
Biometry or Statistical Analysis and software used (describe)	no
Pharmacokinetic Analysis and software used (describe)	no
Medical Writing and skilled languages	no
Owned archives in the same Unit building (describe)	yes

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived Investigator Master File (15 years)

The study files are digitized and converted in a CD or web format	no
Project management	yes

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Study Participants

Kind of participants included in clinical trials performed in the Unit

no Healthy volunteers yes Patients

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

yes Solid tumour yes Haematological tumour yes Adults Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All solid tumors and hemathologic tumors

Recruiting methods for healthy volunteers

NA

Recruting methods for patients patients from our clinic and referrals from other hospitals

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	Yes-5
Do you keep a paper or electronic database of volunteers? (describe)	NA
Have you implemented any measure for avoiding the over-volunteering? (describe)	NA

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	Yes-5	Pulsioximetry devices (number)		12-leads ECG devices (number)	Yes-1
Familiarity with evaluation of the QTc interval prolongation accordingly with current rules			yes		
Availability in the Unit of tests for assessing CNS drug effects			yes		
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports			no		
Familiarity with Electronic Data Capture –EDC applied to clinical trials			yes		
Experience in other kind of PD or PK evaluations not formerly collected			molecular analysis		

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

yes

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence	1	0	0	1	2	2
First single-dose administration in humans						
First multiple-dose administration in humans	17	17	16	24	27	33
Drug interaction						
Food interaction	1	1				
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)	16	20	32	41	6	48
Own research lines	0	0	1	1	1	1
Others (specificying)						

Number of trials linked to a PEI (IND) submission | 2009 | 0 | 2010 | 0 | 2011 | 0 | 2012 | 0 | 2013 | 0 | 2014 | 0

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

EGFr,HER2;IGFr,TGFbet , farnesyl,transferase inhibitors; antiangiogenics; tubulin interacting agents; cititoxics; PI3k inh; MET inh; anti PDL-1; NOTCH inh; porcupine inh; anti CEA, HDM2inh; immunotherapy, etc

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 40 Number of trials promoted by multinational companies 140

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 65

Number of Early Stages trials performed in the Unit and published in the last 4 years 46

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Experience References of clinical trials publications

- **Rodon J**; Tawbi HA; Thomas AL; Stoller R; Turtschi CP; **Baselga J**; Sarantopoulos J; Mahalingam D; Shou Y; Moles MA; Yang L; Granvil C; Hurh E; Rose KL; Amakye DD; Dummer R; Mita AC. A phase I, multicenter, open-label, first-in-human, dose-escalation study of the oral smoothened inhibitor Sonidegib (LDE225) in patients with advanced solid tumors. 2014. Clin Cancer Res. 20: 1900-1909
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- **Rodon, Jordi**; Jacobs, Charlotte D.; Chu, Quincy; Rowinsky, Eric K.; Lopez-Anaya, Arturo; Takimoto, Chris H.; Wakelee, Heather A. A phase I pharmacokinetic study of bexarotene with paclitaxel and carboplatin in patients with advanced non-small cell lung cancer (NSCLC). 2012. Cancer Chemother. Pharmacol. 69: 825-834.
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Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Experience References of clinical trials publications

- Yap TA; Cortes-Funes H; Shaw H; Rodriguez R; Olmos D; Lal R; Fong PC; Tan DS; Harris D; **Capdevila J**; Coronado C; Alfaro V; Soto-Matos A; Fernández-Teruel C; Siguero M; Tabernero JM; Paz-Ares L; de Bono JS; López-Martin JA. First-in-man phase I trial of two schedules of the novel synthetic tetrahydroisoquinoline alkaloid PM00104 (Zalypsis) in patients with advanced solid tumours. 2012. Br. J. Cancer. 106: 1379-1385
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- Cervantes, Andres; **Elez, Elena**; Roda, Desamparados; Ecsedy, Jeffrey; **Macarulla, Teresa**; Venkatakrishnan, Karthik; Rosello, Susana; Andreu, Jordi; Jung, JungAh; Sanchis-Garcia, Juan Manuel; Piera, Adelaida; Blasco, Inma; Manos, Laura; Perez-Fidalgo, Jose-Alejandro; Fingert, Howard; **Baselga**, **Jose; Tabernero, Josep**. Phase I Pharmacokinetic/Pharmacodynamic Study of MLN8237, an Investigational, Oral, Selective Aurora A Kinase Inhibitor, in Patients with Advanced Solid Tumors. 2012. Clin. Cancer Res. 18: 4764-4774.
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- Bendell JC, **Rodon J**, Burris HA, de Jonge M, Verweij J, Birle D, Demanse D, De Buck SS, Ru QC, Peters M, Goldbrunner M, **Baselga J**. Phase I, dose-escalation study of BKM120, an oral pan-Class I PI3K inhibitor, in patients with advanced solid tumors. J Clin Oncol. 2012 Jan 20;30(3):282-90. Epub 2011 Dec 12.
- Soria JC, **Cortes J,** Massard C, Armand JP, De Andreis D, Ropert S, Lopez E, Catteau A, James J, Marier JF, Beliveau M, Martell RE, **Baselga J**. Phase I safety, pharmacokinetic and pharmacodynamic trial of BMS-599626 (AC480), an oral pan-HER receptor tyrosine kinase inhibitor, in patients with advanced solid tumors. Ann Oncol. 2012 Feb;23(2):463-71. Epub 2011 May 16
- Wakelee HA, Takimoto CH, Lopez-Anaya A, Chu Q, Middleton G, Dunlop D, Ramlau R, Leighl N, Rowinsky EK, Hao D, Zatloukal P, Jacobs CD, **Rodon J**. The effect of bexarotene on atorvastatin pharmacokinetics: results from a phase I trial of bexarotene plus chemotherapy in patients with advanced non-small cell lung cancer. Cancer Chemother Pharmacol. 2012 Feb;69(2):563-71. Epub 2011 Nov 6.

Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

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Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Experience References of clinical trials publications

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Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Experience References of clinical trials publications

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Unidad de Ensayos Clínicos Fase I de Oncología Médica– Hospital Vall d´Hebron

Annexes

http://vhio.conocimiento.com/files/File/memoria_b.pdf

Unidad de Ensayos Clínicos de Alicante (UECA)

Unidad de Ensayos Clínicos de Alicante (UECA)

General Information

Who filled in this survey	María de los Ángeles Pena Pardo
E-mail contact (Phone number)	pena_marpar@gva.es (+34 965913868)
Date of survey filling in	5-May-2015
Unit web address	http://ueca.comuf.com
Formal name of the unit	UNIDAD DE ENSAYOS CLINICOS DE ALICANTE (UECA) Clinical Trials Unit of Alicante
Postal address	HOSPITAL GENERAL UNIVERSITARIO DE ALICANTE C/ PINTOR BAEZA, 12 EDIF. GRIS 6ª PLANTA 03010 Alicante. Telephone and fax: +34-965-913975

Unidad de Ensayos Clínicos de Alicante (UECA)

Location

For additional information about access and public transportation: http://alicante.san.gva.es/

Unidad de Ensayos Clínicos de Alicante (UECA)

Ownership

Ownership	Public- Clinical Pharmacology
Established	2010 in HGUA (before, 2000-2009, this Unit was located at Miguel Hernandez University, campus ofl San Juan, in Alicante)
Linked hospital	General University Hospital Alicante
Distance between linked hospital and Unit	0 (same location)
Linked Ethics Committee (CEIC)	CEIC del Hospital General Universitario de Alicante

Unit Manager

First and last names	José Francisco Horga de la Parte
Qualifications	MD, PhD
Medical specialty	Clinical pharmacology
Manager since	2000
E-mail and phone	horga_jos@gva.es +34 965913868

Short CV

Academic

- Medicine degree
- PhD in Medicine

Profesional Experience

- Professor in pharmacology of the University Miguel Hernández
- Director of Dep. of Pharmacology, Pediatry and Organic Chemistry, UMH
- Head of Clinical Pharmacology Unit in HGUA

Research experience

- Member of different research groups
- Member of different Ethics Committees at the Alicante province
- Member of assessors for observational and prospective post-authorized studies of the regions' administration (Conselleria Valenciana de Sanitat)
- Member of the Scientific Committee for Research of the regions' administration

Unidad de Ensayos Clínicos de Alicante (UECA)

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

The Unit received (in April, 2013) the favourable evaluation result by the Health Inspection Service (Department of Health of Generalitat Valenciana, Spain).

Audits by regulatory agencies (last 3 years)

None

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **YES**

Audits by sponsors (last 3 years)

5 may 2012; 3 july 2013

Do you follow your own Standard Operating Procedures (SOPs)? **YES** Do you supply with a SOP copy to a sponsor if requested? **YES**

Would you follow the sponsor SOPs if requested: **YES**, if there are not major conflicts with the Unit SOPs

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial:
1 general audits and 1 audit after each finalized trial

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:
All the studies files are archived under key. Electronic data are stored at one computer devoted specifically to that. There are automated backups that are also archived in a different place.

Unidad de Ensayos Clínicos de Alicante (UECA)

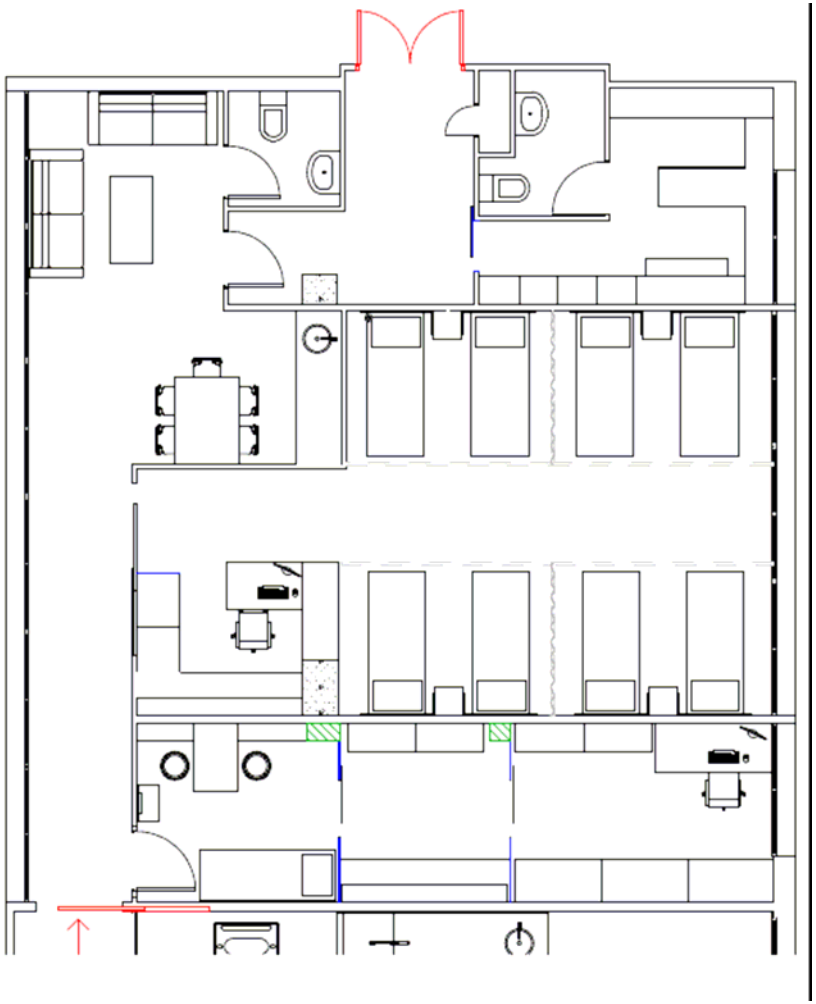
Facilities

Year of Unit building	1972	Last Unit reform	2009-10
Usable space	116 m^2	The Unit building is separate from the linked hospital	NO
Number of CTs the unit could perform simultaneously	2	Number of beds	8
Beds distribution	1 room with 8 beds with possible divisions in pairs		
Beds distribution allows a complete and continuous visual control by nurses			YES
Number of beds with intensive or continuous monitoring	2	Number of armchairs suitable for subject monitoring	2
Owned kitchen	NO	Meals supervision by dietitian	YES
Dining-room available for volunteers	YES	Individual lockers available for volunteers	YES
Relaxing room available for volunteers independent from the beds area			YES
Availability in the unit of an emergency trolley for cardiopulmonary resuscitation			YES
The emergency trolley has available suitable medications with immediate by controlled access			YES
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Advanced Life Support		
Unit availability of an evacuation plan for volunteers in emergency situations			YES
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			YES
Volunteers/patients healthcare would be covered by the national or the regional health system if required			YES
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Emergencies, ICU of the HGUA. SAMU/Emergecies staff:physicians and nurses within the UECA.		
Distance and time to get the former services	Located in the same hospital (200 m and 5 min)		
Unit entrance/Exit door controlled	YES	Unit with Closed Circuit Television	NO
Availability of an alternate electrical generating set that automatically works in case of a general system failure			YES

Unidad de Ensayos Clínicos de Alicante (UECA)

Facilities

Unit distribution plan:



Unidad de Ensayos Clínicos de Alicante (UECA)

Staffing and Resources

Unit employees

Permanent staff 4 Fixed-term/contracted staff (internship, grant holders) 1 Part-time collaborators 12

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	4	
Co-investigator (physician)	4	5
Nurse		7
Monitor or CRA		1
Pharmacist		1
Biometry	4	
Data management	4	1
Medical writing	4	1
Pharmacokinetics	4	
Quality assurance		1
Project Management	4	1
Finance	4	1
Recruitment	4	1
IT (informatics)	1	
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician X Nurse

Unidad de Ensayos Clínicos de Alicante (UECA)

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameters)	General Hospital of Alicante Laboratory (Rule ISO9001-2008)
The quality assurance activities are subcontracted by the Unit	YES, Foundation FISABIO
Availability of a specific area for drug storing and preparation of medications for the study	YES
The former area or room has restricted access by key or code	YES
Laminar flow chamber availability for preparation of parenteral treatments	NO
Perfusion pumps for intravenous treatment	YES
Who is the responsible for drug preparation and dispensing	**Dispensing:** Clinical Pharmacologist **Preparation**: Farmacy Service
Drug accountability procedures, such as reception, preparation and dispensing forms	YES
SOPs available for drug preparation and dispensing	YES
SOPs available for drawing and managing of biological fluids	YES
System or procedure used for samples identification	Tubes labels
Availability of a specific area for blood samples managing	YES
The former area or room has restricted access by key or code	YES
Number of centrifuges available	2 refrigerated
System for plasma/fluids samples storing	Tubes for freezing (cryovirals)
Fridges and freezers available in the Unit	2 fridges and 4 freezers
The Unit has its owned Bioanalytical Department	NO
Availability of genotyping or fenotyping methods for participants	

Unidad de Ensayos Clínicos de Alicante (UECA)

Services Capabilities

Data Management and software used	YES, Software: Excel and Access
Biometry or Statistical Analysis and software used	YES, Software: SPSS
Pharmacokinetic Analysis and software used	YES
Software WinNonlin	
Medical Writing and skilled languages	YES, Spanish and English
Owned archives in the same Unit building	YES
Fireproof cabinets in locked area with key access	
Regarding a specific clinical trial what documents are sent to the archives and for long time are archived	
All the study files on paper (from the initial project to close monitoring) are archived. Digitised copies for pharmacokinetic data and clinical data (keeping confidentiality of the subjects) are also stored according to the time set by law	
The study files are digitised and converted in a CD or web format	YES
Project management	YES

Unidad de Ensayos Clínicos de Alicante (UECA)

Study Participants

Kind of participants included in clinical trials performed in the Unit

X Healthy volunteers X Patients

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

- Solid tumour - Haematological tumour - Adults - Paediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Recruiting methods for healthy volunteers

Students recruited from the linked University by means of advertisements

Recruiting methods for patients

Collaboration with the suitable hospital services and Primary Care centers

Do you have surgery rooms available for screening (separated from the in-house area)? YES, 1 room

Do you keep a paper or electronic database of volunteers? NO

Have you implemented any measure for avoiding the over-volunteering? YES

Subjects' participation restricted to a limited number of clinical trials per year.

* The UECA is the only Unit that performs phase I studies in healthy volunteers in Valencia Autonomous Community. Others units of studies in early phases in Valencian Community only conduct studies in patients.

Unidad de Ensayos Clínicos de Alicante (UECA)

Pharmacodynamic / Pharmacokinetic Capabilities

Digital blood pressure devices	YES, 9	Pulsioximetry devices	YES, 2	12-leads ECG devices	YES, 3

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	YES
Availability in the Unit of tests for assessing CNS drug effects	NO
Familiarity in poblational analysis and PK/PD modelling, including writing of clinical reports	NO
Familiarity with Electronic Data Capture –EDC applied to clinical trials	YES
Experience in other kind of PD or PK evaluations not formerly collected	NO

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

-

Unidad de Ensayos Clínicos de Alicante (UECA)

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence				1	2	2
First single-dose administration in humans						
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)			1			1
Own research lines						5
Others (specifying)			2	3	2	2

Number of trials linked to a PEI (IND) submission | 2009 | 0 | 2010 | 0 | 2011 | 0 | 2012 | 0 | 2013 | 0 | 2014 | 0

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Opioids; fluids; digestive system: bile acids and antivirals; cardiovascular system: antihypertensives, cholesterol-lowering drugs; anti-canceR drugsr; analgesic-anesthetic.

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 2 Number of trials promoted by multinational companies 3

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 1

Unidad de Ensayos Clínicos de Alicante (UECA)

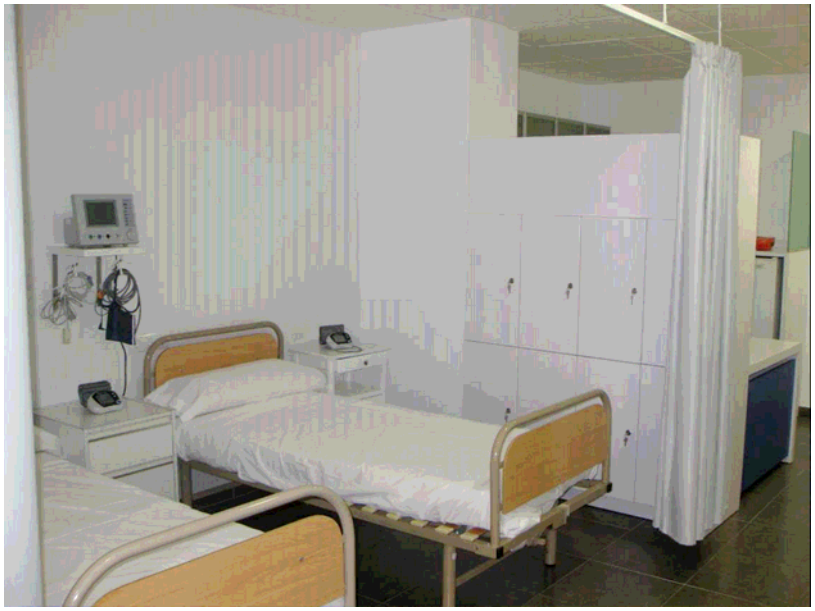
Annexes

Brochure not available in English

References of clinical trials publications

Peiró AM, Novalbos J, Zapater P, Moreu R, López-RodrIguez R, RodrIguez V, Abad-Santos F, Horga JF.
Pharmacogenetic relevance of the CYP2C9*3 allele in a tenoxicam bioequivalence study performed on Spaniards. Pharmacol Res. 2009;59 (1): 62-8.

Unit images



Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA

General Information

Who filled in this survey	Yolanda de la Cruz
E-mail contact (Phone number)	ydelacruz@incliva.es
Date of survey filling in	29/04/15
Unit web address	www.incliva.es (web Phase I under construction)
Formal name of the unit	Hematology and Oncology Clinical Trials Unit
Postal address	Servicio de Hematología y Oncología Médica, Pab. A, 8ª planta Hospital Clínico Universitario de Valencia Avda. Blasco Ibáñez, 17 46010 Valencia (España)

Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA

Location

Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA

Ownership

Ownership	Public – Hospital Clínico Universitario de Valencia
Established	2004
Linked hospital	Hematology and Oncology Dept. (HCUV)
Distance between linked hospital and Unit	Same location
Linked Ethics Committee (CEIC)	CEIC HCUV

Unit Manager

First and last names	Andrés Cervantes Ruipérez
Qualifications	Doctor
Medical specialty	Medical Oncology
Manager since	01/01/2004
E-mail and phone	Andres.cervantes@uv.es 626 858 757

Short CV

Education

Bachelor of Medicine by the Universidad de Murcia on June 20, 1980
MD specialized in Medical Oncology by the Universidad de Valencia on February 28, 1986
PhD in Medicine by the Universidad de Valencia on June, 1987

Current Professional Status

Professor at the Universidad de Valencia
Head of Section - Hematology and Medical Oncology, Hospital Clínico Universitario de Valencia
Responsible of the Hematology and Oncology Clinical Trials Unit of the Hospital Clínico Universitario de Valencia

Experience as Investigator

Research Projects: Principal Investigator of four Research Projects. He has also participated as a collaborator investigator in other projects.

Clinical Trials: Principal Investigator in 120 clinical trials, thirty of them being Phase I clinical trials.

Publications: Co-author of 48 international articles and 13 national articles (1st author: 14 international articles and 7 national articles)

Doctoral theses: Director of 6 doctoral theses.

Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA

Accreditations and audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

NO

Audits by regulatory agencies (last 3 years)

NO

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **YES**

Audits by sponsors (last 3 years)

NO

Do you follow your own Standard Operating Procedures (SOPs)? YES Do you supply with a SOP copy to a sponsor if requested? YES

Would you follow the sponsor SOPs if requested: -

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: -

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Confidentiality is granted with the patient information sheet and the consent form. A specific folder with all base documents relative to the patient is used during his participation in the clinical trial. When his participation is over, this folder is transfered to the patient's medical record.

Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA

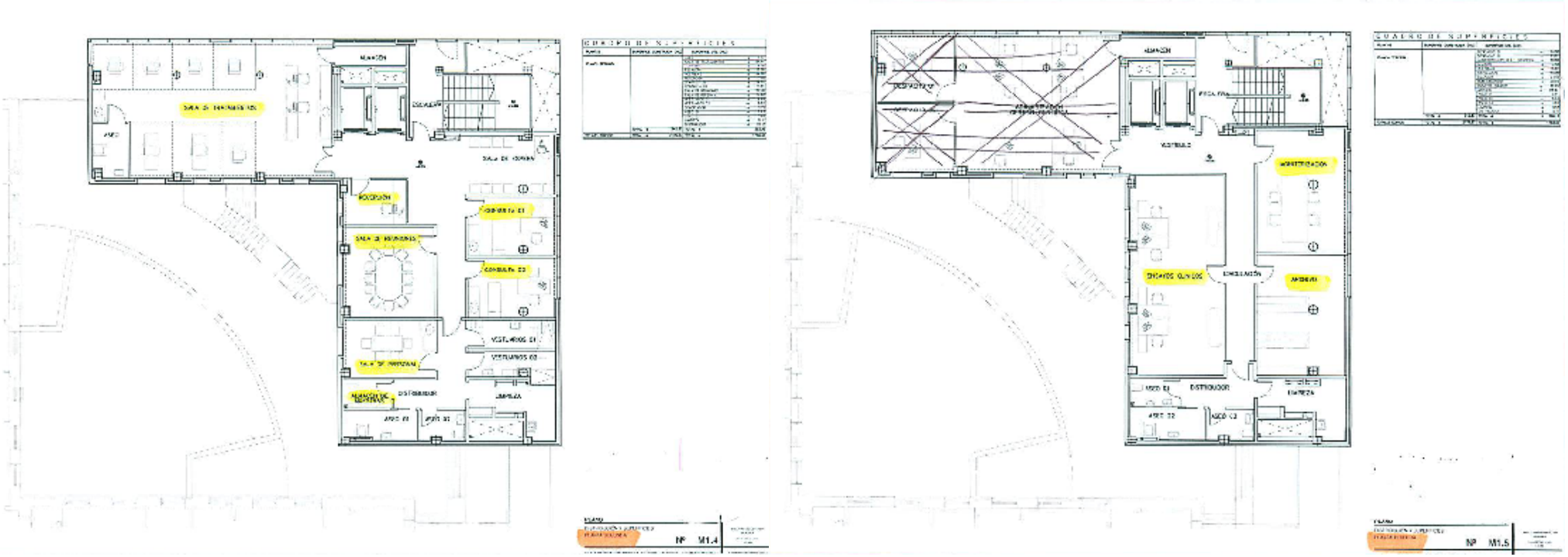
Facilities

Year of Unit building	2013	Last Unit reform	-
Usable space	377.84m^2	The Unit building is separate from the linked hospital	YES
Number of CTs the unit could perform simultanously	15	Number of beds	2
Beds distribution	Oncology Day Hospital is an Unit that has two beds and five armchairs		
Beds distribution allows a complete and continuous visual control by nurses			YES
Number of bed with intensive or continuous monitoring	ALL BEDS AND ARMCHAIRS	Number of armchairs suitable for subject monitoring	5
Owned kitchen	NO	Meals supervision by dietitian	YES
Dining-room available for volunteers	NO	Individual lockers available for volunteers	NO
Relaxing room available for volunteers independent from the beds area			NO
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			YES
The emergency trolly has available suitable medications with immediate by controlled access			YES
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	ADVANCED LS		
Unit availability of an evacuation plan for volunteers in emergency situations			YES
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			YES
Volunteers/patients healthcare would be covered by the national or the regional health system if required			YES
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Anesthesia and resuscitation Department		
Distance and time to get the former services	50 m, in the Hospital		
Unit entrance/Exit door controlled	YES	Unit with Closed Circuit Television	NO
Availability of an alternate electrical generating set that automatically works in case of a general system failure			YES

Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA

Facilities

Unit distribution plan



Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA

Staffing and Resources

Unit employees

Permanent staff 13 Fixed-term/contracted staff (internship, grant holders) Part-time collaborators

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	4	
Nurse	2	
Monitor or CRA	-	
Pharmacist	2	
Biometry	-	
Data management	1	
Medical writing	-	
Pharmacokinetics	-	
Quality assurance	-	
Project Management	3	
Finance	-	
Recruitment	-	
IT (informatics)	-	
Other (specify): CTA, psychologist, etc	-	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit
The are no volunteers

Physician Nurse

Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	Central Laboratory Hospital
The quality assurance activities are subcontracted by the Unit	NO
Availability of a specific area for drug storing and preparation of medications for the study	NO, it is the Hospital's Pharmacy
The former area or room has restricted access by key or code	NO
Laminar flow chamber availability for preparation of parenteral treatments	YES
Perfusion pumps for intravenous treatment	YES
Who is the responsible for drug preparation and dispensing	**Dispensing:** Two pharmacists dedicated to clinical trials located in the Hospital's Pharmacy **Preparation**: Two pharmacists dedicated to clinical trials located in the Hospital's Pharmacy
Drug accountability procedures, such as reception, preparation and dispensing forms	YES
SOPs available for drug preparation and dispensing	YES
SOPs available for drawing and managing of biological fluids	YES
System or procedure used for samples identification	
Identificative tags issued by the sponsor or the institution	
Availability of a specific area for blood samples managing	YES
The former area or room has restricted access by key or code	NO
Number of centrifuges available	1
System for plasma/fluids samples storing	FREEZER -80º
Fridges and freezers available in the Unit	1 FRIDGE AND 2 FREEZERS
The Unit has its owned Bioanalytical Department	NO
Availability of genotyping or fenotyping methods for participants	NO

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Services Capabilities

Data Management and software used (describe)	NO
Biometry or Statistical Analysis and software used (describe)	NO
Pharmacokinetic Analysis and software used (describe)	NO
Medical Writing and skilled languages	NO
Owned archives in the same Unit building (describe)	Located in the third floor of INCLIVA, which is access with a key only by the clinical trial personnel.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

It's send to an external archive for 15 years

The study files are digitized and converted in a CD or web format	NO
Project management	YES

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Study Participants

Kind of participants included in clinical trials performed in the Unit

- Healthy volunteers — X Patients
- Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour — X Haematological tumour — X Adults — Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All

Recruiting methods for healthy volunteers

There are no volunteers

Recruting methods for patients

Refered by oncology specialist from the same department

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	YES, 2
Do you keep a paper or electronic database of volunteers? (describe)	-
Have you implemented any measure for avoiding the over-volunteering? (describe)	-

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Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	YES, 6	Pulsioximetry devices (number)	YES, 8	12-leads ECG devices (number)	YES, 4

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	YES
Availability in the Unit of tests for assessing CNS drug effects	-
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	-
Familiarity with Electronic Data Capture –EDC applied to clinical trials	YES
Experience in other kind of PD or PK evaluations not formerly collected	-

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted:

Código: 20040235. TItulo: ESTUDIO ABIERTO MULTICENTRICO DE BUSQUEDA DE DOSIS PARA EVALUAR LA SEGURIDAD Y TOLERABILIDAD DEL AMG 706, PANITUUMAB. Y LA COMBINACION DE AMG 706 Y PANITUMUMAB CUANDO SON ADMINISTRADOS CON QT DE INDUCCION Y/O QUIMIORRADITERAPIA EN SUJETOS CON CARCINOMA DE CELULAS ESCAMOSA DE CABEZA Y CUELLO LOCOREGIONAL AVANZADO.
Promotor: AMGEN
Año de Inicio: 2006 Año de Cierre: 2011

Código: C14002. TItulo: ENSAYO EN FASE I, CLÍNICO Y FARMACODINAMICO, DE MLN8237, UN NOVEDOSO INHIBIDOR DE LA AURORA A CINASA, EN PACIENTES CON PROCESOS MALIGNOS AVANZADOS, VERSIÓN ORIGINAL, 14 FEB 2007
Promotor: MILLENNIUM PHARMACEUTICALS, INC
Año de Inicio: 2007 Año de Cierre: 2011

Código: MK 8669-004. TItulo: ESTUDIO EN FASE I DE MK-8669 (DEFOROLIMUS) EN COMBINACION CON MK-0646 (IGF-1R ANTICUERPOS MONOCLONALES EN PACIENTES CON CANCER AVANZADO
Promotor: MERCK SHARP & DOHME ESPAÑA S.A.
Año de Inicio: 2008 Año de Cierre: 2011

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Pharmacodynamic/Pharmacokinetic Capabilities

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Código: BO21495. TItulo: "Estudio de fase I/II multicéntrico, abierto, de escalada de dosis, para evaluar la seguridad, farmacocinética y actividad de RO5083945, un anticuerpo glico-modificado anti-EGFR, en pacientes con tumores sólidos malignos metastáticos y/o localmente avanzados EGFR+."
Promotor: ROCHE
Año de Inicio: 2008 Año de Cierre: 2011

Código: MK 0646-013. TItulo: ESTUDIO PARA ESTABLECER PRUEBA DE CONCEPTO BIOLOGICO DE MK-0646 EN EL CANCER DE MAMA
Promotor: MERCK SHARP & DOHME ESPAÑA S.A.
Año de Inicio: 2008 Año de Cierre: 2011

Código: 1200.70. TItulo: ENSAYO CLÍNICO ABIERTO DE FASE IB, CON TRATAMIENTO CONTINUO UNA VEZ AL DIA VIA ORAL CON BIBW 2992 Y SIROLIMUS (RAPAMUNE ®) EN PACIENTES CON CARCINOMA NO MICROCITICO DE PULMÓN CON UNA MUTACIÓN DE EGFR Y/O CON ENFERMEDAD EN PROGRESIÓN TRAS ERLOTINIB (TARCEVA®)
Promotor: BOEHRINGER INGELHEIM ESPAÑA.S.A.
Año de Inicio: 2009 Año de Cierre: 2013

Código: 20070411. TItulo: ESTUDIO ABIERTO DE FASE 1B/2 CON ESCALADA DE DOSIS DE AMG655 EN COMBINACIÓN CON AMG479 EN SUJETOS CON TUMORES SÓLIDOS REFRACTARIOS Y AVANZADOS
Promotor: AMGEN
Año de Inicio: 2009 Año de Cierre: 2012

Código: ALN-VSP02-001. TItulo: A MULTI-CENTER, OPEN LABEL PHASE 1 DOSE-ESCALATION TRIAL TO EVALUATE THE SAFETY, TOLERABILITY, PHARMACOKINETICS AND PHARMACODYNAMICS OF INTRAVENOUS ALN-VSP02 EN PATIENTS WITH ADVANCED SOLID TUMORS WITH LIVER INVOLVEMENT.
Promotor: ALNYLAM PHARMACEUTICALS INC
Año de Inicio: 2010 Año de Cierre: 2011

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Pharmacodynamic/Pharmacokinetic Capabilities

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Código: ALN-VSP02-002. TItulo: A MULTI-CENTER, OPEN-LABEL, EXTENSION STUDY OF ALN-VSP02 IN CANCER PATIENTS WHO HAVE RESPONDED TO ALN-VSP02 TREATMENT
Promotor: ALNYLAM PHARMACEUTICALS INC
Año de Inicio: 2010 Año de Cierre: 2011

Código: PAM4743G. TItulo: AN OPEN LABEL, PHASE I, DOSE ESCALATION STUDY EVALUATING THE SAFETY AND TOLERABILITY OF GDC 0068 ADMINISTERED DAILY IN PATIENTS WITH REFRACTORY SOLID TUMORS
Promotor: GENENTECH/ROCHE
Año de Inicio: 2010 Año de Cierre: 2013

Código: BO25341. TItulo: "ESTUDIO DE FASE IB ADAPTATIVO, COMPARATIVO, ALEATORIZADO, DE GRUPOS PARALELOS, MULTICÉNTRICO, DE RITUXIMAB POR VIA SUBCUTÁNEA (S.C.) FRENTE A RITUXIMAB POR VIA INTRAVENOSA (I.V.), AMBOS EN COMBINACIÓN CON QUIMIOTERAPIA (FLUDARABINA Y CICLOFOSFAMIDA), EN PACIENTES CON LLC NO TRATADA PREVIAMENTE"
Promotor: ROCHE FARMA S.A.
Año de Inicio: 2011 Año de Cierre: Cerrado a la inclusión de pacientes

Código: INK128-001. TItulo: "ESTUDIO DE FASE I, ABIERTO, DE ESCALADA DE DOSIS DEL FÁRMACO INK128 EN ADMINISTRACIÓN ORAL EN SUJETOS CON TUMORES SÓLIDOS AVANZADOS SEGUIDO DE UNA COHORTE DE EXPANSIÓN A SUJETOS CON ENFERMEDAD MEDIBLE ""
Promotor: INTELLIKINE
Año de Inicio: 2011 Año de Cierre: Abierto actualmente

Código: DAF4873g. TItulo: "ESTUDIO DE FASE I, ABIERTO, DE ESCALADA DE DOSIS SOBRE LA SEGURIDAD Y LA FARMACOCINÉTICA DE MEHD7945A ADMINISTRADO POR VIA INTRAVENOSA EN PACIENTES CON TUMORES EPITELIALES LOCALMENTE AVANZADOS O METASTÁSICAS""
Promotor: GENENTECH
Año de Inicio: 2011 Año de Cierre: Cerrado a la inclusión de pacientes

Código: SYM004-01. TItulo: "ESTUDIO ABIERTO, MULTICÉNTRICO, DE FASE I, DE DOSIS ESCALADAS, PARA INVESTIGAR LA SEGURIDAD Y TOLERABILIDAD DE VARIAS DOSIS DE SYM004 EN PACIENTES CON TUMORES SÓLIDOS AVANZADOS""
Promotor: SYMPHOGEN
Año de Inicio: 2011 Año de Cierre: Pendiente de cierre

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Pharmacodynamic/Pharmacokinetic Capabilities

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Código: CBKM120X2107. TItulo: "ESTUDIO DE FASE IB/II, MULTICÉNTRICO, ABIERTO, PARA EVALUAR LA SEGURIDAD Y EFICACIA DE BKM120 EN COMBINACIÓN CON TRASTUZUMAB EN PACIENTES CON RECIDIVA DE CÁNCER DE MAMA CON SOBREEXPRESIÓN DE HER2 Y FALLO DEL TTO PREVIO CON TRASTUZUMAB"
Promotor: NOVARTIS
Año de Inicio: 2011 Año de Cierre: 2014

Código: P05615. TItulo: "Farmacocinética y seguridad de una formulación sólida oral de posaconazol (SCH56592) en sujetos con riesgo elevado de contraer micosis invasoras (Fase 1b)"
Promotor: SHERING-PLOUG RESEARCH INSTITUTE
Año de Inicio: 2011 Año de Cierre: 2012

Código: CBEZ235A2101. TItulo: "Estudio de fase I/II, multicéntrico, abierto de BEZ235, administrado oralmente de forma diaria y continua en pacientes adultos con tumores sólidos avanzados incluyendo pacientes con cáncer de mama avanzado"
Promotor: NOVARTIS FARMACEUTICA S.A.
Año de Inicio: 2011 Año de Cierre: 2013

Código: PAM4983g. TItulo: "Estudio en fase Ib, abierto, de aumento de la dosis, sobre la seguridad y la farmacología de GDC-0068 en combinación con docetaxel o fluoropirimidina más oxaliplatino en pacientes con tumores sólidos avanzados"
Promotor: GENENTECH, Inc
Año de inicio: 2011 Año de Cierre: 2013

Código: V212-013. TItulo: "Ensayo Clínico Fase I, abierto y multicéntrico para evaluar la seguridad y la inmunogenicidad de V212/Vacuna inactivada contra el virus de la varicela-zóster (VVZ) en adultos con neoplasias malignas hematológicas que reciben tratamiento con anticuerpos monoclonales CD-20"
Promotor: MERCK SHARP & DOHME CORP
Año de inicio: 2012 Año de Cierre: Cerrado a la inclusión de pacientes

Código: GEICAM 2010-10. TItulo: "Ensayo Clínico de fase I/II, aleatorizado, de paclitaxel neoadyuvante frente a imprimación con BIBF 1120 seguida por BIBF 1120 mas paclitaxel en cáncer de mama HER-2 negativos con estucios correlativos proteómicos y de imagen dinámica"
Promotor: FUND CENTRO NACIONAL INV ONCOL (CNIO)
Año de inicio: 2012 Año de Cierre: 2014

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Pharmacodynamic/Pharmacokinetic Capabilities

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Código: BP27771. TItulo: "Estudio de fase Ia/Ib, multicéntrico, abierto de escalada de dosis, seguido de uan fase dextensión, para evaluar la seguridad farmacocinética y actividad de RO5479599, un anticuerpo glicomodificado contra HER3, administrado en monoterapia (Parte A) o en combianación con cetuximab (Parte B) o con erlotinib (Parte C), en pacientes con tumores sólidos malignos de origen epitelial HER3-positivo, metastáticos y/o localmente avanzados"
Promotor: ROCHE FARMA
Año de inicio: 2012 Año de Cierre: Abierto actualmente

Código: D3610C00002 FASE IB. TItulo: "Estudio fase I/Ib multicentrico que comprende una evaluación previa de la seguridad de la combinación de AZD5363 con paclitaxel en pacientes con cáncer de mama avanzado o metastático, seguido de una expansión aleatorizada de AZD5363 combinado con paclitaxel fente a paclitaxel más placebo en pacientes con cáncer de mama RE-positivo, avanzado o metastático, estratificadas por estado de mutación de PIK3CA (BEECH)."
Promotor: ASTRA ZENECA AB
Año de inicio: 2012 Año de Cierre: Abierto actualmente

Código: PMT4979g. TItulo: "Estudio abierto de fase I, con aumento de la dosis para evaluar la seguridad y la tolerabilidad de GDC-0032 en pacientes con tumores sólidos localmente avanzados o metastáticos y en combinación con tratamiento endocrino en pacientes con cáncer de mama con receptores hormonales positivos localmente avanzado o metastásico"
Promotor: GENENTECH
Año de inicio: 2012 Año de Cierre: Abierto actualmente

Código: CLJM716X2102. TItulo: "Estudio fase I, multicéntrico, abierto, de escalada de dosis, de LJM716 administrado por vIa intravenosa en combinación con trastuzumab, en pacientes con cáncer de mama metastático que sobreexpresa HER2"
Promotor: NOVARTIS FARMACEUTICA
Año de inicio: 2012 Año de Cierre: Cerrado a la inclusión de pacientes

Código: CC-122-ST-001 CELGENE. TItulo: "Estudio de fase IA/IB, multicéntrico, abierto de búsqueda de dosis para evaluar la seguridad , tolerabilidad, farmacocinética y eficacia preliminar del modificador de la ruta plelotrópica, CC-122, administrado por vIa oral a sujetos con tumores sólidos avanzados, linfoma no-Hodgkin o mieloma múltiple"
Promotor: CELGENE CORPORATION.
Año de inicio: 2013 Año de Cierre: Abierto actualmente

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Pharmacodynamic/Pharmacokinetic Capabilities

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Código: DOXILNAP1002. TItulo: "A Pivotal bioequivalence study of DOXIL®/CAELYX® manufactured at a new site in subjects with advanced or refractory solid malignancies including subjects with ovarian cancer DOXILNAP1002".
Promotor: JANSSEN
Año de inicio: 2013 Año de Cierre: 2014

Código: BP28752 FASE I. TItulo: "Estudio de fase Ib, abierto, multicéntrico, de escalada de dosis seguida por una fase de extensión, para evaluar la seguridad, farmacocinética y actividad de RO5479599, un anticuerpo glicomodificado frente a HER3, administrado en combinación con pertuzumab y paclitaxel en pacientes con cáncer de mama metastático que expresan proteInas HER3 y HER2"
Promotor: ROCHE FARMA S.A.
Año de inicio: 2013 Año de Cierre: Abierto actualmente

Código: GE28079. TItulo: "Estudio fase Ib, abierto, con Aumento escalonado de la dosis, para evaluar la seguridad, tolerabilidad y farmacocinética de GDC-0973 y GDC-0068 en pacientes con tumores sólidos localmente avanzados metastásicos"
Promotor: GENENTECH
Año de inicio: 2013 Año de Cierre: Pendiente de cierre

Código: D2610C00001 FASE I´. TItulo: "Ensayo fase I, abierto, multicéntrico, para evaluar la seguridad, tolerabilidad, farmacocinética y actividad antitumoral preliminar de dosis ascendentes de AZD4547 en pacientes con tumores malignos sólidos avanzados"
Promotor: ASTRA ZENECA
Año de inicio: 2013 Año de Cierre: 2014

Código: MK 3475-001. TItulo: "Estudio en fase I de MK-3475 en monoterapia en pacientes con carcinoma, melanoma o carcinoma de pulmón no microcItico progesivos, localmente avanzados o metastásicos"
Promotor: MERCK
Año de inicio: 2013 Año de Cierre: Abierto actualmente

Código: BP28179 FASE I. TItulo: "Estudio de fase I multicéntrico, abierto, de escalada de dosis de RO5520985 como agente único administrado en infusión intravenosa a pacientes con tumores sólidos localmente avanzados o metastásicos"
Promotor: Roche Farma S.A.
Año de inicio: 2013 Año de cierre: Abierto actualmente

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Pharmacodynamic/Pharmacokinetic Capabilities

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Código: 42756493EDI1001 FASE I. TItulo: "Estudio fase I para evaluar la seguridad, farmacocinética y farmacodinamia de JNJ-42756493, un pan-inhibidor tirosina quinasa del receptor factor de crecimiento de los fibroblastos, en sujetos con tumores sólidos avanzados o resistentes, o con linfoma"
Promotor: JANSSEN-CILAG INTERNATIONAL N.V.
Año de inicio: 2013 Año de cierre: Abierto actualmente

Código: D3610C00001 FASE I. TItulo: "Estudio fase I abierto, multicéntrico, para evaluar la seguridad tolerabilidad, farmacocinética y la actividad antitumoral, de forma preliminar, de dosis ascendentes de AZD5363 en esquemas de dosis adaptables en pacientes con tumores sólidos malignos avanzados."
Promotor: ASTRA ZENECA
Año de inicio: 2013 Año de cierre: Abierto actualmente

Código: GO29030. TItulo: "Estudio de fase Ib, abierto, con incremento de la dosis, de la seguridad, tolerabilidad y farmacocinética de MEHD7945A y Cobimetinib en pacientes con cáncer localmente avanzado o metastático con mutación de KRas"
Promotor: GENENTECH Inc.
Año de inicio: 2014 Año de cierre: Abierto actualmente

Código: 1280.4. TItulo: "Ensayo Clínico de Fase Ib/II, aleatorizado, de BI 836845 en combinación con Exemestano y Everolimus frente a Exemestano y Everolimus en mujeres con cáncer de mama localmente avanzado o metastásico."
Promotor: Boehringer Intelheim España,S.A.
Año de inicio: 2014 Año de cierre: Abierto actualmente

Código: BP29360. TItulo: "Estudio de Fase Ib/II multicéntrico, abierto, de RO5479599 en combinación con carboplatino y paclitaxel en pacientes con cáncer de pulmón no microcItico (CPNM) de histologIa escamosa, avanzado o metastásico, que no han recibido previamente quimioterapia o terapia dirigida para CPNM"
Promotor: ROCHE FARMA S.A.
Año de inicio: 2014 Año de cierre: Abierto actualmente

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Pharmacodynamic/Pharmacokinetic Capabilities

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Código:: GO27802. TItulo: "Estudio de fase Ib abierto, de aumento de dosis sobre la seguridad y la farmacología de GDC-0032 en combinación con docetaxel o paclitaxel en pacientes con cáncer de mama localmente recurrente o metastático negativo para HER2 o cáncer de pulmón de células no microcIticas"
Promotor: Genentech Inc.
Año de inicio: 2015 Año de cierre: Abierto actualmente

Código: WP29158. TItulo: "Estudio de fase Ib de la seguridad y la farmacología de MPDL3280A administrado con erlotinib en pacientes con cáncer de pulmón no microcItico avanzado"
Promotor:: F. Hoffmann-La Roche Ltd
Año de inicio: 2015 Año de cierre: Abierto actualmente

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Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						
First multiple-dose administration in humans	1	3	4	3	6	0
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)	1	0	4	3	3	3
Own research lines						
Others (specificying)						

Number of trials linked to a PEI (IND) submission 2009 2 2010 3 2011 4 2012 2 2013 2 2014 1

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 1 Number of trials promoted by multinational companies 32

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 90 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 15

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Annexes References of clinical trials publications

2015

Combination of the mTOR Inhibitor Ridaforolimus and the Anti-IGF1R Monoclonal Antibody Dalotuzumab: PreClínical Characterization and Phase I Clínical Trial.
Di Cosimo S, Sathyanarayanan S, Bendell JC, **Cervantes A**, Stein MN, Braña I, Roda D, Haines BB, Zhang T, Winter CG, Jha S, Xu Y, Frazier J, Klinghoffer RA, Leighton-Swayze A, Song Y, Ebbinghaus S, Baselga J.
Clin Cancer Res. 2015 Jan 1;21(1):49-59

2014

FCGR polymorphisms and cetuximab efficacy in chemorefractory metastatic colorectal cancer: an international consortium study.
Geva R, Vecchione L, Kalogeras KT, Vittrup Jensen B, Lenz HJ, Yoshino T, Paez D, Montagut C, Souglakos J, Cappuzzo F, **Cervantes A**, Frattini M, Fountzilas G, Johansen JS, Høgdall EV, Zhang W, Yang D, Yamazaki K, Nishina T, Papamichael D, Vincenzi B, Macarulla T, Loupakis F, De Schutter J, Spindler KL, Pfeiffer P, Ciardiello F, Piessevaux H, Tejpar S.
Gut. 2014 Jul 10. pii: gutjnl-2014-307234. doi: 10.1136/gutjnl-2014-307234. [Epub ahead of print]

Activity of dalotuzumab, a selective anti-IGF1R antibody, in combination with erlotinib in unselected patients with Non-small-cell lung cancer: a phase I/II randomized trial.
Moran T, Felip E, Keedy V, Borghaei H, Shepherd FA, **Insa A**, Brown H, Fitzgerald T, Sathyanarayanan S, Reilly JF, Mauro D, Hsu K, Yan L, Johnson DH.
Exp Hematol Oncol. 2014 Nov 7;3(1):26.

Open-label, multicentre expansion cohort to evaluate imgatuzumab in pre-treated patients with KRAS-mutant advanced colorectal carcinoma.
Delord JP, Tabernero J, García-Carbonero R, **Cervantes A**, Gomez-Roca C, Bergé Y, Capdevila J, Paz-Ares L, Roda D, Delmar P, Oppenheim D, Brossard SS, Farzaneh F, Manenti L, Passioukov A, Ott MG, Soria JC.
Eur J Cancer. 2014 Feb;50(3):496-505

2013

Evaluation and Clínical analyses of downstream targets of the Akt inhibitor GDC-0068.
Yan Y, Serra V, Prudkin L, Scaltriti M, Murli S, RodrIguez O, Guzman M, Sampath D, Nannini M, Xiao Y, Wagle MC, Wu JQ, Wongchenko M, Hampton G, Ramakrishnan V, Lackner MR, Saura C, Roda D, **Cervantes A**, Tabernero J, Patel P, Baselga J.
Clin Cancer Res. 2013 Dec 15;19(24):6976-86

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Annexes References of clinical trials publications

First-in-humans trial of an RNA interference therapeutic targeting VEGF and KSP in cancer patients with liver involvement.
Tabernero J, Shapiro GI, LoRusso PM, **Cervantes A**, Schwartz GK, Weiss GJ, Paz-Ares L, Cho DC, Infante JR, Alsina M, Gounder MM, Falzone R, Harrop J, White AC, Toudjarska I, Bumcrot D, Meyers RE, Hinkle G, Svrzikapa N, Hutabarat RM, Clausen VA, Cehelsky J, Nochur SV, Gamba-Vitalo C, Vaishnaw AK, Sah DW, Gollob JA, Burris HA 3rd.
Cancer Discov. 2013 Apr;3(4):406-17

2012

Phase I pharmacokinetic/pharmacodynamic study of MLN8237, an investigational, oral, selective aurora a kinase inhibitor, in patients with advanced solid tumors.
Cervantes A, Elez E, Roda D, Ecsedy J, Macarulla T, Venkatakrishnan K, Roselló S, Andreu J, Jung J, Sanchis-Garcia JM, Piera A, Blasco I, Maños L, Pérez-Fidalgo JA, Fingert H, Baselga J, Tabernero J.
Clin Cancer Res. 2012 Sep 1;18(17):4764-74

2011

Phase I pharmacokinetic and pharmacodynamic dose-escalation study of RG7160 (GA201), the first glycoengineered monoclonal antibody against the epidermal growth factor receptor, in patients with advanced solid tumors.
Paz-Ares LG, Gomez-Roca C, Delord JP, **Cervantes A**, Markman B, Corral J, Soria JC, Bergé Y, Roda D, Russell-Yarde F, Hollingsworth S, Baselga J, Umana P, Manenti L, Tabernero J.
J Clin Oncol. 2011 Oct 1;29(28):3783-90

A phase I first-in-human pharmacokinetic and pharmacodynamic study of serdemetan in patients with advanced solid tumors.
Tabernero J, Dirix L, Schöffski P, **Cervantes A**, Lopez-Martin JA, Capdevila J, van Beijsterveldt L, Platero S, Hall B, Yuan Z, Knoblauch R, Zhuang SH.
Clin Cancer Res. 2011 Oct 1;17(19):6313-21

A phase I pharmacokinetic and pharmacodynamic study of dalotuzumab (MK-0646), an anti-insulin-like growth factor-1 receptor monoclonal antibody, in patients with advanced solid tumors.
Atzori F, Tabernero J, **Cervantes A**, Prudkin L, Andreu J, RodrIguez-Braun E, Domingo A, Guijarro J, Gamez C, Rodon J, Di Cosimo S, Brown H, Clark J, Hardwick JS, Beckman RA, Hanley WD, Hsu K, Calvo E, Roselló S, Langdon RB, Baselga J.
Clin Cancer Res. 2011 Oct 1;17(19):6304-12

Unidad de Ensayos Clínicos Fase I de Hematología y Oncología Médica de INCLIVA

Annexes References of clinical trials publications

Phase I Assessment of New Mechanism-Based Pharmacodynamic Biomarkers for MLN8054, a Small-Molecule Inhibitor of Aurora A Kinase.
Chakravarty A, Shinde V, Tabernero J, Cervantes A, Cohen RB, Dees EC, Burris H, Infante JR, Macarulla T, Elez E, Andreu J, Rodriguez-Braun E, Rosello S, von Mehren M, Meropol NJ, Langer CJ, Oneil B, Bowman D, Zhang M, Danaee H, Faron-Yowe L, Gray G, Liu H, Pappas J, Silverman L, Simpson C, Stringer B, Tirrell S, Veiby OP, Venkatakrishnan K, Galvin K, Manfredi M, Ecsedy JA.
Cancer Res. 2011 Feb 1;71(3):675-85

2010

Phase I safety, pharmacokinetics, and inhibition of SRC activity study of saracatinib in patients with solid tumors.
Baselga J, Cervantes A, Martinelli E, Chirivella I, Hoekman K, Hurwitz HI, Jodrell DI, Hamberg P, Casado E, Elvin P, Swaisland A, Iacona R, Tabernero J.
Clin Cancer Res. 2010 Oct 1;16(19):4876-83..

Phase I study of the selective Aurora A kinase inhibitor MLN8054 in patients with advanced solid tumors: safety, pharmacokinetics, and pharmacodynamics.
Macarulla T, Cervantes A, Elez E, RodrIguez-Braun E, Baselga J, Roselló S, Sala G, Blasco I, Danaee H, Lee Y, Ecsedy J, Shinde V, Chakravarty A, Bowman D, Liu H, Eton O, Fingert H, Tabernero J.
Mol Cancer Ther. 2010 Oct;9(10):2844-52. Epub 2010 Aug 19.

Pharmacogenomic and pharmacoproteomic studies of cetuximab in metastatic colorectal cancer: biomarker analysis of a phase I dose-escalation study.
Tabernero J, Cervantes A, Rivera F, Martinelli E, Rojo F, von Heydebreck A, Macarulla T, Rodriguez-Braun E, Eugenia Vega-Villegas M, Senger S, Ramos FJ, Roselló S, Celik I, Stroh C, Baselga J, Ciardiello F.
J Clin Oncol. 2010 Mar 1;28(7):1181-9.

Cetuximab administered once every second week to patients with metastatic colorectal cancer: a two-part pharmacokinetic/pharmacodynamic phase I dose-escalation study.
Tabernero J, Ciardiello F, Rivera F, Rodriguez-Braun E, Ramos FJ, Martinelli E, Vega-Villegas ME, Roselló S, Liebscher S, Kisker O, Macarulla T, Baselga J, Cervantes A.
Ann Oncol. 2010 Jul;21(7):1537-45.

2009

Aurora kinase inhibitors: a new class of drugs targeting the regulatory mitotic system. Pérez Fidalgo JA, Roda D, Roselló S, RodrIguez-Braun E, Cervantes A.
Clin Transl Oncol. 2009 Dec;11(12):787-98. Review.

Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia

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General Information

Who filled in this survey	JAVIER MILARA PAYÁ
E-mail contact (Phone number)	xmilara@hotmail.com / ceicvalencia_hgv@gva.es
Date of survey filling in	19-05-2015
Unit web address	
Formal name of the unit	Clinical Research Unit. Research Foundation of University General Hospital Consortium
Postal address	Hospital Clínico Universitario de Valencia AVENIDA TRES CRUCES Nº 2, Consorcio HOSPITAL General de Valencia, Unidad de Investigación Clínica, Pabellón B, D-2-4, 2ª PLANTA, VALENCIA, SPAIN. CP: 46014

Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia

Location

The Clinical Research Unit of the University General Hospital Consortium of Valencia (CHGUV) is located in the Av.DE LES TRES CREUS (Av. tres cruces) nº2, in the second floor, Pabillion B, D2-4 section of the CHGUV, Valencia,Spain. Postal code: 46014.

Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia

Ownership

Ownership	Public - Research foundation of the University General Hospital of Valencia
Established	2011
Linked hospital	University Consortium General Hospital of Valencia, Spain
Distance between linked hospital and Unit	The Clinical Research Unit is integrated into the University Consortium General Hospital of Valencia
Linked Ethics Committee (CEIC)	CEIC of the University Consortium General Hospital of Valencia

Unit Manager

First and last names	Julio Cortijo Gimeno
Qualifications	Full professor of pharmacology, PhD, PharmD
Medical specialty	Pharmacology
Manager since	2011
E-mail and phone	julio.cortijo@uv.es

Short CV

- Head of Unit of Teaching and Research and Chief of Research Foundation of the University General Hospital of Valencia. HGUV consortium.
- Doctor of Pharmacy from University of Valencia. Professor at the University of Valencia, Department of Pharmacology, Faculty of Medicine and Dentistry.
- His scientific work has been awarded with the Galien Award in Pharmacology Research; with the University-Society Award; with the Upiohn-Spanish Society of Pharmacology Award; National Prize of the V Military Hospital, Valencia; National Young Investigator Award from the Spanish Society of Pharmacology; the award M.I. Official College of Pharmacists of Valencia and the prize of the Royal Academic of Medicine and Surgery of Valencia, in five contests.
- He is member of the Spanish Society of Pharmacology, the Spanish Respiratory Society and the British Pharmacological Society and academic corresposal of the Royal Academy of Medicine of Valencia and the Royal National Academy of Pharmacy.
- He has more than 200 indexed publication with more than 500 cumulative impact factor and H index higher than 30.

Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia

Accreditations and audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

An official accreditation is spected by the General Directorate of Pharmacy and Health Products of the Valencian community, Spain.

Audits by regulatory agencies (last 3 years)

- May 2014: Pharmaceutical Inspection of Sanitary Services Department of Health. Territorial delegation Valencian

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? YES

Audits by sponsors (last 3 years)

June 2014: AUDIT Amgen Inc.

Do you follow your own Standard Operating Procedures (SOPs)? YES Do you supply with a SOP copy to a sponsor if requested? YES

Would you follow the sponsor SOPs if requested: YES

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: **2**

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:
The Clinical Research Unit has a Standard Operating Procedures (SOPs) developed by those responsible for it and known to the rest of the staff working in the studies. The SOPs are written for all operations that make up the conduct of a clinical trial, providing researchers, research assistants and monitors the exact instructions of activity in different areas of competence description. All persons involved in any of the activities of the UIC must know the SOPs and commit to comply.

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Accreditations and audits

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data (cont.):

Group 4 of the working procedures of the SOPs covers all the activities undertaken with participant subjects, their security and confidentiality of their data following the requirements of Law 15/1999, of 13 December, data protection character staff. All actions involving trial subjects shall conform to the recommendations of the Declaration of Helsinki, including its latest update.
Safety of subjects: direct and continuous supervision of volunteers during the time they remain admitted to the unit, the unit has security cameras connected to the area of supervision of medical staff. Access to the locked unit delimited.
Data security: log files and access keys. CRF and medical records on file with limited access. All computer equipment under safety standards with access by key hospital and periodic backups according PNT's.
The UIC will have a database with all the volunteers who have expressed their desire to participate in further studies or who have participated in previous studies. This list personal data and contact information are included. The subjects entered in the database of interested volunteers accept having read and understood how to proceed with the processing of data. Treatment, communication and transfer of personal data from all participating subjects, shall comply with the provisions of the legislation on protection of personal data. According to the provisions of the above legislation, subjects can exercise the rights of access, modification, opposition and cancellation of data.

Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia

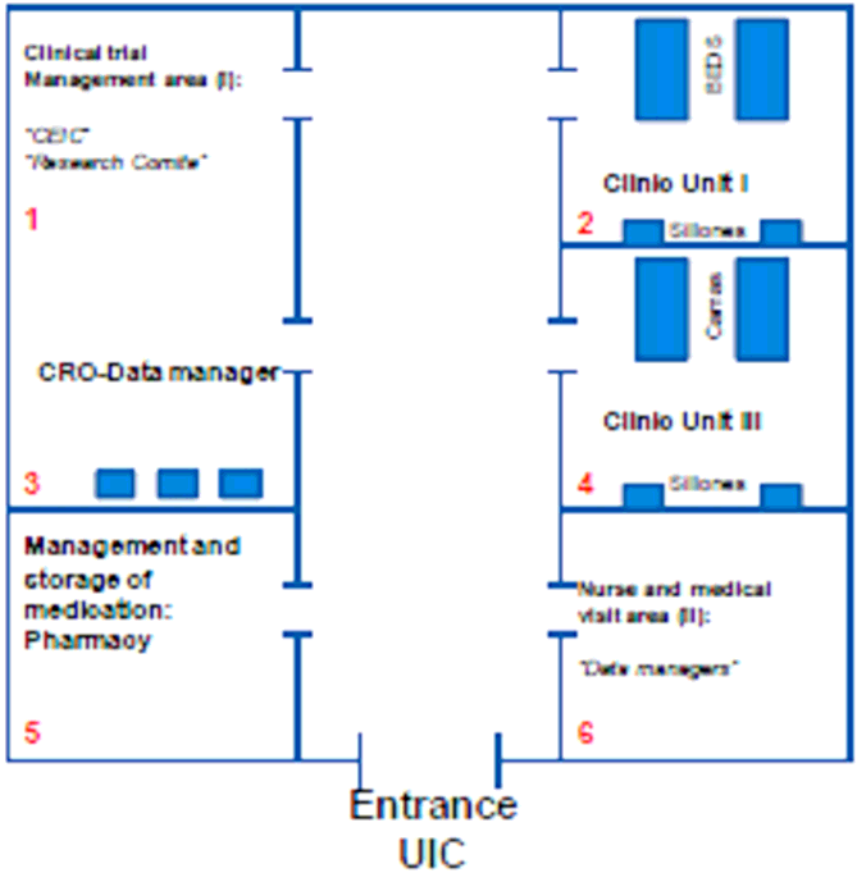
Facilities

Year of Unit building	1962	Last Unit reform	2011
Usable space	2350 m^2	The Unit building is separate from the linked hospital	NO
Number of CTs the unit could perform simultaneously	3	Number of beds	4
Beds distribution	1 room with 4 beds and another room with 8 treatment chairs		
Beds distribution allows a complete and continuous visual control by nurses			YES
Number of bed with intensive or continuous monitoring	4	Number of armchairs suitable for subject monitoring	8
Owned kitchen	YES	Meals supervision by dietitian	YES
Dining-room available for volunteers	YES	Individual lockers available for volunteers	YES
Relaxing room available for volunteers independent from the beds area			YES
Availability in the unit of an emergency trolley for cardiopulmonary resuscitation			YES
The emergency trolley has available suitable medications with immediate by controlled access			YES
The medical and paramedical staff are trained and skilled to provide			Advanced Life Support
Unit availability of an evacuation plan for volunteers in emergency situations			YES
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			YES
Volunteers/patients healthcare would be covered by the national or the regional health system if required			YES
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers			Intensive Care Unit
Distance and time to get the former services	100 metres, 2 minutes walking		
Unit entrance/Exit door controlled	YES, Locked glass door	Unit with Closed Circuit Television	YES
Availability of an alternate electrical generating set that automatically works in case of a general system failure			YES

Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia

Facilities

Unit distribution plan



1. **Clinical trial Management area:** management documentation of CEIC and Clinical Research Committee; file reports and communications, testing and billing documents. Paper and computer processing of contracts between promoters, management and principal investigator.

2, 3 y 4. **Clinical Units:** Clinical Trial areas conducting Phase I to III, equipped with beds, monitoring equipment, emergency equipments, making medical gases, armchairs for drug administration, collection of biological samples etc ..

5. **Management and storage of medication: Pharmacy:** area with a fridge and freezer with computerized temperature control. Lockers for storing oral and intravenous medication. Lockers for archiving and documentation relating to Clinical trial Pharmacy Service.

6. **Nurse and medical visit area:** clinical data management concerning the initiation, inclusion, exclusion and monitoring and termination of Clinical Trials.

Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia

Staffing and Resources

Unit employees

Permanent staff 6 Fixed-term/contracted staff (internship, grant holders) 4 Part-time collaborators 15

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	15	10
Nurse	2	
Monitor or CRA	1	2
Pharmacist	1	1
Biometry	1	
Data management	4	
Medical writing	1	
Pharmacokinetics	1	
Quality assurance	1	
Project Management	1	
Finance	1	
Recruitment	1	
IT (informatics)	1	
Other (specify)		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician X Nurse

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Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameters)	YES

Certification of the Spanish Society of Hematology and Hemotherapy (AEHH, PEEC-H), Certification Committee for Quality Assurance and Accreditation of Laboratory of the Spanish Society of Clinical Biochemistry and Molecular Pathology (SEQC)

The quality assurance activities are subcontracted by the Unit	NO
Availability of a specific area for drug storing and preparation of medications for the study	YES
The former area or room has restricted access by key or code	YES
Laminar flow chamber availability for preparation of parenteral treatments	YES
Perfusion pumps for intravenous treatment	YES
Who is the responsible for drug preparation and dispensing	**Dispensing:** HOSPITAL PHARMACIST AND NURSE **Preparation**: HOSPITAL PHARMACIST
Drug accountability procedures, such as reception, preparation and dispensing forms	YES
SOPs available for drug preparation and dispensing	YES
SOPs available for drawing and managing of biological fluids	YES

System or procedure used for samples identification

To avoid confusion, all tubes in which the blood (or other biological sample) obtained in each extraction is collected will be marked with an identification of the study in question, with the number of volunteer, time that corresponds to the sample and, if appropriate, with a key number that matches the key number that identifies the pipe where serum or plasma is stored. The latter is indicated only if the samples to be analyzed are sending with a blinded key.
All tubes will be placed in racks properly labeled and identified by the number of volunteers to which they relate. All material collection of biological samples will be labeled and identified in the manner appropriate to each case. All tubes will be left prepared the day before the test day. Samples must be stored in freezers at -20 ° C or -80 ° C in the UIC.

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Services Capabilities

System or procedure used for samples identification (cont.)

The sample storage racks will be made or waterproof plastic bags and sealed and labeled with the following information:
Freezing Date, Issue protocol, Day collection, Number of patient
All calibrated annually certified and temperature monitoring system with computerized record probe.

Availability of a specific area for blood samples managing	YES
The former area or room has restricted access by key or code	YES
Number of centrifuges available	2
System for plasma/fluids samples storing	YES
Fridges and freezers available in the Unit	2 FRIDGES AND 2 FREEZERS
The Unit has its owned Bioanalytical Department	YES
Availability of genotyping or fenotyping methods for participants	YES
Data Management and software used	NO
Biometry or Statistical Analysis and software used	NO
Pharmacokinetic Analysis and software used	NO
Medical Writing and skilled languages	NO
Owned archives in the same Unit building	YES

Closed access only accessible by nurses and members of investigation team

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Docs, such as study file, study data, subject files, or SOP's are sent to an external archive for a minimum of 15 years

The study files are digitised and converted in a CD or web format	NO
Project management	YES

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Services Capabilities

Data Management and software used	YES (Fundanet)
Biometry or Statistical Analysis and software used	Yes (SPSS, stata, prisma v6, WinOnline Softwares)
Pharmacokinetic Analysis and software used	Yes (WinOnline) (Attached document with available techniques)
Medical Writing and skilled languages	Yea, Spanish and English
Owned archives in the same Unit building	Yes

Access control and protection measures as required by legislation. Total capacity of 36 m2

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Legislation RD 223/224 Art. 39

Article 39. The documents forming the master file of a clinical trial must be retained for the time and according to the specifications in the Instructions for completion of Clinical Trials in Spain or, when appropriate, the guidelines of the European Commission or those published by the ministry of Health.

TMF, CRF trials remain in the file itself, in the unit for 15 years from the end of the clinical trial. The patient history file is returned to the hospital center.

The study files are digitised and converted in a CD or web format	YES
Project management	YES

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Study Participants

Kind of participants included in clinical trials performed in the Unit

X Healthy volunteers X Patients

X Other populations Special risk groups, pediatrics, olders, renal or hepatic failure

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour X Haematological tumour X Adults X Paediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

The Unit has experience in LUNG tumor treatments, but not exclude other tumors

Recruiting methods for healthy volunteers

Since not all interested persons can be reached with a single method, the UIC develops different recruiting techniques to reach various groups and ensure the availability of volunteers to initiate a clinical trial. Some media described to reach interested individuals are described:
University General Hospital Consortium and its environment:

Medical reference (these may offer other colleagues recruitment)

1. Database center "Quering Database"
2. Conduct meetings with:
- All services
- Nurses,
- Medical center, residents, adjuncts,
- Patient,
- Services involved in the trial
3. Help other centers in the area.
4. Other health professionals
5. Magazines of the University
6. Website of the FiCHGUV
7. Facilitate quizzes, brochures ... in admissions, information point, center entrance, waiting rooms, secretarial service.
8. Signs
9. Pharmacy near the CHGUV
10. Cofee shops
11. Dental Clinics
12. Universities
13. Sports Institutions

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Study Participants

Recruiting methods for patients

Medical reference (these may offer other colleagues recruitment)

1. Database center "Quering Database"
2. Conduct meetings with:
- All services
- Nurses
- Medical center, residents, adjuncts,
- Patient,
- Services involved in the trial

3. Help other centers in the area

Do you have surgery rooms available for screening (separated from the in-house area)? YES

Do you keep a paper or electronic database of volunteers? YES

Date of inclusion, , name, surname, date of birth, age, sex, dni, nationality, address, location, cp, province, phone, mail.

Have you implemented any measure for avoiding the over-volunteering? YES

There is a procedure that limits the number of volunteers per year. The file lists the number of entries for each volunteer

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Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices	YES, 2	Pulsioximetry devices	YES, 2	12-leads ECG devices	YES, 1

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules YES

Availability in the Unit of tests for assessing CNS drug effects YES

Psychomotor performance tests, neuropsychological evaluations (EEG and evoked potentials), pupillometry, stabilometry and polysomnography.

Familiarity in poblational analysis and PK/PD modelling, including writing of clinical reports YES

Familiarity with Electronic Data Capture –EDC applied to clinical trials YES

Experience in other kind of PD or PK evaluations not formerly collected YES

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

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Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						
First multiple-dose administration in humans			5	12	11	6
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)			1			
Own research lines						
Others (specifying)						

Number of trials linked to a PEI (IND) submission | 2009 | 0 | 2010 | 0 | 2011 | 1 | 2012 | 0 | 2013 | 0 | 2014 | 0

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Antiangiogenic inhibitors of EGFR, HER2, IGFR, TGFbeta-R, farnesyl transferase, tubulin-interacting agents, cytotoxic, antiarrhythmics, antihypertensives, statins, antidiabetic agents, antibiotics, antifungals, antidepressants, SSRIs, IBP, monoclonal, anti-dementia, muscle relaxants etc

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 2 Number of trials promoted by multinational companies

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 45 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 0

Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia

Annexes References of clinical trials publications

20 11	Circulating DNA is a useful prognostic factor in patients with advanced non-small cell lung cancer. Sirera R, Bremnes RM, Cabrera A, Jantus-Lewintre E, Sanmartin E, Blasco A, Del Pozo N, Rosell R, Guillarro R, Galbis J, Sánchez JJ, Camps C. J Thorac Oncol. 2011 Feb;6(2):286-90.
20 11	Ustekinumab for the treatment of palmar-plantar pustulosis]. de Unamuno-Bustos B, Ballester-Sánchez R, Oliver-Martínez V, Alegre de Miquel V. Actas Dermosifiliogr. 2011 Dec;102(10):833-6.
20 11	The social nature of chronic noncommunicable diseases (NCDs) and how to tackle them through communication technology, training and outreach. Martin JM, Apfel F, Alfonso-Sánchez JL, Galea G, Jakab Z. Journal of Health Communication, 16 supp 2011.
20 11	Telaprevir for retreatment of HCV infection. Zeuzem S, Andreone P, Pol S, Lawitz E, Diago M, Roberts S, Focaccia R, Younossi Z, Foster GR, Horban A, Ferenci P, Nevens F, Müllhaupt B, Pockros P, Terg R, Shouval D, van Hoek B, Weiland O, Van Heeswijk R, De Meyer S, Luo D, Boogaerts G, Polo R, Picchio G, Beumont M; REALIZE Study Team. N Engl J Med. 2011 Jun 23;364(25):2417-28.
20 11	Phase II clinical trial with gemcitabine and paclitaxel sequential monotherapy as first-line treatment for advanced non-small-cell lung cancer (SLCG 01-04). Iranzo V, Sirera R, Carrato A, Cabrera A, Jantus E, Guillarro R, Sanmartin E, Blasco A, Gil M, Gómez-Aldaravi L, González-Larriba JL, Massuti B, Velasco A, Provencio M, Rosell R, Camps C. Clin Transl Oncol. 2011 Jun;13(6):411-8.
20 11	Sphingosine-1-phosphate is increased in patients with idiopathic pulmonary fibrosis and mediates epithelial to mesenchymal transition. Milara J, Navarro R, Juan G, Peiró T, Serrano A, Ramón M, Morcillo E, Cortijo J. Thorax. 2012 Feb;67(2):147-56.
20 11	[The OASIS study: therapeutic management of acromegaly in standard clinical practice. Assessment of the efficacy of various treatment strategies]. Luque-Ramírez M, Carreño A, Alvarez Escolá C, del Pozo Picó C, Varela da Costa C, Falardo Montañana C, Gilabert M, Webb S; Grupo Español del estudio OASIS. Endocrinol Nutr. 2011 Nov;58(9):478-88.
20 11	Persistent lipid abnormalities in statin-treated patients with diabetes mellitus in Europe and Canada: results of the Dyslipidaemia International Study. Leiter LA, Lundman P, da Silva PM, Drexel H, Jüngner C, Gitt AK; DYSIS Investigators. Diabet Med. 2011 Nov;28(11):1343-51.

Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia

Annexes References of clinical trials publications

20 11	Induction of PGC-1α expression can be detected in blood samples of patients with ST-segment elevation acute myocardial infarction. Fabregat-Andrés Ó, Tierrez A, Mata M, Estornell-Erill J, Ridocci-Soriano F, Moncalve M. PLoS One. 2011;6(11):e28813.
20 10	Long-term safety and efficacy of etanercept in the treatment of psoriasis]. Zaragoza V, Pérez A, Sánchez JL, Oliver V, Martínez L, Alegre V. Actas Dermosifiliogr. 2010 Jan-Feb;101(1):47-53.
20 10	Clinical inertia in the diagnosis and treatment of hypertension: Quantification and associated factors. Gil-Guillén V, Orozco-Beltrán D, Pérez RP, Alfonso JL, Redon J, Pertusa-Martínez D, Navarro J, Cea-Calvo L, Quiles-Andrés F, Merino-Sánchez J, Carratalá C, Martín-Moreno JM. Revista: Blood Press 2010; 19:3-10
20 10	Drug utilization and off-label drug use among Spanish emergency room paediatric patients. Morales-Carpi C, Estañ L, Rubio E, Lurbe E, Morales-Olivas FJ. Eur J Clin Pharmacol. 2010 Mar;66(3):316-20.
20 10	Identifying hepatitis C virus genotype 2/3 patients who can receive a 16-week abbreviated course of peginterferon alfa-2a (40KD) plus ribavirin. Diago M, Shiffman ML, Bronowicki JP, Zeuzem S, Rodriguez-Torres M, Pappas SC, Tietz A, Nelson DR. Hepatology. 2010 Jun;51(6):1897-903.
20 10	The effects of the financial crisis on primary prevention of cancer. Martín-Moreno JM, Alfonso-Sánchez JL, Harris M, López-Valcárcel BG. Eur J Cancer. 2010 Sep;46(14):2525-33.
20 10	A sustained virologic response is durable in patients with chronic hepatitis C treated with peginterferon alfa-2a and ribavirin. Swain MG, Lai MY, Shiffman ML, Cooksley WG, Zeuzem S, Dieterich DT, Abergel A, Pessôa MG, Lin A, Tietz A, Connell EV, Diago M. Gastroenterology. 2010 Nov;139(5):1593-601.
20 09	Delayed generalized inflammatory psoriasis flare during efalizumab treatment. Martín B, Sánchez-Carazo JL, Pérez-Ferriols A, Oliver V, Alegre V. Br J Dermatol. 2009 Jul;161(1):212-3.

Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia

Annexes References of clinical trials publications

2009

Treatment of insulin resistance with metformin in naive genotype 1 chronic hepatitis C patients receiving peginterferon alfa-2a plus ribavirin. Romero-Gómez M, Diago M, Andrade RJ, Calleja JL, Salmerón J, FernAndez-Rodriguez CM, Solà R, Garcia-Samaniego J, Herrerias JM, De la Mata M, Moreno-Otero R, Nuñez O, Oliveira A, DurAn S, Planas R; Spanish Treatment of Resistance to Insulin in Hepatitis C Genotype 1 Group. Hepatology. 2008 Dec;60(6):1702-8.

2008

Efficacy of etanercept in psoriatic patients previously treated with infliximab. Pitarch G, SAnchez-Carazo JL, Mahiques L, Oliver V. Dermatology. 2008;216(4):312-6.

2008

Efficacy and safety results from the randomized controlled comparative study of adalimumab vs. methotrexate vs. placebo in patients with psoriasis (CHAMPION). Saurat JH, Stingl G, Dubertret L, Papp K, Langley RG, Ortonne JP, Unnebrink K, SAnchez-Carazo JL, Kaul M, Camez A; CHAMPION Study Investigators. Br J Dermatol. 2008 Mar;158(3):558-66.

2008

Pemphigus vulgaris associated with cocaine snorting. Laguna C, SAnchez-Carazo JL, Pérez-Ferriols A, Alegre V. J Eur Acad Dermatol Venereol. 2008 May;22(5):645-6.

2008

A randomised trial of three counselling strategies for lifestyle changes in patients with hypercholesterolemia treated with ezetimibe on top of statin therapy (TWICE). Steg PG, Verdier JC, Carré F, Darne B, Ducardonnet A, Juillien G, Farnier M, Giral P, Haïat R; TWICE Investigators, France. Arch Cardiovasc Dis. 2008 Nov-Dec;101(11-12):723-35.

2007

Late gadolinium-enhanced cardiovascular magnetic resonance identifies patients with standardized definition of ischemic cardiomyopathy: a single centre experience. Soriano CJ, Ridocci F, Estornell J, Pérez-BoscA JL, Pomar F, Trigo A, Planas A, Nadal M, Jacas V, Martinez V, Paya R. Int J Cardiol. 2007 Mar 20;116(2):167-73.

2007

Squamous cell carcinoma over tattoos. Pitarch G, Martinez-Menchón T, Martinez-Aparicio A, SAnchez-Carazo JL, Muñoz D, Fortea JM. J Am Acad Dermatol. 2007 Jun;56(6):1072-3.

2007

Analysis of lymphocyte populations in psoriatic plaques following inhibition of tumor necrosis factor alpha with etanercept]. Mahiques L, Pitarch G, SAnchez-Carazo JL, Pérez-Ferriols A, Soriano CJ, Alegre V. Actas Dermosifiliogr. 2007 Oct;98(8):539-44.

Unidad de Investigación Clínica del Consorcio Hospital General Universitario de Valencia

Annexes References of clinical trials publications

20 07	Clinical trial: pharmacodynamics and pharmacokinetics of re-treatment with fixed-dose induction of peginterferon alpha-2a in hepatitis C virus genotype 1 true non-responder patients. Diago M, Crespo J, Oliveira A, Pérez R, BArcena R, SAnchez-Tapias JM, Muñoz-SAnchez M, Romero-Gómez M. Aliment Pharmacol Ther. 2007 Oct 15;26(8):1131-8.
20 07	Are we really seeing the total cost of surgical site infections? A Spanish study. Alfonso JL, Blasco S, Moreno J, Melgar M, Martinez I, Martin JM. Revista Wound Repair Regen 2007; 15:474-481. Mycosis fungoid treated with oral bexarotene: study of 13 cases]. Roche Gamón E, Pérez Ferriols A, Vilata Corell JJ, Alegre de Miquel V. Med Clin (Barc). 2007 Nov 10;129(17):677.
20 06	Electrophysiologic evaluation of phrenic nerve and diaphragm function after coronary bypass surgery: prospective study of diabetes and other risk factors. Merino-Ramirez MA, Juan G, Ramón M, Cortijo J, Rubio E, Montero A, Morcillo EJ. J Thorac Cardiovasc Surg. 2006 Sep;132(3):530-6, 536.e1-2.
20 04	Drug utilisation in outpatient children. A comparison among Tenerife, Valencia, and Barcelona (Spain), Toulouse (France), Sofia (Bulgaria), Bratislava (Slovakia) and Smolensk (Russia).Sanz E, HernAndez MA, Ratchina S, Stratchounsky L, Peiré MA, Lapeyre-Mestre M, Horen B, Kriska M, Krajnakova H, Momcheva H, Encheva D, Martinez-Mir I, Palop V. Eur J Clin Pharmacol. 2004 Apr;60(2):127-34.
20 04	Pharmacological treatment of acute otitis media in children. A comparison among seven locations: Tenerife, Barcelona and Valencia (Spain), Toulouse (France), Smolensk (Russia), Bratislava (Slovakia) and Sofia (Bulgaria). Sanz E, HernAndez MA, Kumarl M, Ratchina S, Stratchounsky L, Peiré MA, Lapeyre-Mestre M, Horen B, Kriska M, Krajnakova H, Momcheva H, Encheva D, Martinez-Mir I, Palop V. Eur J Clin Pharmacol. 2004 Mar;60(1):37-43.

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Datos de filiación

Persona que contesta la encuesta (nombre)	Begoña Jeweinat Figuerola
Contacto correo electrónico (teléfono)	Investigacion_Clinica@iislafe.es / 961246611
Fecha en que se completó la encuesta	18/05/15
Página web	www.iislafe.es/en/uicab
Nombre oficial en inglés	Unit for Clínical Research and Biological Activity
Dirección	Unidad de Investigación Clínica y Actividad Biológica UICAB Instituto de Investigación Sanitaria La Fe Hospital Universitari i Politècnic La Fe Avinguda de Fernando Abril Martorell, nº 106 46026 Valencia (Spain)

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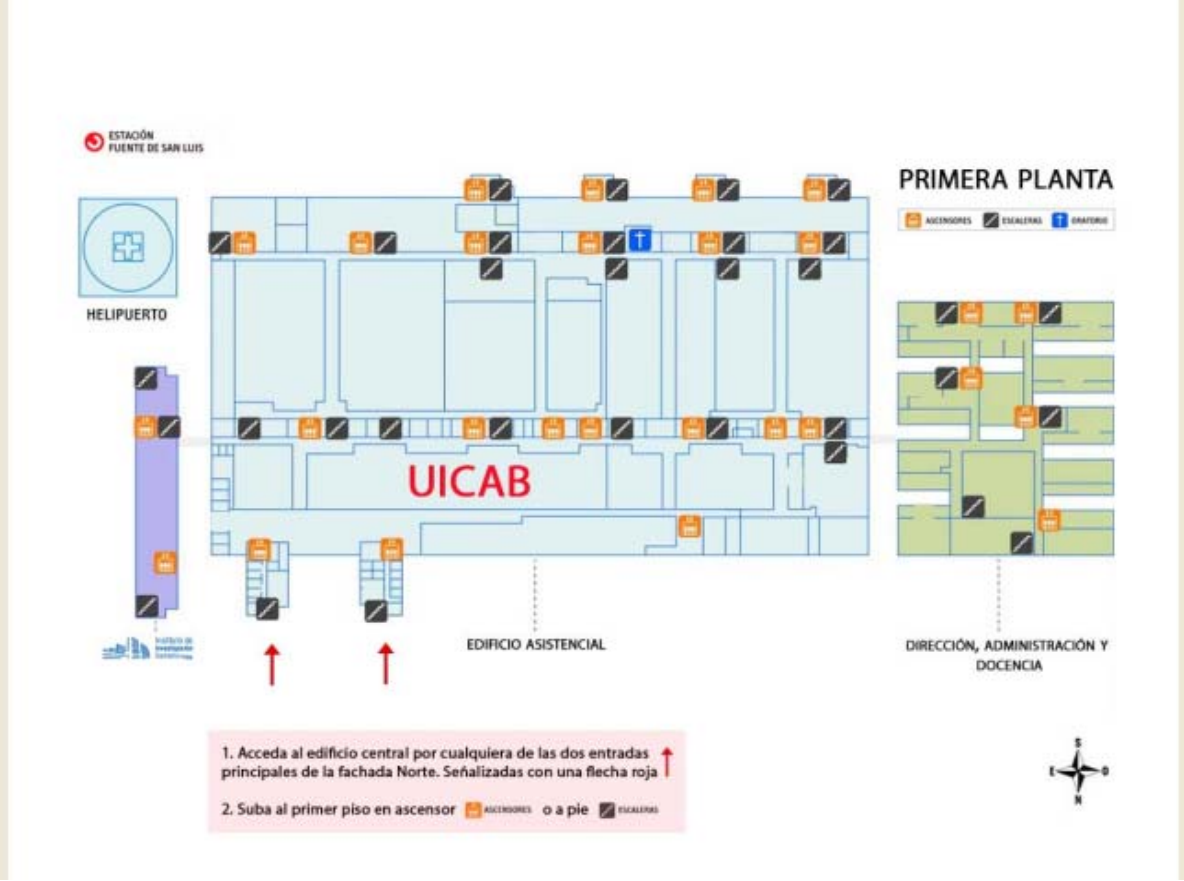
Location



UICAB - Instituto de Investigación Sanitaria La Fe

Ownership

Ownership	Health research Institute La fe (IIS La Fe)
Established	October 2013.
Linked hospital	Hospital U I P La Fe.
Distance between linked hospital and Unit	0m, It is integrated.
Linked Ethics Committee (CEIC)	CEIC Hospital La Fe.

Unit Manager

First and last names	DR. JOSÉ VICENTE CASTELL RIPOLL
Qualifications	BIOQUÍMICO
Medical specialty	
Manager since	2013
E-mail and phone	JOSE.CASTELL@UV.ES

Short CV

Bachelor of Science in Chemistry FACULTY OF SCIENCES, UNIVERSITY OF VALENCIA 1968 Bachelor of Pharmacy FACULTY OF PHARMACY,UNIVERSITY OF VALENCIA 1978
PhD in Biological Science UNIVERSITY OF VALENCIA, 1977
PhD in Medicine UNIVERSITY OF VALENCIA,1990

CURRENT EMPLOYMENT POSITION
Group Leader START DATE 27/08/1979
ORGANISATION Health Research Institute Hospital La Fe
UNIT EXPERIMENTAL HEPATOLOGY

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Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

None.

Audits by regulatory agencies (last 3 years)

None.

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **Yes**

Audits by sponsors (last 3 years)

1, October 2014.

Do you follow your own Standard Operating Procedures (SOPs)? yes Do you supply with a SOP copy to a sponsor if requested? yes

Would you follow the sponsor SOPs if requested: yes

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 1general audit and 5 or 6 specific per year.

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Regarding the safety of patients UICAB follows the clinical trial protocols and own protocols of the Hospital on Patient Safety. The treatment of personal data of subjects complies with the Organic Law 15/99 of December 13, Protection of Personal Data and the EU directive 95/45 / EC on the protection of individuals with regard to the processing of personal data and the free movement of such data.

UICAB - Instituto de Investigación Sanitaria La Fe

Facilities

Year of Unit building	2011	Last Unit reform	
Usable space	300 m2.	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	8	Number of beds	4
Beds distribution	Two bedrooms with two beds.		
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	4	Number of armchairs suitable for subject monitoring	9
Owned kitchen	yes	Meals supervision by dietitian	yes
Dining-room available for volunteers	No	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			No
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Advanced LS		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	ICU and Emergency Services.		
Distance and time to get the former services	ICU and Emergency services are in the same building, just 50 m2; 2/8 minutes		
Unit entrance/Exit door controlled	Yes	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

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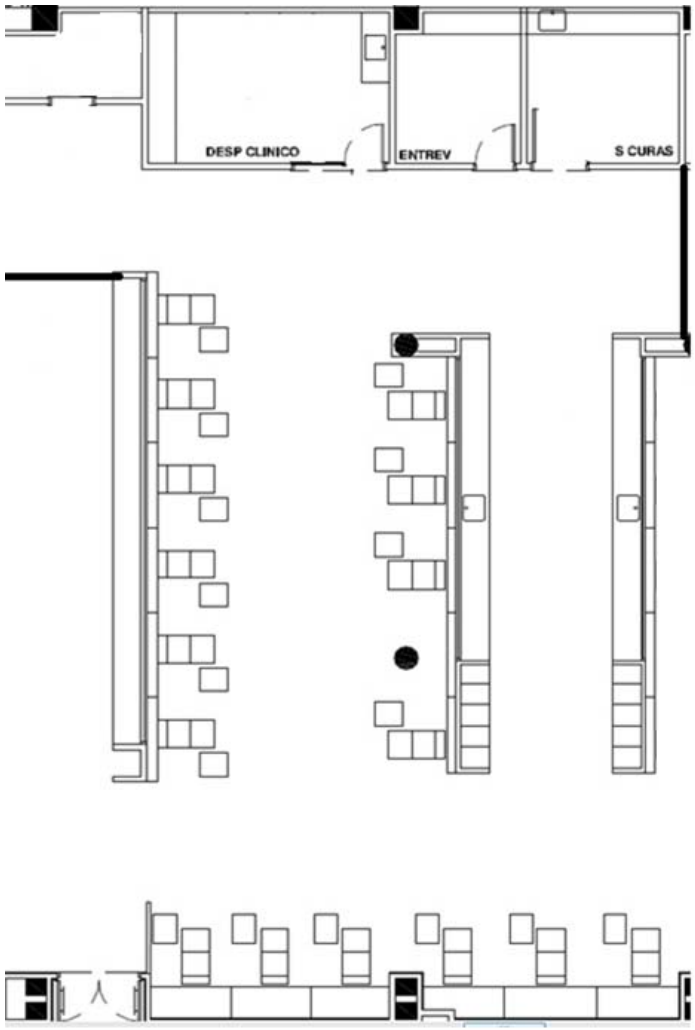
Facilities

Unit distribution plan:



UICAB - Instituto de Investigación Sanitaria La Fe

Staffing and Resources

Unit employees

Permanent staff 18 Fixed-term/contracted staff (internship, grant holders) Part-time collaborators 5

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)		
Nurse	4	2
Monitor or CRA	3	
Pharmacist	1	
Biometry		1
Data management		1
Medical writing		
Pharmacokinetics	1	
Quality assurance	2	
Project Management		1
Finance	3	
Recruitment	4	
IT (informatics)	2	
Other (specify): CTA, psychologist, etc	2 laboratory technicians.	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

x Physician **x** Nurse

UICAB - Instituto de Investigación Sanitaria La Fe

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	Yes
The quality assurance activities are subcontracted by the Unit	No, the Unit have its own quality department.
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	Yes
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Pharmacists. **Preparation**: Nurses.
Drug accountability procedures, such as reception, preparation and dispensing forms	Pharmacy assistant.
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification	
Tags and systems provided by sponsors of clinical trials	
Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes
Number of centrifuges available	2
System for plasma/fluids samples storing	Freezers and Fridges properly monitored and controlled.
Fridges and freezers available in the Unit	Fridges: 1 Freezers -70ºC: 2
The Unit has its owned Bioanalytical Department	
Availability of genotyping or fenotyping methods for participants	Yes

UICAB - Instituto de Investigación Sanitaria La Fe

Services Capabilities

Data Management and software used (describe)	Software R versión 3.1.2
Biometry or Statistical Analysis and software used (describe)	Software R versión 3.1.2
Pharmacokinetic Analysis and software used (describe)	Non compartmental and compartmental pharmacokinetics analysis depending on the study drug was used. Softwares used: PKS y Nonmen.
Medical Writing and skilled languages	No.
Owned archives in the same Unit building (describe)	60 m2 with access control by key with fire protection measures.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

All original source documents and records are kept for 5 years, the rest of the documentation is digitized.

The study files are digitized and converted in a CD or web format	The study files are digitized and converted in a CD format
Project management	Yes

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Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers Yes Patients Yes

Other populations Pediatrics population.

If the Unit has experience in oncology, detail kind of tumour and age groups

Yes Solid tumour Yes Haematological tumour Yes Adults Yes Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All kinds of tumors to be a reference center of them all.

Recruiting methods for healthy volunteers

Accompanying patients in outpatient clinics, web and newspaper advertisements.

Recruting methods for patients

Patients who came to outpatient clinics regularly and patients referred from other hospitals.

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	Yes we have 1room for screening.
Do you keep a paper or electronic database of volunteers? (describe)	No
Have you implemented any measure for avoiding the over-volunteering? (describe)	No

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Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	2	Pulsioximetry devices (number)	1	12-leads ECG devices (number)	1

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Yes
Availability in the Unit of tests for assessing CNS drug effects	No
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	Yes
Familiarity with Electronic Data Capture –EDC applied to clinical trials	No
Experience in other kind of PD or PK evaluations not formerly collected	Dose increases and decreases and AUC

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

All the Phase I trials conducted in our Center involved the realization of at least one PK evaluation that were performed in external sponsor departments .

UICAB - Instituto de Investigación Sanitaria La Fe

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						1
First single-dose administration in humans						1
First multiple-dose administration in humans						1
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						1
Proof of concept (Phase Ib or I/II)						4
Own research lines						1
Others (specificying)						

Number of trials linked to a PEI (IND) submission	2009	2010	2011	2012	2013	2014

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Cytostatics, oral anticoagulants, monoclonal antibody, anti-TNF, immunosuppressants, anti-angiogenic inhibitors of EGFR, HER2, IGFR, TGFbeta-R, farnesyl transferase, etc

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 1 Number of trials promoted by multinational companies 8

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60 days

Number of Early Stages trials performed in the Unit and published in the last 4 years

UICAB - Instituto de Investigación Sanitaria La Fe

Annexes

Unidad de Fase I – Instituto Valenciano de Oncología IVO

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

Unidad de Fase I – Instituto Valenciano de Oncología IVO

General Information

Who filled in this survey	Laura Calabuig
E-mail contact (Phone number)	coordinacion@fincivo.org / 0034 96 111 4013
Date of survey filling in	10/07/2015
Unit web address	
Formal name of the unit	FaseI- Instituto Valenciano Oncología
Postal address	C/ Gregorio Gea 31, 3ª palnta- Hospital Dia 46009 Valencia, SPAIN

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Location

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Ownership

Ownership	Fase I- Instituto Valenciano Oncología
Established	
Linked hospital	
Distance between linked hospital and Unit	Same Hospital
Linked Ethics Committee (CEIC)	CEIC: Instituto Valenciano Oncología

Unit Manager

First and last names	Ángel Guerrero Zotano
Qualifications	Médico
Medical specialty	Oncología
Manager since	2009
E-mail and phone	aguerrero@fivo.org 96 111 4229

Short CV

Degree in Medicine and Surgery in Autonoma University of Madrid (1994-2000) marked with 3 possible 4.
Spring 2001: National Examination for entrance into specialist training (MIR system).
Four-year training residency in Medical Oncology in University Hospital La Fe in Valencia.
2001-2003: Completed initial two years of PhD at the Universitat Autònoma de Barcelona.
Awarded title of research proficiency in October 2003.
Three months training at Royal Marsden Hospital in Breast Cancer Unit (2005)
Three months training at NYU Langone Medical Center in New York (2008)
Two years Master in Molecular Oncology at CNIO (Spanish National Cancer Research Center).
Finish 1 year course:" Principles of Oncology Research, Epidemiolgy and Statistics" at Catalunya University, November 2006.
Last GCP training done on 03/jun/2013
Member of Spanish Society of Medical Oncology (SEOM)
Member of Spanish Breast Cancer Research Group (GEICAM)
Language Certificate 2007: University of Cambridge Advanced Certificated in English: grade a pass

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Acreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

none

Audits by regulatory agencies (last 3 years)

none

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **yes**

Audits by sponsors (last 3 years)

Do you follow your own Standard Operating Procedures (SOPs)? yes Do you supply with a SOP copy to a sponsor if requested? yes

Would you follow the sponsor SOPs if requested: yes

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial:

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Data base,

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Facilities

Year of Unit building	2009	Last Unit reform	
Usable space	25 m2	The Unit building is separate from the linked hospital	no
Number of CTs the unit could perform simultanously	4	Number of beds	2
Beds distribution	In same room		
Beds distribution allows a complete and continuous visual control by nurses			yes
Number of bed with intensive or continuous monitoring	2	Number of armchairs suitable for subject monitoring	4
Owned kitchen	no	Meals supervision by dietitian	yes
Dining-room available for volunteers	no	Individual lockers available for volunteers	no
Relaxing room available for volunteers independent from the beds area			no
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			yes
The emergency trolly has available suitable medications with immediate by controlled access			yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Basic life Support		
Unit availability of an evacuation plan for volunteers in emergency situations			yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	UCI, emergency room, hospitalization		
Distance and time to get the former services	200m		
Unit entrance/Exit door controlled	no	Unit with Closed Circuit Television	no
Availability of an alternate electrical generating set that automatically works in case of a general system failure			yes

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Facilities

Unit distribution plan:

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Staffing and Resources

Unit employees

Permanent staff 3 Fixed-term/contracted staff (internship, grant holders) Part-time collaborators 1

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	5	2
Nurse	2	
Monitor or CRA	1	
Pharmacist	2	2
Biometry		
Data management	12	
Medical writing		
Pharmacokinetics		
Quality assurance		
Project Management		
Finance	1	
Recruitment		
IT (informatics)	2	
Other (specify): CTA, psychologist, etc	2	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

Physician **X** Nurse

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	YES
The quality assurance activities are subcontracted by the Unit	ISO
Availability of a specific area for drug storing and preparation of medications for the study	YES
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	Yes
Perfusion pumps for intravenous treatment	yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** nurse **Preparation**: pharmacy
Drug accountability procedures, such as reception, preparation and dispensing forms	yes
SOPs available for drug preparation and dispensing	yes
SOPs available for drawing and managing of biological fluids	yes
System or procedure used for samples identification : number patient	
Availability of a specific area for blood samples managing	yes
The former area or room has restricted access by key or code	yes
Number of centrifuges available	2
System for plasma/fluids samples storing	yes
Fridges and freezers available in the Unit	3
The Unit has its owned Bioanalytical Department	no
Availability of genotyping or fenotyping methods for participants	Molecular biology department

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Services Capabilities

Data Management and software used (describe)	Yes, windows 7
Biometry or Statistical Analysis and software used (describe)	no
Pharmacokinetic Analysis and software used (describe)	No owner, only for sponsors
Medical Writing and skilled languages	Spanish and English
Owned archives in the same Unit building (describe)	Yes,

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Yes, all the time requieired by sponsor

The study files are digitized and converted in a CD or web format	yes
Project management	yes

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers X Patients

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour Haematological tumour X Adults Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Ovarian cancer, breast, kidney, lung, endometrius, cervix, urothelial

Recruiting methods for healthy volunteers

Data base

Recruting methods for patients

Data base

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	yes
Do you keep a paper or electronic database of volunteers? (describe)	Electronic data base
Name, date of birth, demographic data, pathology	
Have you implemented any measure for avoiding the over-volunteering? (describe)	no

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	3	Pulsioximetry devices (number)	1	12-leads ECG devices (number)	4

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	15, 2014
Availability in the Unit of tests for assessing CNS drug effects	no
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	no
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes, more than 40
Experience in other kind of PD or PK evaluations not formerly collected	yes

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans					1	
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)	1		2			2
Own research lines						2
Others (specificying)						

Number of trials linked to a PEI (IND) submission 2009 1 2010 0 2011 2 2012 0 2013 1 2014 4

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

oncology

Sponsor typology for Early Stages trials performed in the last 4 years (2003 to 2006) pharmaceuticals, owner

Number of trials promoted by Spanish companies 2 Number of trials promoted by multinational companies 3

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 30 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 1 (2015 ASCO)

Unidad de Fase I – Instituto Valenciano de Oncología IVO

Anexos

Estudios más relevantes - Ángel Guerrero Zotano

- "Phase I/II study of biweekly vinorelbine and oxaliplatin as first-line treatment in patients with metastatic breast cancer." **Guerrero A**, Servitja S, Rodríguez-Lescure A, Calvo L, del Barco S, Quintanar MT, Juárez JI, Gayo J, Llombart A, Tusquets I.Anticancer Drugs. 2011 Mar;22(3):283-9.

- "Incidence and predictors of ovarian function recovery (OFR) in exemestane patients with breast cancer (BC) with chemotherapy-induced amenorrhea (CIA) using two estradiol assays. **A. Guerrero-Zotano**, J. Gavila, E. Folkerd, B. Ortiz, T. Labrador, F. Martinez, A. Garcia, M. A. Climent, V. Guillem, M. Dowsett, A. Ruiz. Poster Discussion at ASCO 2011. J Clin Oncol 29: 2011 (suppl; abstr 521)

- A polymorphism at the 3'-UTR region of the aromatase gene defines a subgroup of postmenopausal breast cancer patients with poor response to neoadjuvant letrozole. Garcia-Casado Z, **Guerrero-Zotano A**, Llombart-Cussac A, BMC Cancer. 2010 Feb 9;10:36.

- "Doxorubicin/pemetrexed followed by docetaxel versus doxorubicin/ cyclophosphamide followed by docetaxel as neoadjuvant treatment for early-stage breast cancer: a randomized phase II trial. Schneeweiss A, Lauschner I, Ruiz A, **Guerrero A**,et al. Clin Breast Cancer. 2007 Apr;7(7):555-8.

- "Analysis of Androgen Receptor (AR) in Positive Estrogen Receptors (ER) Tumors Treated with Neoadjuvant Letrozol". **Angel Guerrero**, Rachel Ruoff , Susan Logan, Joaquín Gavilá, Amparo Ruíz and Vicente Guillem. Oral Session at Spanish Society of Medical Oncology Congress 2011.

- "Endocrine Therapy for Advanced Breast Cancer: Beyond Tamoxifen and Aromatase Inhibitors". Guerrero-Zotano, Angel; Muggia, Franco. Current Cancer Therapy Reviews, Volume 6, Number 1, February 2010 , pp. 51-61(11)

2015 ASCO poster

CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

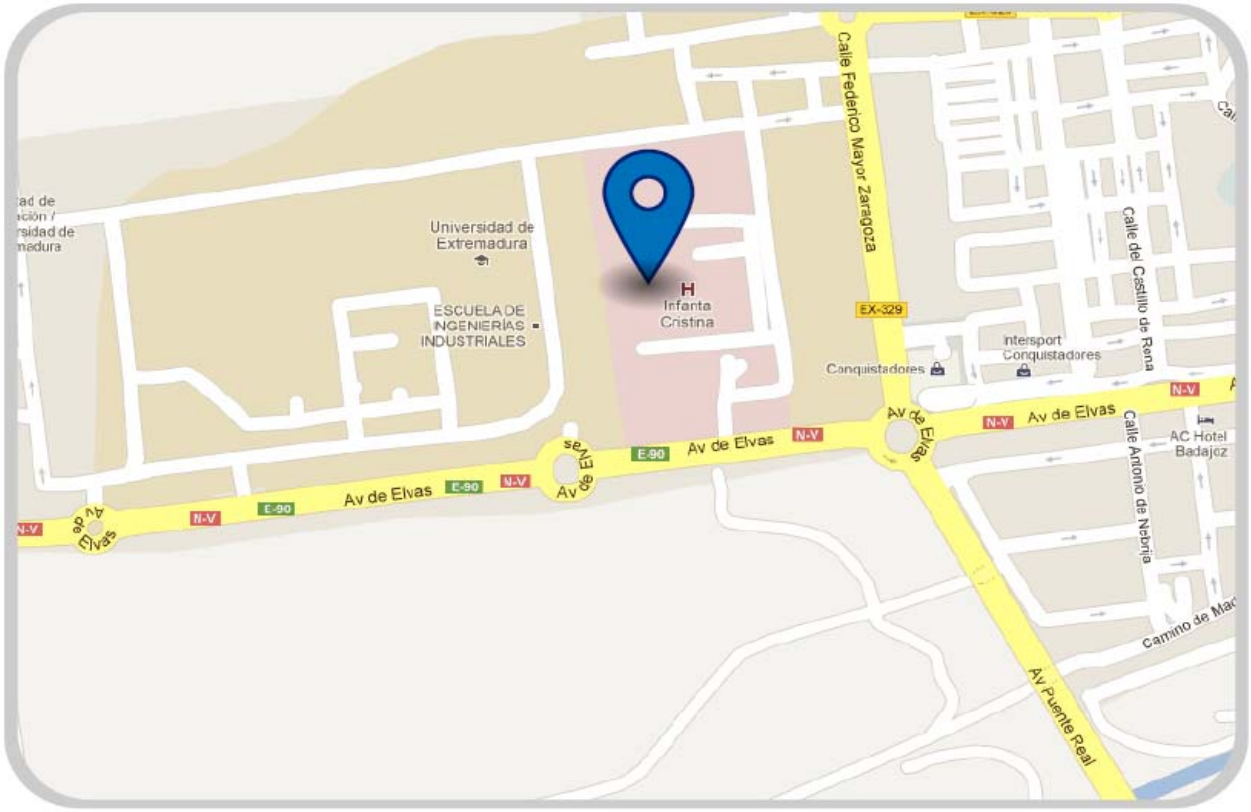
CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

General Information

Who filled in this survey	Adrián Llerena Ruiz
E-mail contact (Phone number)	allerena@unex.es
Date of survey filling in	05/05/2015
Unit web address	
Formal name of the unit	CICAB (Clinical Research Center of Badajoz)
Postal address	CICAB Complejo Hospitalario Universitario de Badajoz Avenida de Elvas s/n Planta Semisótano C.P. 06006 Badajoz Spain

CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Location



CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Ownership

Ownership	Extremadura Health System
Established	2007
Linked hospital	Badajoz Universitary Hospitalary Complex. Universitary Hospital Infanta Cristina
Distance between linked hospital and Unit	None, located in the hospital building
Linked Ethics Committee (CEIC)	CEIC Hospital Infanta Cristina, Comité Ético de Investigación Clínica Autonómico de Extremadura (CEICEx)

Unit Manager

First and last names	Adrián LLerena Ruíz
Qualifications	MD, PhD, Pharmacology Professor enabled
Medical specialty	Pharmacology
Manager since	2007
E-mail and phone	allerena@unex.es +34924218040

Short CV

Director of the Clinical Research Center in the University Hospital in Badajoz Spain. He is also professor of Pharmacology and Clinical Pharmacology in the Medical School of the University of Extremadura; between 1989-1993 he did his post doc at Karolinska Institute Sweden focusing on Clinical Pharmacogenetics. His teaching experience is of more than 20 years in Spain and of about 9 years in Portugal. He has supervised more than 10 Ph.D. theses so far. He has also been an invited professor in different Universities in USA such as University of California at Los Angeles 2004 Mount Sinai Medical School at NY 2005 and Miller Medical School at Miami 2006 and in Latin America such as UNAM in Mexico San Marcos in Peru, Chile UFMG Brasil, Australian National University in Camberra, etc. He has published more than 150 peer reviewed papers and book chapters. He is also coordinating the Iberoamerican network of Pharmacogenetics since 2006. He served in different Scietific societies as IberoAmerican Society of Pharmacogenomics. He has been principal investigator in more than 30 national and european research projects.

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Ownership

Unit Manager

First and last names: Adrián LLerena Ruíz

Short CV (cont.)

He has also served as reviewer in all journals related to clinical pharmacology and mainly pharmacogenetics and clinical psychopharmacology. He has organized several national and international workshops and Scientific conferences in Spain and Latin America. Currently he is Vicepresident of the Spanish Society of Pharmacogenetics and Pharmacogenomics and Vicepresident of the Spanish Society for Clinical Pharmacology. Since 2010 he is a member of the EMA Pharmacogenomics Working Parthy

CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Accreditations and audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

None in the last 3 years

Audits by regulatory agencies (last 3 years)

None

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **Yes**

Audits by sponsors (last 3 years)

2014 GlaxoSmithKline

Do you follow your own Standard Operating Procedures (SOPs)? yes Do you supply with a SOP copy to a sponsor if requested? yes

Would you follow the sponsor SOPs if requested: yes

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 1

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

All the study data are processed in accordance with the procedures and current legislation on Clinical Trials and Protection of Personal Data. Paper documentation is stored in a fireproof cabinet, with limited access locked. Access to computer equipment is restricted by password only personnel of CICAB have the access required to his role. All computer files and medical records of patients are stored on the servers of the Extremadura Health Service.

CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Facilities

Year of Unit building	1984	Last Unit reform	2014
Usable space	390	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	4	Number of beds	9-12
Beds distribution	3 rooms (3-4 beds per room)		
Beds distribution allows a complete and continuous visual control by nurses			yes
Number of bed with intensive or continuous monitoring	0	Number of armchairs suitable for subject monitoring	4
Owned kitchen	none	Meals supervision by dietitian	yes
Dining-room available for volunteers	yes	Individual lockers available for volunteers	yes
Relaxing room available for volunteers independent from the beds area			yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			yes
The emergency trolly has available suitable medications with immediate by controlled access			yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	yes		
Unit availability of an evacuation plan for volunteers in emergency situations			yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers			Yes

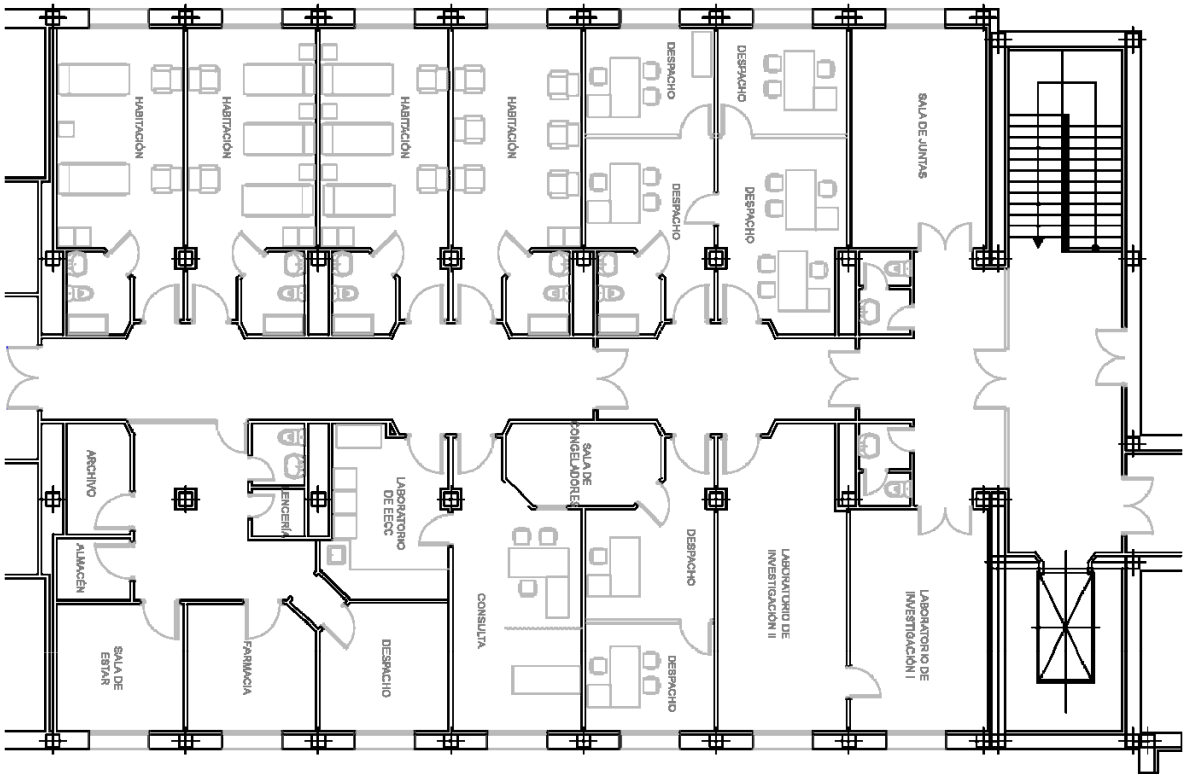
The phase I unit is integrated into the hospital itself .The Intensive Care Unit and Emergency Service are informed of clinical trials underway and of admission of patients so they are ready in case of emergency

Distance and time to get the former services	Emergency service is at the top of the unit (ground floor) at a distance of 1.5 minutes and the Intensive Care Unit on the 1st floor to floor about 3 minutes distance.		
Unit entrance/Exit door controlled	yes	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Facilities

Unit distribution plan



CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Staffing and Resources

Unit employees

Permanent staff Fixed-term/contracted staff (internship, grant holders) Part-time collaborators

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	1	1
Nurse	1	1
Monitor or CRA		1
Pharmacist	Pharmacy Hospital Service	
Biometry		1
Data management		
Medical writing		
Pharmacokinetics		1 (Manager of Clinical Trial Laboratory)
Quality assurance		
Project Management		
Finance	2	
Recruitment	10	10
IT (informatics)	Informatic Hospital Service	
Other (specify): CTA, psychologist, etc		Project Technicians (3), Research fellows (2), Statistic/Methodologist (1)

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

Physician Nurse

CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	yes
The quality assurance activities are subcontracted by the Unit	no
Availability of a specific area for drug storing and preparation of medications for the study	yes
The former area or room has restricted access by key or code	yes
Laminar flow chamber availability for preparation of parenteral treatments	yes
Perfusion pumps for intravenous treatment	yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Principal Investigator or Nurse as applicable **Preparation**: Pharmacist or Nurse as applicable
Drug accountability procedures, such as reception, preparation and dispensing forms	yes
SOPs available for drug preparation and dispensing	yes
SOPs available for drawing and managing of biological fluids	yes
System or procedure used for samples identification	

Anonymous codes:
- Traxis system (Micronic): use of tubes with 2D encoding.
- Labeling of alphanumeric coding that relates to the code of the protocol, the subject, visit number and sample data collection.
- Labeling provided by the sponsor with the information required in each case

Availability of a specific area for blood samples managing	yes
The former area or room has restricted access by key or code	yes
Number of centrifuges available	2

CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Services Capabilities

System for plasma/fluids samples storing

In clear plastic boxes labeled with the protocol code, subject code and collection date, stored at the required temperature according to the protocol of the clinical trial. The material provided by the specific promoter is used in each case.

Fridges and freezers available in the Unit	4 fridges, 5 freezers
The Unit has its owned Bioanalytical Department	yes
Availability of genotyping or fenotyping methods for participants	yes
Data Management and software used (describe)	yes

Excell, Access, Meditata RAVE, Inform, DataLabs, Enable, Sbir, Clinphone, Cenduit, Impala,etc.

Biometry or Statistical Analysis and software used (describe)	yes

SPSS

Pharmacokinetic Analysis and software used (describe)	no
Medical Writing and skilled languages	English and Spanish

Owned archives in the same Unit building (describe)

The archive unit is located at the research center with restricted access by key and all the security controls provided by Hospital security. If necessary the archive unit of the hospitalary complex could also be used

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

The study files are digitized and converted in a CD or web format	If required
Project management	no

CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Study Participants

Kind of participants included in clinical trials performed in the Unit

X Healthy volunteers X Patients

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour Haematological tumour X Adults Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All kind of cancer except hematologic cancer

Recruiting methods for healthy volunteers

Website, brochures, students from Health Sciences Faculties.

Recruting methods for patients

Recruitment in Hospital and Primary Care centers, other hospitals and associations of patients.

Do you have sugery rooms available for screening (separated from the in-house area)? (number) yes

Do you keep a paper or electronic database of volunteers? (describe) yes

Electronic (in process)

Have you implemented any measure for avoiding the over-volunteering? (describe) yes

- Set as exclusion criteria to have participated in a clinical trial in the past X months (depending on the protocol).
- CICAB has a database that includes all patients who have participated in clinical trials at the Centre, this will allow us to verify that the subject has not participated in an clinical trial in the previous three months (there is only one Phase I unit acreditated in Extremadura).

CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	2	Pulsioximetry devices (number)	2	12-leads ECG devices (number)	2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	yes
Availability in the Unit of tests for assessing CNS drug effects	CANTAB Neurocognitive Evaluation Program
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	no
Familiarity with Electronic Data Capture –EDC applied to clinical trials	yes
Experience in other kind of PD or PK evaluations not formerly collected	yes

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

yes

CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						2
First single-dose administration in humans		1	1			
First multiple-dose administration in humans				1	2	7
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)			1	1	1	3
Proof of concept (Phase Ib or I/II)			1	1	2	7
Own research lines	6	6	8	13	7	2
Others (specificying)	_	3	5	9	21	30

Number of trials linked to a PEI (IND) submission | 2009 | 0 | 2010 | 0 | 2011 | 0 | 2012 | 0 | 2013 | 1 | 2014 | 2

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Central nervous system drugs, antineoplastic and immunomodulating agents, musculoskeletal system agents, Antiinfectives for systemic use.

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 0 Number of trials promoted by multinational companies 9

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 30 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 3

CICAB- Centro de Investigación Clínica del Área de Salud de Badajoz

Annexes

Brochure not available in English

Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

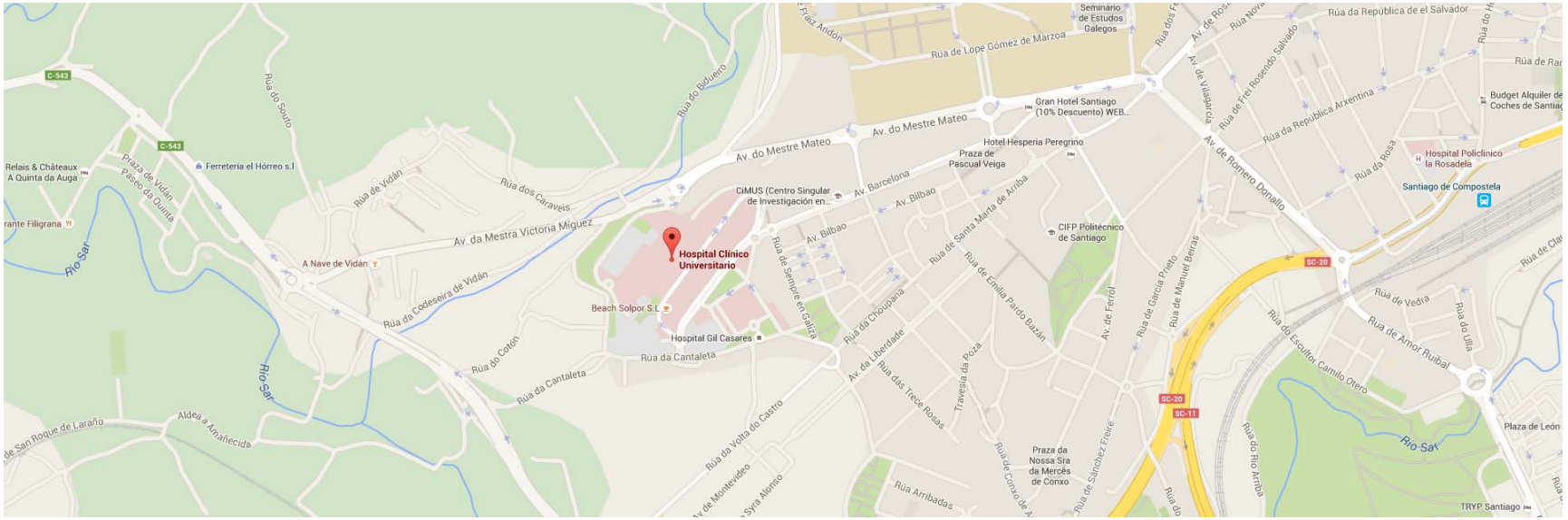
Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

General Information

Persona que contesta la encuesta (nombre)	María J. Gómez-Reino Garrido
Contacto correo electrónico (teléfono)	investigacion.frd@sergas.es / 981950088
Fecha en que se completó la encuesta	20/05/15
Página web	
Nombre oficial en inglés	Clínical Trials Unit
Dirección	Unidad de Ensayos Clínicos Hospital Clínico Universitario de Santiago TravesIa da Choupana, s/n 15706. Santiago de Compostela

Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

Location



Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

Ownership

Ownership	Hospital Clínico Universitario de Santiago/Fundación Ramón Domínguez
Established	Currently studies are carried out independently in each Hospital Department. It is expected that by the end of 2015 the new Unit will be constituted.
Linked hospital	
Distance between linked hospital and Unit	They are in same building
Linked Ethics Committee (CEIC)	CEIC de Galicia (Servicio Gallego de Salud)

Unit Manager

First and last names	Rafael López López
Qualifications	MD, PhD
Medical specialty	Oncologist
Manager since	
E-mail and phone	Rafael.lopez.lopez@sergas.es 981 951 471

Short CV

Actual Position: Head of Medical Oncology Department. Hospital Clínico de Santiago
Qualifications:
1983: Degree in Medicine and Surgery
1995: Doctor in Medicine and Surgery
1988 Specialist in Medical Oncology (Hospital General de Asturias)
Previous positions: 2005-to date: Associate Medical Oncology Professor. Universidad de Santiago de Compostela.
1993-1998: Acting Head of Medical Oncology Department. Hospital Txagorritxu.
Co-author of more thab 30 papers in different national and internaticonal publications.

Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

Accreditations and audits (*)

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

No. Nowadays, their is not any official accreditation in our region.

Audits by regulatory agencies (last 3 years)

NA

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **Yes**

Audits by sponsors (last 3 years)

2010 and 2013

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? Yes

Would you follow the sponsor SOPs if requested: As a general rule forever. Each case will be examined on an individual basis.

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 2 (according to department)

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

The system for collecting clinical data of patients is done through electronic medical records, with individual access and identification of responsibility for the patient. The personal data and other specific study of each patient are collected for each service and are guarded by the personnel responsible on computers with personalized access.

Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

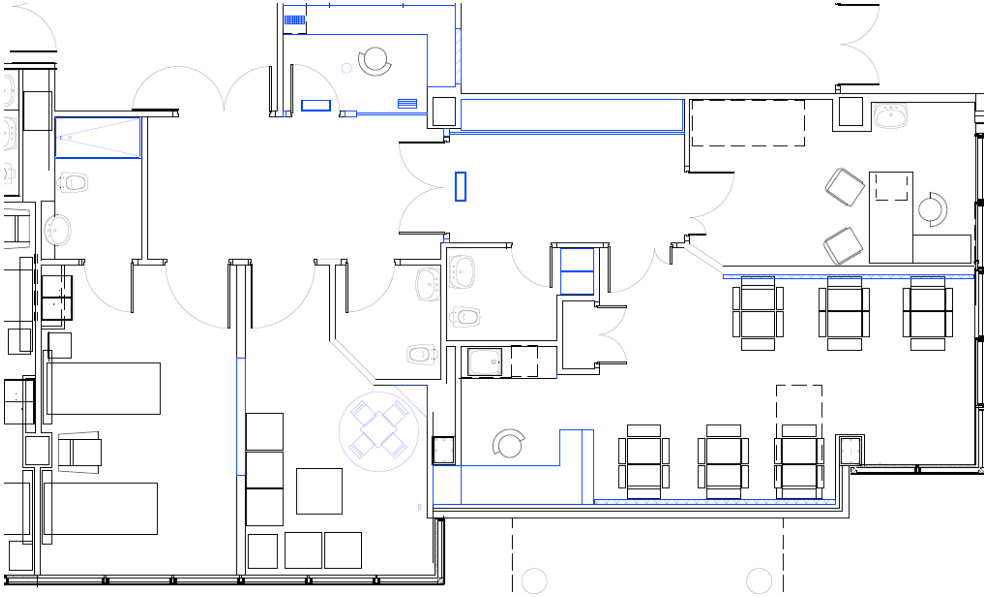
Facilities (*)

Year of Unit building	1999	Last Unit reform	NA
Usable space	Different areas inside Hospital	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	6 aprox.	Number of beds	6
Beds distribution	One bedroom with 4 beds and another with 2 (new Unit).		
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	2 (new Unit)	Number of armchairs suitable for subject monitoring	16+6 (new Unit)
Owned kitchen	No	Meals supervision by dietitian	Yes
Dining-room available for volunteers	No	Individual lockers available for volunteers	No
Relaxing room available for volunteers independent from the beds area			No
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes, both		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Urgencies and Intensive Care Unit		
Distance and time to get the former services	Same building		
Unit entrance/Exit door controlled	No	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

Facilities (*)

Unit distribution plan (new Unit):



Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

Staffing and Resources (*)

Unit employees

Permanent staff 32 Fixed-term/contracted staff (internship, grant holders) 13 Part-time collaborators 0

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	3	
Co-investigator (physician)	17	6
Nurse	9	
Monitor or CRA		
Pharmacist	2	
Biometry		
Data management	4	
Medical writing	3	
Pharmacokinetics		
Quality assurance		
Project Management	1	
Finance		
Recruitment		
IT (informatics)		
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician X Nurse

Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

Services Capabilities (*)

Availability of Central laboratory for safety analysis (biochemical and haematological parameters)	Yes
The quality assurance activities are subcontracted by the Unit	No
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	Yes
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Hospital pharmacist specializing in Clinical Trials. **Preparation**: Hospital pharmacist specializing in Clinical Trials.
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification	Samples analyzed in the hospital (clinical analysis) are identified by a barcode. Samples with different purposes are identified by sponsor code.
Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes
Number of centrifuges available	8 (6 refrigerated)
System for plasma/fluids samples storing	Freezers: -20 an -80 ºC
Fridges and freezers available in the Unit	4 fridges and 19 freezers
The Unit has its owned Bioanalytical Department	No
Availability of genotyping or fenotyping methods for participants	No

Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

Services Capabilities (*)

Data Management and software used (describe)	No
Biometry or Statistical Analysis and software used (describe)	No
Pharmacokinetic Analysis and software used (describe)	No
Medical Writing and skilled languages	Yes, Spanish and English
Owned archives in the same Unit building (describe)	Yes

Own archive for closed studies with control by identity card and fire control.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Following Sponsor instructions.

The study files are digitized and converted in a CD or web format	No
Project management	Yes

Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

Study Participants (*)

Kind of participants included in clinical trials performed in the Unit

	Healthy volunteers	X	Patients
X	Other populations	Target population healthy volunteers in vaccine studies (from two months to 18 years old)	

If the Unit has experience in oncology, detail kind of tumour and age groups

X	Solid tumour		Haematological tumour	X Adults	Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All solid tumors: breast, lung, colorectal, bladder, prostate, melanoma, ovarian, gastric, pancreatic, gist, sarcomas ...

Recruiting methods for healthy volunteers

NA

Recruting methods for patients

Patients recruited through the daily patient care of each department involved.

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	Yes, 12.
Do you keep a paper or electronic database of volunteers? (describe)	NA
Have you implemented any measure for avoiding the over-volunteering? (describe)	NA

Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

Pharmacodynamic/Pharmacokinetic Capabilities (*)

Digital blood pressure devices (number)	6	Pulsioximetry devices (number)	6	12-leads ECG devices (number)	6

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Yes
Availability in the Unit of tests for assessing CNS drug effects	No
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	No
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes
Experience in other kind of PD or PK evaluations not formerly collected	No

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

NA

Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

Experience (*)

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans		1				
First multiple-dose administration in humans	2	1			2	
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)			2	1	2	2
Own research lines						
Others (specificying)	1	1	1			1

Number of trials linked to a PEI (IND) submission | 2009 | 2 | 2010 | 2 | 2011 | 0 | 2012 | 1 | 2013 | 1 | 2014 | 2

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Vaccines, monoclonal antibodies, antineoplastic agents, immunosuppressants.

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 0 Number of trials promoted by multinational companies 17

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60 days

Number of Early Stages trials performed in the Unit and published in the last 4 years

Unidad de Ensayos Clínicos - Hospital Clínico Universitario de Santiago

Anexos

(*) NOTE.-

During 2015 Hospital Clínico de Santiago and Fundación Ramón Domínguez will launch a Clinical Trials Unit specializing in early phases, which will increase current activity (detailing in this document).
(*) Data in this document are referred to resources pooled from the different departments at the day of the survey. It was not taken into account the new Unit under construction, except where indicated.

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

General Information

Who filled in this survey	Silvia Antolin Novoa
E-mail contact (Phone number)	silviaantolin@hotmail.com 982178353(292851)
Date of survey filling in	06/07/2015
Unit web address	Fase I Medical Oncology Unit. A Coruña University Hospital. As xubias s/n 15006 A Coruña
Formal name of the unit	
Postal address	Fase I Medical Oncology Unit. A Coruña University Hospital. As xubias s/n 15006 A Coruña

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Location

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Ownership

Ownership	Complejo Hospitalario Universitario A Coruña
Established	2010
Linked hospital	Complejo Hospitalario Universitario A Coruña
Distance between linked hospital and Unit	0km
Linked Ethics Committee (CEIC)	CEIC Comunidad Autónoma de Galicia

Unit Manager

Short CV

First and last names	Silvia Antolín Novoa
Qualifications	Oncólogo Médico
Medical specialty	Oncólogo Médico
Manager since	2010
E-mail and phone	silviaantolin@hotmail.com 981178353 (292851)

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

No

Audits by regulatory agencies (last 3 years)

NO

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **YES**

Audits by sponsors (last 3 years)

NO

Do you follow your own Standard Operating Procedures (SOPs)? YES Do you supply with a SOP copy to a sponsor if requested? YES

Would you follow the sponsor SOPs if requested: YES IF THESES SOPs AREA ADPATED TO OUR SITE AND SOC

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 0

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Internal and external monitoring of each Clnical Trail. With an average of 4-6 visits per year

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Facilities

Year of Unit building	1985	Last Unit reform	1995
Usable space	NA	The Unit building is separate from the linked hospital	NO
Number of CTs the unit could perform simultanously	6	Number of beds	16
Beds distribution	2 BED PER ROOM		
Beds distribution allows a complete and continuous visual control by nurses			YES
Number of bed with intensive or continuous monitoring	2	Number of armchairs suitable for subject monitoring	20
Owned kitchen	NO	Meals supervision by dietitian	YES
Dining-room available for volunteers	NO	Individual lockers available for volunteers	NO
Relaxing room available for volunteers independent from the beds area			YES
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			YES
The emergency trolly has available suitable medications with immediate by controlled access			YES
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	BASIC LIFE SUPPORT		
Unit availability of an evacuation plan for volunteers in emergency situations			YES
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			YES
Volunteers/patients healthcare would be covered by the national or the regional health system if required			YES
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers			1 ICU
Distance and time to get the former services	Les than 500m		
Unit entrance/Exit door controlled	Yes, with key	Unit with Closed Circuit Television	NO
Availability of an alternate electrical generating set that automatically works in case of a general system failure			YES

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Facilities

Unit distibution plan:

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Staffing and Resources

Unit employees

Permanent staff 9 Fixed-term/contracted staff (internship, grant holders) 3 Part-time collaborators

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	4	
Co-investigator (physician)	9	3
Nurse	1	
Monitor or CRA		
Pharmacist	3	
Biometry		
Data management	4	
Medical writing		
Pharmacokinetics		
Quality assurance		
Project Management		
Finance	1	
Recruitment		
IT (informatics)		
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

1 Physician **1** Nurse

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	YES
The quality assurance activities are subcontracted by the Unit	BIO Rad laboratorios EQAS Lab nº 001898
Availability of a specific area for drug storing and preparation of medications for the study	YES
The former area or room has restricted access by key or code	YES
Laminar flow chamber availability for preparation of parenteral treatments	YES
Perfusion pumps for intravenous treatment	YES
Who is the responsible for drug preparation and dispensing	**Dispensing:** PHARMACISTS **Preparation**: PHARMACISTS
Drug accountability procedures, such as reception, preparation and dispensing forms	YES
SOPs available for drug preparation and dispensing	YES
SOPs available for drawing and managing of biological fluids	YES
System or procedure used for samples identification	
PACIENT NAME AND BARCODING IN SAMPLES AND REQUEST	
Availability of a specific area for blood samples managing	YES
The former area or room has restricted access by key or code	YES
Number of centrifuges available	2
System for plasma/fluids samples storing	Freezer, FRIDGES
Fridges and freezers available in the Unit	2 FRIDGES AND 2 FREEZERS (-70ºc)
The Unit has its owned Bioanalytical Department	NO
Availability of genotyping or fenotyping methods for participants	YES

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Services Capabilities

Data Management and software used (describe)	NO
Biometry or Statistical Analysis and software used (describe)	NO
Pharmacokinetic Analysis and software used (describe)	NO
Medical Writing and skilled languages	NO
Owned archives in the same Unit building (describe)	YES

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

WHEN THE CLINICAL TRIAL IS CLOSED ALL DOCUMENTS ARE SENT TO CENTRAL ARCHIVE AND ARE ARCHIVED FOLLOWING THE LEGISLATION

The study files are digitized and converted in a CD or web format	YES
Project management	NO

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Study Participants

Kind of participants included in clinical trials performed in the Unit

X Healthy volunteers X Patients

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour Haematological tumour X Adults Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

ALL SOLID TUMOUR

Recruiting methods for healthy volunteers

OUR OWN PATIENTS OR PATIENTS FROM OTHER HOSPITALS IN THE SAME COUNTRY

Recruting methods for patients

OUR OWN PATIENTS OR PATIENTS FROM OTHER HOSPITALS IN THE SAME COUNTRY

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	YES, 7
Do you keep a paper or electronic database of volunteers? (describe)	NO
Have you implemented any measure for avoiding the over-volunteering? (describe)	NO

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	YES	Pulsioximetry devices (number)	YES	12-leads ECG devices (number)	YES

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	YES
Availability in the Unit of tests for assessing CNS drug effects	TAC, BRAIN RMN, BRAIN SPECT
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	NO
Familiarity with Electronic Data Capture –EDC applied to clinical trials	YES
Experience in other kind of PD or PK evaluations not formerly collected	
Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted	

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)	5	5	5	6	7	12
Own research lines						
Others (specificying)						

Number of trials linked to a PEI (IND) submission | 2009 | 0 | 2010 | 0 | 2011 | 0 | 2012 | 0 | 2013 | 0 | 2014 | 0

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Pi3K INH,AKT, mtor, PARP INH, ANTIANGIOGENICS, TK INH

Sponsor typology for Early Stages trials performed in the last 4 years (2003 to 2006)

Number of trials promoted by Spanish companies

Number of trials promoted by multinational companies 40

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 30

Number of Early Stages trials performed in the Unit and published in the last 4 years 1

Unidad de Fase I Servicio de Oncología Médica. Complejo Hospitalario Universitario A Coruña

Annexes

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

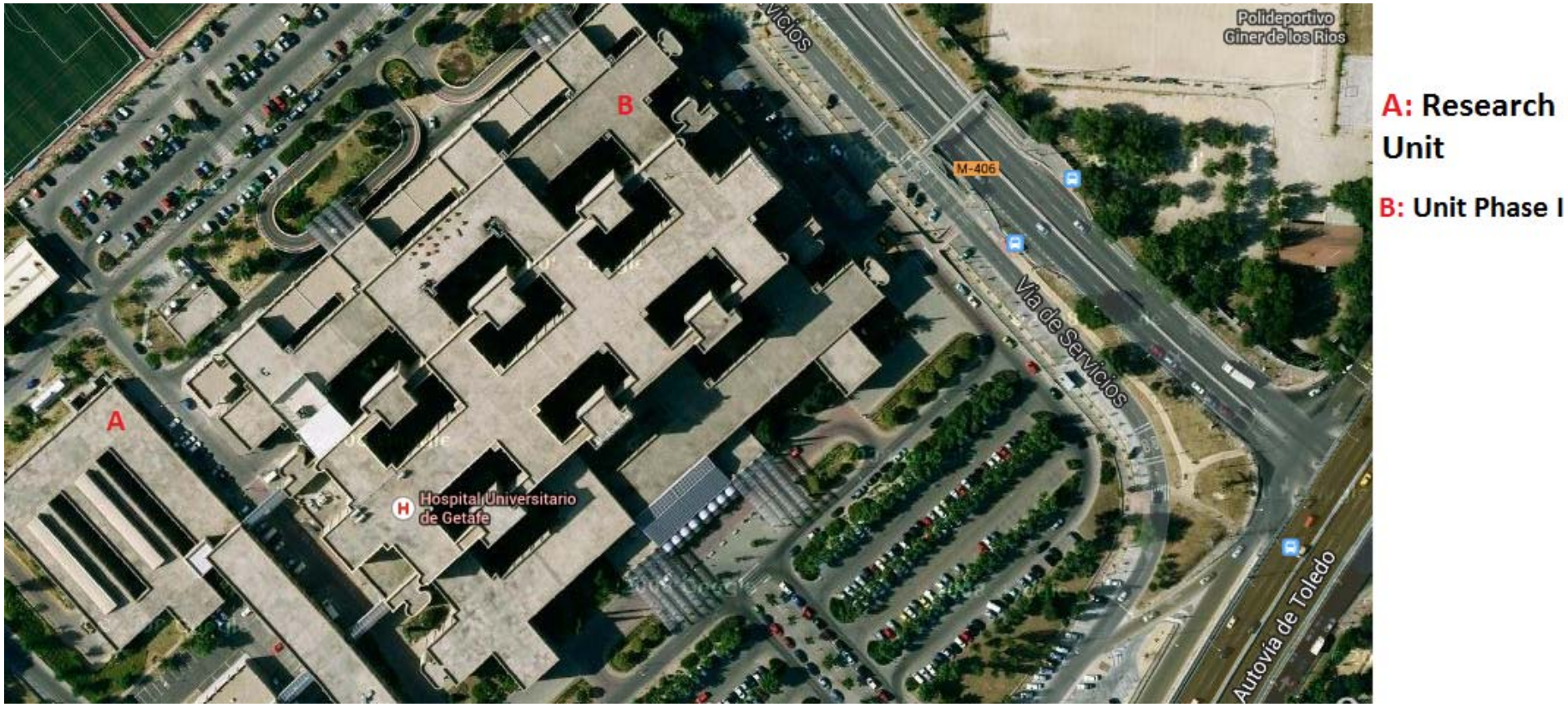
Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

General Information

Persona que contesta la encuesta (nombre)	Olga Laosa / Laura Pedraza
Contacto correo electrónico	olga.laosa@salud.madrid.org / laura.pedraza@salud.madrid.org
Fecha en que se completó la encuesta	06/05/15
Página web	http://iisgetafe.es/infraestructuras/plataforma-clinica/#CICA
Nombre oficial en inglés	Clínical research center for the elderly (CICA)
Dirección	Academic Hospital of Getafe. Ctra. de Toledo, Km 12.500, 28905 Getafe

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Location



A: Research Unit - Ground floor. Teaching building. Foundation for Biomedical Research
B: Unit Phase I. 4th floor. 4D section. Clinical research center of the elderly. 476-479 offices.

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Ownership

Ownership	Belen Riquelme
Established	Foundation for Biomedical Research
Linked hospital	Academic Hospital of Getafe.
Distance between linked hospital and Unit	The same building
Linked Ethics Committee (CEIC)	CEIC Area 10. Madrid

Unit Manager

First and last names	Leocadio Rodríguez Mañas
Qualifications	Medical doctor
Medical specialty	Geriatrician
Manager since	2010
E-mail and phone	leocadio.rodriguez@salud.madrid.org 00 34 916839360 (ext. 6412)

Short CV

Head of the Department of Geriatrics at the Academic Hospital of Getafe (Madrid), President of the Research Committee of the University Hospital of Getafe and teacher "honorary" Department of Medicine, Faculty of Medicine, Faculty of Medicine, University of Madrid, Spain.

Coordinator of the Spanish Cooperative Research Network on Aging and Fragility - RETICEF (Ministry of Science and Innovation), co-director of the epidemiological study "Study on Healthy Aging Toledo" involving 2,845 elderly residents in the community and member and Chairman of the Latin American Academy of Medicine for Older Persons (ALMA) founder. Coordinator 5 international multicenter project, funded by the European Commission.

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Ownership

Unit Manager

First and last names: Leocadio Rodríguez Mañas

Short CV (cont.)

Principal investigator on 23 research projects of public and private funding, with emphasis on diabetes, frailty, aging and disability. Ex-president of the Spanish Society of Geriatric Medicine, member of the Global Initiative for the EASD (European Association for the Study of Diabetes) in diabetes and the elderly, Advisor to the Pan American Health Organization, the Ministry of Health Spanish and the Ministry of Science and Innovation.
Main publications:

- Nevado J, Vallejo S, M El-Assar, Peiro C, Sánchez-Ferrer CF, Rodríguez-Mañas L. Changes in the human peritoneal mesothelial cells During aging. Kidney International, 2006; 69: 313-322.
- Rodríguez-Mañas L, Sánchez-Rodríguez C, Vallejo S, M El-Assar, Peiro C, Azcutia V, Fences E, Sánchez-Ferrer CF, Snowy J. Pro-inflammatory effects of early non-enzymatic glycated proteins in human mesothelial donor's cells vary with cell age. Br J Pharmacol 2006, 149; 979-987. Online: 30 October 2006; doi: 10.1038 / sj.bjp.0706864.
- Baztán JJ, Garcia Suarez-FM, López-Arrieta J, Rodríguez-Mañas L, Rodríguez Artalejo F. Effectiveness of acute geriatric units on functional decline, living at home, and case fatality ADMITTED Among older patients to hospital for acute medical disorders : meta-analysis. Br Med J 2009; 338: b50

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

- Reference Site for care of the elderly population of the European Union, as Region of Madrid Health Department, Academic Hospital of Getafe. 01/07/2013
- The investigation of Hospital of Getafe has obtained quality certification under the UNE 166002 Management Research, Development and Innovation (R + D + i). Granted by the Ministry of Health Planning and Infrastructure. 03/12/2014

Audits by regulatory agencies (last 3 years)

Non

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? Yes

Audits by sponsors (last 3 years)

Non

Do you follow your own Standard Operating Procedures (SOPs)? Yes

Do you supply with a SOP copy to a sponsor if requested? Yes

Would you follow the sponsor SOPs if requested: We will assume the SOPs after agreement of both parties and as long as this doesn't interfere with the objectives and ethical standards of the unit.

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: the monitoring visits as established by each promoter

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

All documents relating to a clinical trial shall be filed in a folder labeled with the name and study code, in the clinical trials unit (CICA). Within each section the documents are ordered of date entry (the newest at the top). The documents from a clinical trial, described in ICH GCP and the Organic Law 15/1999 of 13 December on the protection of personal data, would be retained until sponsor notification and for 15 years after the completion of the study.

The personal data that are available in these units relate to health, which, according to this Law, are specially protected. All data and documents of the study could be provided to regulatory authorities, if they request them.

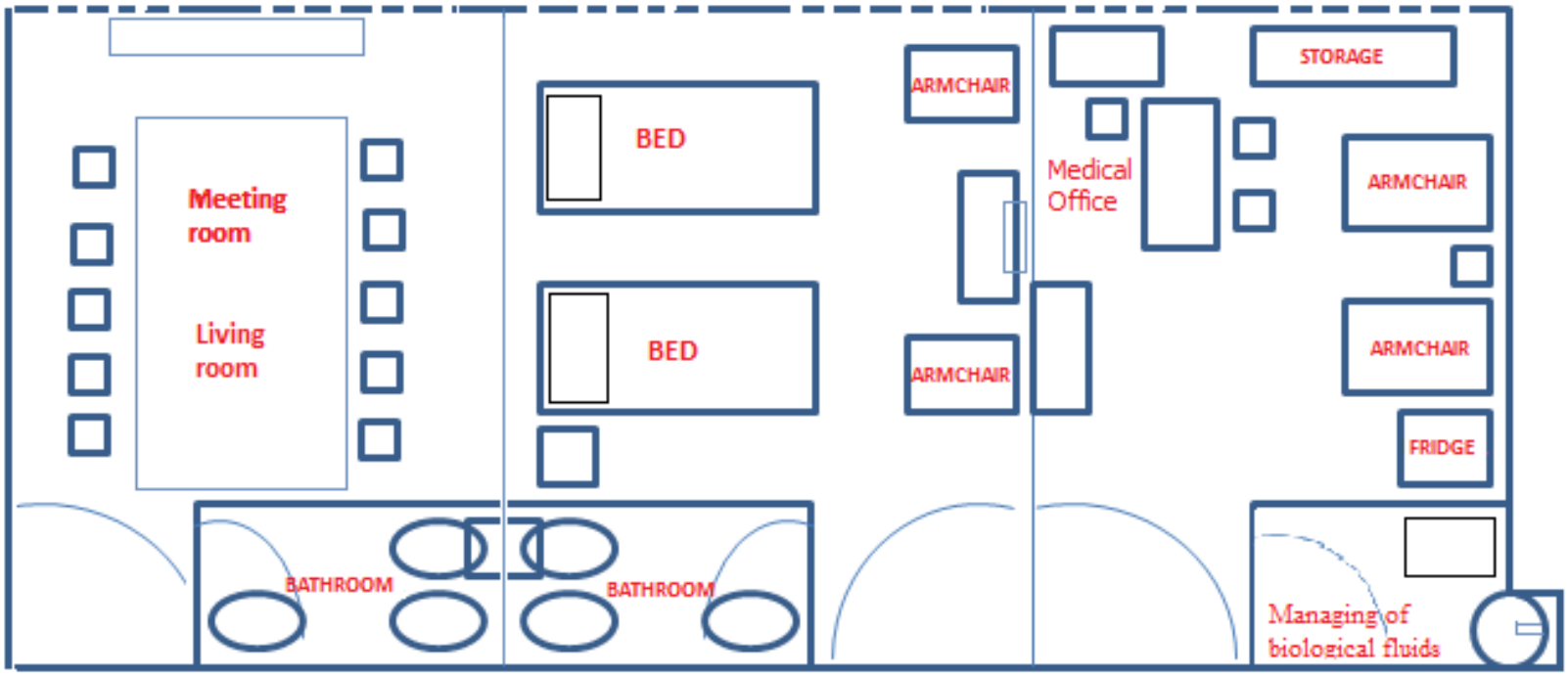
Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Facilities

Year of Unit building	1986	Last Unit reform	Non
Usable space	38m2	The Unit building is separate from the linked hospital	Non
Number of CTs the unit could perform simultanously	2	Number of beds	2
Beds distribution	A room with 2 beds and 4 recliners.		
Beds distribution allows a complete and continuous visual control by nurses			2
Number of bed with intensive or continuous monitoring	Yes	Number of armchairs suitable for subject monitoring	4
Owned kitchen	No	Meals supervision by dietitian	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Advance LS		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	A geriatrician and nurse will take care of the basic life support, and they will decide if the patient requires admission in geriatric ward, the intensive care unit or some other unit available to the hospital, and these procedures should be responsibility for the geriatrician on duty in the unit.		
Distance and time to get the former services	The Unit is located in the premises of the Hospital		
Unit entrance/Exit door controlled	Key that only the nurse or doctor has, and each patient should register the date and time of arrival and signature	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Facilities Unit distribution plan



Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Staffing and Resources

Unit employees

Permanent staff 12 Fixed-term/contracted staff (internship, grant holders) 10 Part-time collaborators 4

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1-3-4-5-6-7	20-21-22-23-24-25-26-27
Co-investigator (physician)	3-4-5-6-7	14:27
Nurse	7	
Monitor or CRA		
Pharmacist	10	14-15
Biometry		
Data management	3-4-5-6-7-9	
Medical writing	1-3-4-5-6-7-9	14:27
Pharmacokinetics		
Quality assurance	3-4-7	
Project Management	3-4-7	
Finance	1-11	
Recruitment	3-4-5-6-7	14:27
IT (informatics)	12-13	
Other (specify): CTA, psychologist, etc	9-statistical	

Total: 13 employees collaborating as Permanent Staff and 14 as Part-time collaborators, 6 of them under MIR.

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

1 Physician **1** Nurse

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	Yes, Academic Hospital of Getafe laboratory
The quality assurance activities are subcontracted by the Unit	yes

Physiotherapy, Pharmacogenetics, CRO. To hire any of the companies, the founding values the CV and budgets of each.

Availability of a specific area for drug storing and preparation of medications for the study	yes
The former area or room has restricted access by key or code	yes
Laminar flow chamber availability for preparation of parenteral treatments	yes
Perfusion pumps for intravenous treatment	yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Pharmacy Service in the Academic Hospital of Getafe **Preparation**: Pharmacy Service in the Academic Hospital of Getafe
Drug accountability procedures, such as reception, preparation and dispensing forms	yes
SOPs available for drug preparation and dispensing	yes
SOPs available for drawing and managing of biological fluids	yes
System or procedure used for samples identification	

The samples shall be identified by the code of the study participants with labels.

Availability of a specific area for blood samples managing	yes
The former area or room has restricted access by key or code	yes
Number of centrifuges available	1 refrigerated
System for plasma/fluids samples storing	Refrigerator freezer 4 ° C and -80 ° C
Fridges and freezers available in the Unit	2 Fridge /2 freezer

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Services Capabilities

The Unit has its owned Bioanalytical Department	Yes, Academic Hospital of Getafe laboratory
Availability of genotyping or fenotyping methods for participants	Yes, Sistemas genómicos / SERMAS / CAMBRIDGE / Evercyte / Cardiff Metropolitan / Mosaiques / University of Innsbruck / JENA

Data Management and software used (describe)

Yes, SPPS, Excel

Biometry or Statistical Analysis and software used (describe)

Yes , SPPS - R

Pharmacokinetic Analysis and software used (describe)

Non

Medical Writing and skilled languages	Spanish - English - French

Owned archives in the same Unit building (describe)

4 offices requiring key to get in, with lockable cupboards.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

15 years

The study files are digitized and converted in a CD or web format	No
Project management	Yes,

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Study Participants

Kind of participants included in clinical trials performed in the Unit

x Healthy volunteers x Patients

x Other populations Geriatrics

If the Unit has experience in oncology, detail kind of tumour and age groups

x Solid tumour x Haematological tumour x Adults Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

We have tracking service geriatric, palliative patients and have the cooperation of the service of general oncology.

Recruiting methods for healthy volunteers

Advertising unit (advertising (in the hospital, in recreation centers of 3rd age ...), database previously enrolled healthy volunteers

Recruting methods for patients

Geriatric service hasconsultation scheduled, hospital ward, day hospital, associated residences, health centers, Toledo cohort, primary care and patients in other services.

Do you have sugery rooms available for screening (separated from the in-house area)? (number) Yes, 1

Do you keep a paper or electronic database of volunteers? (describe)

Non

Have you implemented any measure for avoiding the over-volunteering? (describe)

The over-volunteering is not a common problem in the elderly

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	Yes, 1	Pulsioximetry devices (number)	yes	12-leads ECG devices (number)	Yes, 1

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Yes
Availability in the Unit of tests for assessing CNS drug effects	Encephalogram Cranial CT Cranial MRI Cranial PET Cognitive assessment
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	Yes, > 100 bioequivalence studies of some members of the unit
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes, > 10 since the beginning of CICA
Experience in other kind of PD or PK evaluations not formerly collected	Non

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

No

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)			1	1	3	5
Proof of concept (Phase Ib or I/II)					1	
Own research lines					1	1
Others (specificying)						

Number of trials linked to a PEI (IND) submission 2009 2010 2011 1 2012 1 2013 1 2014 3

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Hypoglycemic / Psychotropic / Drugs for dementia / Analgesics / Nephroprotective

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 0 Number of trials promoted by multinational companies 0

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 45 - 60

Number of Early Stages trials performed in the Unit and published in the last 4 years 0

Centro de Investigación Clínica del Anciano CICA. Hospital Universitario de Getafe

Annexes

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

General Information

Who filled in this survey	Jesús Frías Iniesta / Blanca Duque Bascuñana
E-mail contact (Phone number)	cfc@uam.es
Date of survey filling in	22/MAY/2015
Unit web address	www.uam.es/cfc
Formal name of the unit	Clinical Trials Unit UAM, Department of Pharmacology and Therapeutics, School of Medicine, Universidad Autónoma de Madrid
Postal address	Arzobispo Morcillo, 2-4 28029 Madrid

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Location

Metro Line: 10 station Virgen de Begoña.
Bus linees: 76,124, 132, 135

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Ownership

Ownership	Public- School of Medicine. Universidad Autónoma de Madrid
Established	1989
Linked hospital	Hospital Universitario La Paz
Distance between linked hospital and Unit	50m
Linked Ethics Committee (CEIC)	IEC of Hospital Universitario La Paz

Unit Manager

First and last names	Jesús Frías Iniesta
Qualifications	Doctor in Medicine
Medical specialty	Clinical Pharmacolgy
Manager since	1989
E-mail and phone	cfc@uam.es 91 497 53 34

Short CV

Academic Background

- General Physician, 1978, Univ. Complutense. Madrid
- Specialist in Clinical Pharmacology, 1983, Univ Autónoma. Madrid
- Doctor in Medicine, 1983, Univ Autónoma. Madrid
- Magister in Bioethic. 1992, Univ. Complutense. Madrid

Profesional Experience

- Head of Clinical Pharmacology Section, 1991-2004, Hospital Universitario La Paz. Madrid
- Head of Clinical Pharmacology Service, 2004, Hospital Universitario La Paz. Madrid
- Full Professor of Pharmacology, 1989-2002, Univ. Autónoma . Madrid
- Head of Pharmacology Departament, 2002, Univ. Autónoma . Madrid

Number of Publications

- Congress communications 70
- Spanish journals papers 53
- Internacional journals papers 48
- Book chapters 23

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

- **GENERAL SUBDIRECTORATE OF EVALUATION AND CONTROL. COMUNIDAD DE MADRID. CONSEJERIA DE SANIDAD D.G.** Inspected to verify compliance with the principal of Good Clinical Practice (GCP) in force of the European Union and Spain and the "Technical requirements for the Units which conduct early stage clinical trials with medicines in the Community of Madrid".The inspection visit took place on October 13th, 2011.

  Re-accredited for four years in February 2013

Audits by regulatory agencies (last 3 years)

Inspection by the AEMPS in July 2012 and November 2008

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **YES**

Audits by sponsors (last 3 years)

Seven by different sponsors

Do you follow your own Standard Operating Procedures (SOPs)? yes Do you supply with a SOP copy to a sponsor if requested? yes

Would you follow the sponsor SOPs if requested: Yes,only if the Sponsor SOPs they do not contradict with SOPs Unit and do not involve additional work or data duplication.

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: One per trial by our QA Unit

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

The team members sign a confidentiality agreement. Unit with controlled limited access. Trial documentation stored in a locked, double door and fire alarm protected archive. Trial electronic files stored in our Unit located server protected with periodic back up. The team members have a password restricted access to the server.

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

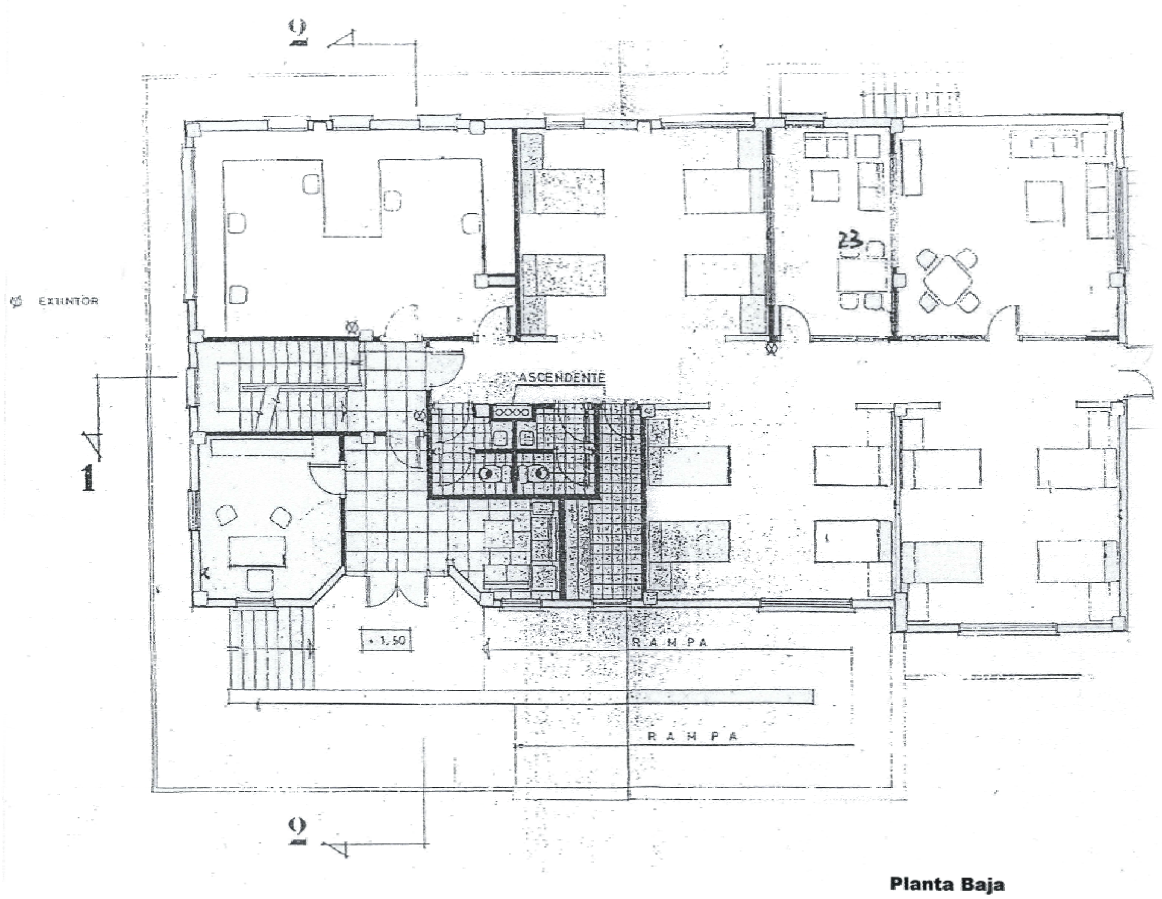
Facilities

Year of Unit building	2000	Last Unit reform	No
Usable space	900m^2	The Unit building is separate from the linked hospital	Yes
Number of CTs the unit could perform simultanously	3	Number of beds	12
Beds distribution	Three open connected rooms with four beds each		
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	2	Number of armchairs suitable for subject monitoring	0
Owned kitchen	No	Meals supervision by dietitian	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)			Yes
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Emergency Service. Hospital Uuniversiario La Paz		
Distance and time to get the former services	100m. Least than 5 minutes		
Unit entrance/Exit door controlled	Yes camera with video intercom	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Facilities

Unit distribution plan:



Planta Baja

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Staffing and Resources

Unit employees

Permanent staff 8 Fixed-term/contracted staff (internship, grant holders) 2 Part-time collaborators 19

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	2	0
Co-investigator (physician)	3	2
Nurse	0	12
Monitor or CRA	0	0
Pharmacist	0	0
Biometry	2	1
Data management	3	2
Medical writing	3	2
Pharmacokinetics	3	2
Quality assurance	1	0
Project Management	3	2
Finance	1	0
Recruitment	2	2
IT (informatics)	3	0
Other (specify): CTA, psychologist, etc	1 Laboratoy technician	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

x Physician x Nurse

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	No, we use Hospital La Paz laboratories
The quality assurance activities are subcontracted by the Unit	No, we have specific department
Availability of a specific area for drug storing and preparation of medications for the study	No, locked cabinet and temperature monitored
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	No
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Investigator Team Members **Preparation:** The clinical pharmacologist responsible for each study day
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes

System or procedure used for samples identification

Samples of each subject are labelled with the number of subject, admission period, sampling time and study code.

Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes, restricted access by key
Number of centrifuges available	1
System for plasma/fluids samples storing	They are stored in labeled transparent plastic bags for each volunteer
Fridges and freezers available in the Unit	2 fridges and 4 freezers (2 of them reach -70ºC and 2 reach -20ºC)
The Unit has its owned Bioanalytical Department	No. Generally, the sponsor outsources bioanalysis laboratory
Availability of genotyping or fenotyping methods for participants	Yes, RT-PCR system

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Services Capabilities

Data Management and software used (describe)	Yes
Clinical pharmacologists team handles the data management unless the sponsor decides otherwise	
Biometry or Statistical Analysis and software used (describe)	Yes
Clinical pharmacologists team handles the data management unless the sponsor decides otherwise. Software: Microsoft Excel 2013, R, STATA 11 and Phoenix WinNolin 6.3	
Pharmacokinetic Analysis and software used (describe)	Yes
Clinical pharmacologists team handles the data management unless the sponsor decides otherwise. No compatimental analysis. Software:Phoenix WinNolin 6.3 and R	
Medical Writing and skilled languages	Yes, English and Spanish
Owned archives in the same Unit building (describe)	Yes
Fireproof access through double doors locked. Smoke detectors. 15m^2	
Regarding a specific clinical trial what documents are sent to the archives and for long time are archived	
All documentation referred to trial (protocol, administration, development of the study, final report, CRDs, medical records and analytical is stored during the period of time according to current legislation.	
The study files are digitized and converted in a CD or web format	No
Project management	No, Unit staff memebers performs that function

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Study Participants

Kind of participants included in clinical trials performed in the Unit

x	Healthy volunteers	x	Patients
x	Other populations		

If the Unit has experience in oncology, detail kind of tumour and age groups

x	Solid tumour	x	Haematological tumour	x	Adults	x	Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All kinds except critically ill patients, the Unit has contact with the oncology department of the Hospital La Paz

Recruiting methods for healthy volunteers

The Clinical Trials Unit performs briefings for each study. Potential participants are advertised briefings dates through Unit website and Twitter account.

Recruting methods for patients

Usually through hospital specialists

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	Yes (1)
Do you keep a paper or electronic database of volunteers? (describe)	Yes

Both

Have you implemented any measure for avoiding the over-volunteering? (describe)	Yes

Database searching to verify that the volunteer has not participated in an trial in previous three months.

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Pharmacodynamic / Pharmacokinetic Capabilities

Digital blood pressure devices (number)	Yes(2)	Pulsioximetry devices (number)	Yes(2)	12-leads ECG devices (number)	Yes(2)

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Yes
Availability in the Unit of tests for assessing CNS drug effects	Yes
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	Yes
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes
Experience in other kind of PD or PK evaluations not formerly collected	Pk/PD, cardiovascular parameters

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Stadistical data analysis, bioequivalence studies, dose linearity, interaction and dose-finding studies

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence	15	8	8	7	7	7
First single-dose administration in humans	1					
First multiple-dose administration in humans						
Drug interaction						
Food interaction						1
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)					1	1
Own research lines			1	2	3	3
Others (specificying)						

Number of trials linked to a PEI (IND) submission	2009	2010	2011	2012	2013	2014

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 40 Number of trials promoted by multinational companies 14

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 10

Number of Early Stages trials performed in the Unit and published in the last 4 years 8

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Experience Published trials

López-RodrIguez R, Cabaleiro T, Ochoa D, Román M, Borobia AM, Carcas AJ, Ayuso C, Novalbos J, Abad-Santos F. Pharmacodynamic genetic variants related to antipsychotic adverse reactions in healthy volunteers. Pharmacogenomics. 2013 Jul;14(10):1203-14. doi: 10.2217/pgs.13.106. Factor de Impacto: 3.857 (Q1)

RamIrez E, Abraira V, Guerra P, Borobia AM, Duque B, López JL, Mosquera B, Lubomirov R, Carcas AJ, FrIas J. A preliminary model to avoid the overestimation of sample size in bioequivalence studies. Drug Res (Stuttg). 2013 Feb;63(2):98-103. doi: 10.1055/s-0032-1333296

Borobia AM, Lubomirov R, RamIrez E, Lorenzo A, Campos A, Muñoz-Romo R, Fernández-Capitán C, FrIas J,Carcas AJ. An acenocoumarol dosing algorithm using Clínical and pharmacogenetic data in spanish patients with thromboembolic disease. PLoS One. 2012;7(7):e41360. Epub 2012 Jul 20. Factor de Impacto: 4.092 (Q1)

Carcas AJ, Borobia AM, Velasco M, Abad-Santos F, DIaz MQ, Fernández-Capitán C, Ruiz-Giménez N, Madridano O, Sillero PL; PGX-ACE Spanish Investigators Group. Efficiency and effectiveness of the use of an acenocoumarol pharmacogenetic dosing algorithm versus usual care in patients with venous thromboembolic disease initiating oral anticoagulation: study protocol for a randomized controlled trial. Trials. 2012 Dec 13;13:239. doi: 10.1186/1745-6215-13-239. Factor de impacto: 2.5 (Q2)

Ramirez E, Laosa P, Guerra P, Duque B, Mosquera B, Borobia AM, Lei SH, Carcas AJ, Frias J. Acceptability and characteristics of 124 human bioequivalence studies with active Substances classified according to BCS. Br J Clin Pharmacol. 2010 Nov;70(5):694-702. Factor de Impacto: 2.958 (Q2)

S. Fudio; A.M. Borobia; E. Piñana; E. RamIrez; B. Tabarés; P. Guerra; A.J. Carcas; J. FrIas. Evaluation of the influence of sex and cyp2c19 and cyp2d6 polymorphisms in the Disposition of citalopram Eur J Pharmacol. 2010 Jan 25;626(2-3):200-4. Factor de Impacto: 2.516 (Q2)

Borobia AM, Novalbos J, Guerra-López P, López-RodrIguez R, Tabares B, RodrIguez B, Abad-Santos F, Carcas AJ. Influence of sex and cyp2d6 genotype on mirtazapine disposition, evaluated in spanish healthy volunteers. Pharmacological Research. 2009 Jun;59(6):393-8 Factor de Impacto: 4.436 (Q1)

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Experience Published trials

L. Alonso, G. Nuno-Almeida, A. Campos, L. Hierro, L. Espinosa, P. Jara, A. Alonso-Melgar, M. García-Mesequer, HY Tong, E. RamIrez, AJ. Carcas. A limited sampling strategy (LSS) for tacrolimus monitoring after Advagraf administration in children with stable renal and liver transplantation. Basic & Clínical Pharmacology & Toxicology, 109(3). Impact Factor: 2.371 (Q3).

A. Campos, L. Espinosa, N. Medrano, A. Alonso Melgar, L. Alonso, G. Nino-Almeida, HY Tong, E. RamIrez, J. FrIas Iniesta, AJ Carcas-Sansuán. Relative bioavailability of two tacrolimus formulations: Prograf (normal release) in children with kidney transplant. Basic & Clínical Pharmacology & Toxicology 2011;109(Suppl.3):33. Impact Factor: 2.371 (Q3).

Carcas-Sansuán AJ, Hierro L, Almeida-Paulo G, Frauca E, Tong HY, DIaz C, Piñana-Efire E, FrIas J, Jara P. Conversion from Prograf to Advagraf in adolescents with stable liver transplants: comparative pharmacokinetics and one-year follow-up. Liver Transplantation. Impact Factor: 3.944 (Q1).

Unidad de Ensayos Clínicos Facultad de Medicina Universidad Autónoma de Madrid

Annexes Photos of the Unit

OUTDOOR VIEW OF THE UNIT

HOSPITALIZATION AREA

SAMPLES MANAGEMENT AREA

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

General Information

Who filled in this survey	Francisco Abad Santos, Dolores Ochoa MAzarro, Manuel nRomán Martínez.
E-mail contact (Phone number)	investigacionclinica.hlpr@salud.madrid.org (+34 915202247)
Date of survey filling in	May 2015
Unit web address	http://www.iis-princesa.org/es/plataformas-de-apoyo/u-ensayos-clinicos.html http://www.madrid.org/cs/Satellite?c=Page&cid=1142400434778&pagename=HospitalLaPrincesa%2FPage%2FHPRI_contenidoFinal
Formal name of the unit	Clinical Trial Unit of Hospital Universitario de La Princesa (UECHUP)
Postal address	Hospital Universitario de La Princesa. Calle Diego de León 62, 7ª Planta, 28006, Madrid, Spain

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Location

Calle Diego de León 62, 7ª Planta, 28006, Madrid, Spain

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Ownership

Ownership	Instituto de Investigación Sanitaria del Hospital Universitario de La Princesa.
Established	1997
Linked hospital	Hospital Universitario de La Princesa
Distance between linked hospital and Unit	It is inside a hospital.
Linked Ethics Committee (CEIC)	CEIC of Hospital Universitario de La Princesa

Unit Manager

First and last names	Francisco Abad-Santos
Qualifications	Medical Doctor, PhD
Medical specialty	Clinical Pharmacologist
Manager since	1997
E-mail and phone	francisco.abad@salud.madrid.org +34 915202247

Short CV

Professional activity: current positions

Medical especialist on Clinical Pharmacology Service of Hospital Universitario de la Princesa since March 1995. Section chief since 2011
Associate Professor of Pharmacology Department, Universidad Autónoma de Madrid since 2000-2001.
Ethics Committee President of Hospital Universitario de la Princesa.
Group leader of Instituto de Investigación Sanitaria del Hospital Universitario de La Princesa.

Experience in Clinical Research

Clinical Trial experience: phase I trials with healthy volunteers and patients (pharmacodynamics, pharmacokinetics, dose finding, bioequivalence) and phase II and III trials in colaboration with other services of Hospital (digestive, oncology, dermatology, psiquiatry, radiotherapy, endocrinology, hematology….)
Extensive knowledge on Good Clinical Practice
Line of investigation: Pharmacogenetics.

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

Comunidad de Madrid, Servicio de Control Farmacéutico y Productos Sanitarios.

24th January 2014. Accreditation of Good Clinical Practices for period 2014-2018.

Audits by regulatory agencies (last 3 years) Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) 10, 11 and 13 of April 2012

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **Yes**

Audits by sponsors (last 3 years)

1 audit in 2012, 2 audits in 2013 and 1 audit in 2014.

Do you follow your own Standard Operating Procedures (SOPs)? YES Do you supply with a SOP copy to a sponsor if requested? YES

Would you follow the sponsor SOPs if requested: Yes, but always that SOPs follow the GCPs and European and Spanish legislation.

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: Around three

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

The quality policy of UECHUP is conducting clinical trials in strict accordance with the study protocol and all its processes comply with all current legislation and the Guidelines for Good Clinical Practice.

Healthy subjects and patients admitted to our unit are constantly monitored by a video surveillance system; at any time in the unit, there is a nurse, a doctor and a member of the Clinical Pharmacology Service properly trained in Life Support. In addition, the UECHUP has the necessary means to monitor a patient and / or volunteer in an emergency. As the UECHUP is fully integrated within the hospital, it is also included within the system of the hospital emergency.

All data are archived in our department, on paper or in electronic format. The data are included in a database which follows the Law 15/1999 on Protection of Personal Data and it is registered in the Data Protection Agency (Clinic Research File of the University Hospital of La Princesa). The members of the Clinical Pharmacology Service are required to maintain the confidentiality of the information. Data may be accessed by a representative of sponsor and / or public health authorities. The information sent to the sponsor is coded for anonymity. The identity of subjects is not revealed if the study results are published.

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Facilities

Year of Unit building	1955	Last Unit reform	2010
Usable space	193	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	2	Number of beds	14
Beds distribution	Two rooms with 6 beds and two rooms with an individual bed		
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	1	Number of armchairs suitable for subject monitoring	1
Owned kitchen	No	Meals supervision by dietitian	Yes
Dining-room available for volunteers	No	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Intensive Care Unit (ICU), Anestesiology and Resuscitation Service and Emergency Service of Hospital Universitario de La Princesa		
Distance and time to get the former services	ICU: One floor (<5 min). Anestesiology and Resuscitation Service: in front of UECHUP (<1 min). Emergency service: 8 floors (<8 min)		
Unit entrance/Exit door controlled	Yes	Unit with Closed Circuit Television	Yes
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Facilities

Unit distribution plan:

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Staffing and Resources

Unit employees

Permanent staff 5 Fixed-term/contracted staff (internship, grant holders) 7 Part-time collaborators 45

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	2	
Co-investigator (physician)		26
Nurse		25
Monitor or CRA	1	1
Pharmacist	1	
Biometry		
Data management	2	1
Medical writing		1
Pharmacokinetics	3	
Quality assurance	1	
Project Management	2	
Finance	1	
Recruitment	5	7
IT (informatics)		
Other (specify): Secretary	1	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

1 Physician **1 or 2** Nurse

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	No
The quality assurance activities are subcontracted by the Unit	No
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	Yes
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Two members of UECHUP **Preparation**: One member of UECHUP and One member of Quality Control Assurance of UECHUP
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes

System or procedure used for samples identification

The plasma samples are labelled with the protocol code, subject number, period and extraction time.

Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes
Number of centrifuges available	2 with temperature control and 1 without temperature control
System for plasma/fluids samples storing	Describes on SOP (UECHUP/PNT-11)
Fridges and freezers available in the Unit	1 fridge and 5 freezers (3 of them of -70ºC)
The Unit has its owned Bioanalytical Department	No, this activity is subcontract by sponsor
Availability of genotyping or fenotyping methods for participants	Yes (CYP2D6, CYP2C9, CYP2C19, CYP2C8, TPMT, HLAB*5701, DPYD, IL23, IL28, TNFα.).

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Services Capabilities

Data Management and software used (describe)	Excel, Acces and eCRF elaborated by Xolomon
Biometry or Statistical Analysis and software used (describe)	SPSS
Pharmacokinetic Analysis and software used (describe)	Winonlin 6.3
Medical Writing and skilled languages	English and Spanish
Owned archives in the same Unit building (describe)	Yes

Capacity for more than 60 clinical trials

Access control of inputs and outputs file. Located in a room with fire detection system

Note: When the archives are completed, the older studies are sended to external archive (ADEA). This archive is provided by Fundación de Investigación Biomédica del Hospital de La Princesa

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

All the essentials documents of study and all study records are archive beetwen 10 and 15 years according legislation and sponsor procedures

The study files are digitized and converted in a CD or web format	Yes
Project management	Yes

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Study Participants

Kind of participants included in clinical trials performed in the Unit

Yes	Healthy volunteers	Yes	Patients
Yes	Other populations	Patients with hepatic or renal impairment. Elderly population and postmenopausal women	

If the Unit has experience in oncology, detail kind of tumour and age groups

Yes	Solid tumour	Yes	Haematological tumour	Yes	Adults	No	Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Leukemias, lymphomas, multiple myeloma, breast, lung, colorectal, urological, prostate

Recruiting methods for healthy volunteers

The existence of the clinical trial is not published in any media. It simply reports the start of the briefing via twitter at the following address:

@UEC_Princesa

Recruting methods for patients

The investigators makes a screening of the stories and looking for potentially eligible patients in a study according to the inclusion and exclusion criteria of the protocol.

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	Yes (3)
Do you keep a paper or electronic database of volunteers? (describe)	Yes

Name, age, sex, direction, DNI and study participation history

Have you implemented any measure for avoiding the over-volunteering? (describe)	Yes

We registrated in own database and we ask them about their participation in other studies.

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	Yes (4)	Pulsioximetry devices (number)	Yes (1)	12-leads ECG devices (number)	Yes (3)

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	No
Availability in the Unit of tests for assessing CNS drug effects	No (in these studies we colaborete with other service of hospital such as psychiatry and neurology)
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	Yes, 3 studies performed on 1997, 2000 and 2003
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes, 10 on the last 3 years
Experience in other kind of PD or PK evaluations not formerly collected	
Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted	

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence	6	5	9	12	20	14
First single-dose administration in humans	1					1
First multiple-dose administration in humans						
Drug interaction						
Food interaction			1			
Special populations (Renal or liver impairment, elderly)					1	1
Proof of concept (Phase Ib or I/II)						
Own research lines			1	1		
Others (specificying) Phases II, III and IV	8	10	15	20	20	22

Number of trials linked to a PEI (IND) submission | 2009 | 8 | 2010 | 10 | 2011 | 15 | 2012 | 20 | 2013 | 20 | 2014 | 22

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Anti-inflammatory drugs, proton-pump inhibitors, iron salts, bisphosphonates, calcium, calcium channel blockers, angiotensin receptor antagonists, vasoconstrictors, diuretics, heparins, hypolipidemic, antipsychotics, selective inhibitors of serotonin reuptake, 5-alpha-reductase inhibitors, estrogen, gout drugs, beta-lactam antibiotics, mucolytics, antiasthmatic, vaccines, cholinesterase inhibitors, functional foods

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 66 Number of trials promoted by multinational companies 22

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 30 days

Number of Early Stages trials performed in the Unit and published in the last 6 years 5

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Experience

Published trials

International journals

- Peiró AM, Novalbos J, Zapater P, Moreu R, López-RodrIguez R, RodrIguez V, Abad-Santos F, Horga JF. Pharmacogenetic relevance of cytochrome the P450 2C9*3 isophorm in a tenoxicam bioequivalence study performed in Spaniard. Pharmacol Res 2009: 59: 62-68.
- Borobia AM, Novalbos J, Guerra-López P, López-RodrIguez R, Tabarés B, RodrIguez V, Abad-Santos F, Carcas AJ. Influence of sex and CYP2D6 genotype on mirtazapine disposition, evaluated in Spanish healthy volunteers. Pharmacol Res 2009 Jun; 59(6):393-8.
- Novalbos J, López-RodrIguez R, Roman R, Gallego-SandIn S, Ochoa D, Abad-Santos F. Effects of CYP2D6 genotype on the pharmacokinetics and safety of risperidone in healthy volunteers. J Clin Psychopharmacol 2010 Oct; 30 (5):504-11.
- Almoguera B, Riveiro-Alvarez R, Gomez-Dominguez B, Lopez-Rodriguez R, Dorado P, Vaquero-Lorenzo C, Dal-Ré R, Fernandez-Piqueras J, Llerena A, Abad-Santos F, Ayuso C, & Spanish Consortium of Pharmacogenetics Research in Schizophrenia. Evaluating a newly developed pharmacogenetic array: screening in a Spanish population. Pharmacogenomics. 2010 Nov;11(11):1619-25.
- Almoguera B, Riveiro-Alvarez R, Lopez-Castroman J, Dorado P, Lopez-Rodriguez R, Fernandez-Navarro P, Baca-García E, Fernandez-Piqueras J, Dal-Ré J, Abad-Santos F, LLerena A, Ayuso C. ATA homozigosity in the IL-10 gene promoter is a risk factor for schizophrenia in Spanish females: a case control study. BMC Medical Genetics 2011 Jun 9;12:81.
- Lopez-Rodriguez R, Roman M, Novalbos J, Pelegrina ML, Ochoa D, Abad-Santos F. DRD2 Taq1A Polymorphism Modulates Prolactin Secretion Induced by Atypical Antipsychotics in Healthy Volunteers. J Clin Psychopharmacol. 2011 Oct;31(5):555-62.
- Lopez-Rodriguez R, Trapero-Marugan M, Borque MJ, Roman M, Hernandez-Bartolome A, Rodriguez-Muñoz Y, Martin-Vilchez S, Abad-Santos F, Muñoz de Rueda P, Vidal-Castiñeira JR, Rodrigo L, Salmeron J, Moreno-Otero R, Sanz-Cameno P. Genetic Variants of Interferon-Stimulated Genes and IL-28B as Host Prognostic Factors of Response to Combination Treatment for Chronic Hepatitis C. Clin Pharmacol Ther. 2011 Nov;90(5):712-21.
- Almoguera B, Riveiro-Alvarez R, Lopez-Castroman J, Dorado P, Vaquero-Lorenzo C, Fernandez-Piqueras J, Llerena A, Abad-Santos F, Baca-García E, Dal-Ré R, Ayuso C. Association of common genetic variants with risperidone adverse events in a Spanish schizophrenic population. Pharmacogenomics J. 2013 Apr;13(2):197-204.

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Experience

Published trials

International journals (cont.)

- González-Vacarezza N, Abad-Santos F, Carcas-Sansuan A, Dorado P, Peñas-LLedó E, Estévez-Carrizo F, LLerena A. Use of Pharmacogenetics in bioequivalence studies to reduce sample size: An example with mirtazapine and CYP2D6. Pharmacogenomics J. 2013 Oct;13(5):452-5.
- Cabaleiro, T., Roman, M., Ochoa, D., Talegon, M., Prieto-Perez, R., Wojnicz, A., Lopez-Rodriguez, R., Novalbos, J., Abad-Santos, F. Evaluation of the relationship between gender, polymorphisms in CYP2C8 and CYP2C9, and pharmacokinetics of angiotensin receptor blockers. Drug Metab Dispos. 2013 Jan;41(1):224-9.
- Cabaleiro T, López-RodrIguez R, Ochoa D, Román M, Novalbos J, Abad-Santos F. Polymorphisms influencing olanzapine metabolism and adverse effects in healthy subjects. Hum Psychopharmacol. 2013;28(3):205-214. PMID: 23559402.
- Almoguera B; Riveiro Álvarez R; López Castroman J; Dorado P; Vaquero Lorenzo C; Fernández Piqueras J; Llerena A; Abad Santos F; Baca García E; Dal-Ré R; Ayuso C; Spanish Consortium of Pharmacogenetics Research in Schizophrenia. CYP2D6 poor metabolizer status might be associated with better response to risperidone treatment. Pharmacogenet Genomics. 2013;23(11):627-630.
- Wojnicz A, Cabaleiro-Ocampo T, Román-MartInez M, Ochoa-Mazarro D, Abad-Santos F, Ruiz-Nuño A. A simple assay for the simultaneous determination of human plasma albendazole and albendazole sulfoxide levels by high performance liquid chromatography in tandem mass spectrometry with solid-phase extraction. Clin Chim Acta. 2013 Nov 15;426:58-63. PMID: 24008168.
- Prieto-Pérez R, Ochoa D, Cabaleiro T, Román M, Sánchez-Rojas SD, Talegón M, Abad-Santos F. Evaluation of the relationship between polymorphisms in CYP2C8 and CYP2C9 and the pharmacokinetics of celecoxib. J Clin Pharmacol. 2013 Dec;53(12):1261-7. PMID: 23996211.
- López-RodrIguez R, Cabaleiro T, Ochoa D, Román M, Borobia AM, Carcas AJ, Ayuso C, Novalbos J, Abad-Santos F. Pharmacodynamic genetic variants related to antipsychotic adverse reactions in healthy volunteers. Pharmacogenomics. 2013 Jul;14(10):1203-14. PMID: 23859574.
- Román M; Ochoa D; Sánchez-Rojas SD; Talegón M; Prieto-Pérez R; Rivas A; Abad-Santos F; Cabaleiro T. Evaluation of the relationship between polymorphisms in CYP2C19 and the pharmacokinetics of omeprazole, pantoprazole, and rabeprazole. Pharmacogenomics. 2014;15(15):1893-1901.

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Experience

Published trials

National journals

- Novalbos J, López-RodrIguez R, Román M, Gallego-SandIn S, Ochoa D, Abad Santos F. Efecto del genotipo de CYP2D6 en la farmacocinética, farmacodinamia y seguridad de la risperidona en voluntarios sanos. Prescr Fárm 2010; 16 (4): 54-5.
- Abad-Santos, F. Bioequivalencia de los genéricos. Actualidad en Farmacología y Terapéutica 2014;12: 152-158.

Oral communications

- Ochoa D, Román M, Novalbos J, Abad Santos F. "Efectos farmacodinámicos y seguridad de fármacos cardiovasculares en dosis única en voluntarios sanos". En XVIII Reunión de Farmacologos de la Comunidad de Madrid, 10 de julio de 2009.
- .Abad-Santos F; Ochoa D; Prieto-Pérez R; Román M; Talegón M; Rivas A; Cabaleiro T. Effect of CYP2C9 and CYP2C8 polymorphisms on pharmacokinetics of ibuprofen enantiomers. XXXV Congreso de la Sociedad Española de Farmacología. Madrid, 24-26 September 2014.

Posters

- López-RodrIguez R, Román M, Ochoa D, Novalbos J, Abad Santos F. "Taq1A DRD2 polymorphism and sex modulate prolactine secretion alter a single dose of risperidone, olanzapine or quetiapine in healthy volunteers". En XXII Congreso de la Sociedad Española de Farmacología Clínica; Badajoz, 13-16 de octubre 2009.
- Gómez-DomInguez B, Novalbos J, Almoguera B, Riveiro-Alvarez R, Abad Santos F, Villaverde-Montero C, Trujillo-Tiebas MJ, Dorado P, Baca E, Llerena A, Ayuso C. "Evaluation of a genotyping chip predictive of drug response". En XXII Congreso de la Sociedad Española de Farmacología Clínica; Badajoz, 13-16 de octubre 2009.
- Riveiro-Alvarez R, Gómez-DomInguez B, Almoguera B, Abad Santos F, Villaverde-Montero C, Trujillo-Tiebas MJ, López-Castroman J, Baca-Garcia E, Dorado P, Llerena A, Ayuso C. "Evaluating a genotyping array predictive of drug response: preliminary results in Spanish schizophrenic patients in relation to adverse effects". En XXII Congreso de la Sociedad Española de Farmacología Clínica; Badajoz, 13-16 de octubre 2009.

Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Experience

Published trials

Posters (cont)

- Román M, Cabaleiro T, Ochoa D, Talegon M, Abad-Santos F. Predicción del sIndorem de Gilbert mediante polimorfismo de UGT1A1*28. En XIV Congreso de Nacional de la Asociación Española de Técnicos de Laboratorio. Granada, 27-28 de mayo de 2011.
- Ochoa-Mazarro D, Román M, López-RodrIguez R, Abad-Santos F, Ayuso C, Cabaleiro T. Asociación de variantes genéticas con reacciones adversas por olanzapina. En V Congreso de la Sociedad Española de Farmacogenética y Farmacogenómica; Pamplona, 3-4 de octubre de 2011.
- Almoguera Castillo B, Riveiro Alvarez R, López Castromán J, Dorado P, Fernández Piqueras J, Llerena A, Abad-Santos F, Baca García E, Dal-Ré R, Ayuso García C. Mayor eficacia en el tratamiento antipsicótico con risperidona en metabolizadotes lentos de CYP2D6. En V Congreso de la Sociedad Española de Farmacogenética y Farmacogenómica; Pamplona, 3-4 de octubre de 2011.
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- Moreno-Arza, MI, Román-MartInez M, Ochoa-Mazarro D, Sánchez-Rojas SD, Pérez-Campa C, Sánchez-Hernández A, Abad-Santos F. Crossover randomized bioequivalence Clínical trial of two formulations of digoxin 0.25 mg tablets after a single dose administration to healthy volunteers. En XXIV Congreso de la Sociedad Española de Farmacología Clínica; Málaga, 5-7 de octubre de 2011. Publicado en: Basic & Clínical Pharmacology & Toxicology 2011; 109 (suppl 3): 42.
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Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Experience

Published trials

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- Moreno Arza I, Román MartInez M, Ochoa Mazarro D, Abad Santos F. Efecto del truncado del área bajo la curva sobre la evaluación de la bioequivalencia en fármacos de vida media larga. En XXI Reunión de Farmacólogos de la Comunidad de Madrid (FARMADRID 2012; Madrid, Julio de 2012).
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Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Experience

Published trials

Posters (cont)

- Tello-Miller AM, Sánchez-Rojas SD, Ochoa-Mazarro D, Román-MartInez M., Moreno-Arza I, Marrodán-RemIrez I, Abad-Santos F. Absorción de desloratadina 5 mg comprimidos vs comprimidos bucodispersables. En XXV congreso de la SEFC; Alicante, 7-29 de septiembre de 2012.
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Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Experience

Published trials

Posters (cont)

- Belmonte C; Román M; Cabaleiro T; Valdez S; Prieto-Pérez R; Talegón M; Abad-Santos F, Ochoa D. Asociación de polimorfismos en receptores dopaminérgicos y serotoninérgicos con reacciones adversas por aripiprazol en voluntarios sanos. XXIII FARMADRID Reunión de Farmacólogos de la Comunidad de Madrid. Madrid, July 3, 2014.
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Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Experience

Published trials

Posters (cont)

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Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Experience

Published trials

Posters (cont)

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Unidad de Ensayos Clínicos del Hospital Universitario de la Princesa UECHUP

Annexes

Brochure not available in English

Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

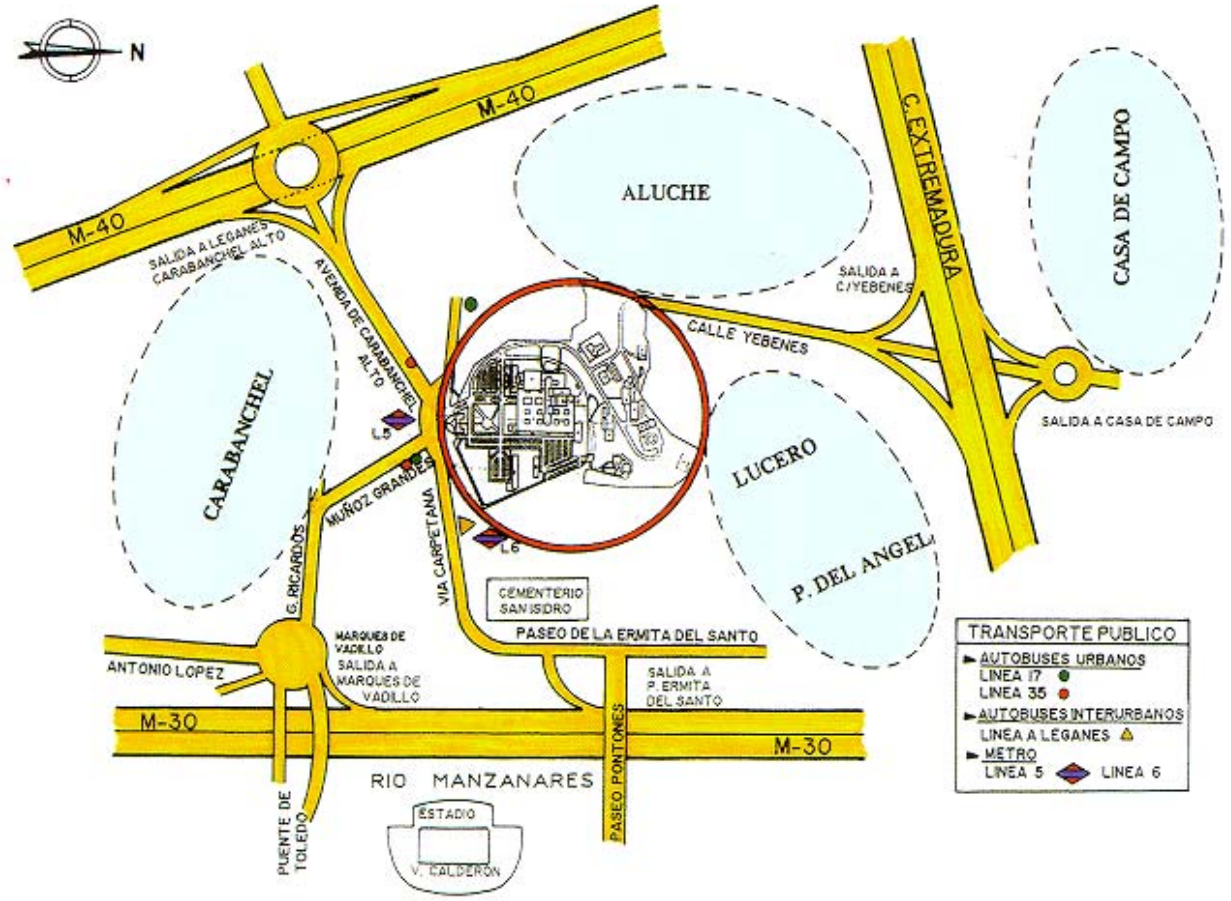
Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

General Information

Who filled in this survey	Miguel Puerro Vicente / Amelia García Luque
E-mail contact (Phone number)	mpuevi1@oc.mde.es (91 422 21 86) agarluq@oc.mde.es (91 422 21 86)
Date of survey filling in	25/05/2015
Unit web address	No
Formal name of the unit	Clinical Trial Unit. Clinical Pharmacology Service
Postal address	Hospital Central de la Defensa "Gómez Ulla" Glorieta del Ejército, 1 28047 Madrid. Spain

Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

Location



Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

Ownership

Ownership	Public. Ministry of Defense.
Established	2002
Linked hospital	Hospital Central de la Defensa "Gómez Ulla"
Distance between linked hospital and Unit	Inside the hospital
Linked Ethics Committee (CEIC)	CEIC del Hospital Central de la Defensa

Unit Manager

First and last names	Miguel Puerro Vicente
Qualifications	Doctor
Medical specialty	Clinical Pharmacology
Manager since	2002
E-mail and phone	mpuevi1@oc.mde.es 91 422 81 86

Short CV

ACADEMIC QUALIFICATIONS:
Bachelor of Medicine and Surgery. Universidad Complutense de Madrid.
Specialist in Clinical Pharmacology.
Doctor of Pharmacology and Special Prize in the section "Fundamental"
PROFESSIONAL EXPERIENCE:
Chief of Clinical Pharmacology, Central Hospital of Defense.
Medical Resident (Clinical Pharmacology) Hospital Clínico San Carlos
TEACHING EXPERIENCE AND RESEARCH:
Associate Professor of Pharmacology, Faculty of Medicine at the Alcalá University of Madrid. 2012 –at the present.
Professor of Pharmacology, Faculty of Medicine of the Universidad San Pablo CEU. 2004-2011.
Associate Professor of Pharmacology, Faculty of Medicine at the Complutense University of Madrid. 1989 -2003.
Director and co-head of 23 doctoral courses.
Participation as a researcher in 22 clinical trials (17 as principal investigator)
Participation as a researcher in 13 research projects funded by official agencies
President of the Research Committee of the Central Hospital of Defense.
Books and publications in national and international magazines

Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

Yes

Audits by regulatory agencies (last 3 years)

No

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? Yes

Audits by sponsors (last 3 years) No

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? No

Would you follow the sponsor SOPs if requested: Usually it is working with a sum of SOPs (own + promoter)

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 1

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

PNT - 15: Process safety analysis.

PNT - 18: Handling Procedures and file.

Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

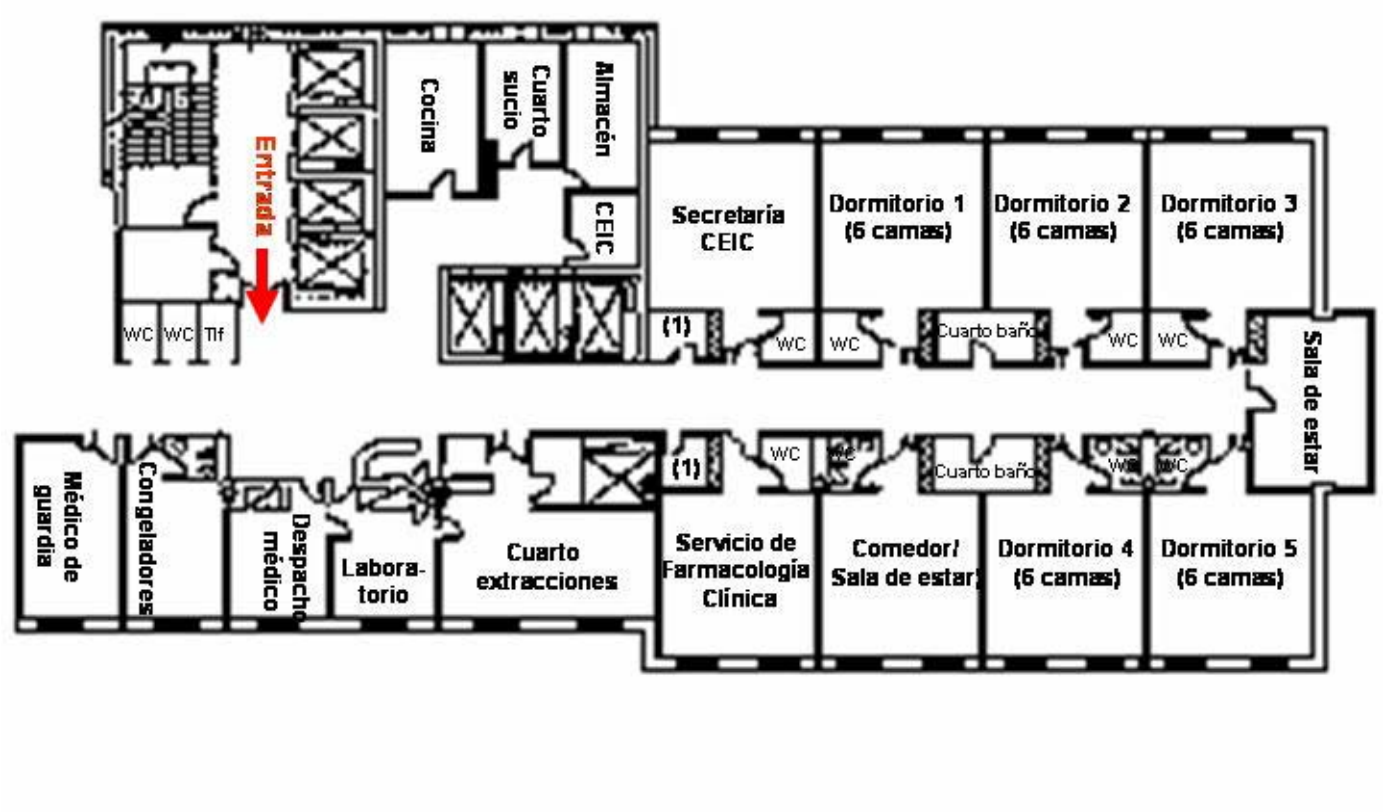
Facilities

Year of Unit building	1973	Last Unit reform	2015
Usable space	600 m^2	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	2	Number of beds	24
Beds distribution	4 bedrooms with 6 beds		
Beds distribution allows a complete and continuous visual control by nurses			No
Number of bed with intensive or continuous monitoring	2	Number of armchairs suitable for subject monitoring	0
Owned kitchen	Yes	Meals supervision by dietitian	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	ICU and Emergency Hospital		
Distance and time to get the former services	Inside the hospital. Few minutes.		
Unit entrance/Exit door controlled	No	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

Facilities

Unit distribution plan



Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

Staffing and Resources

Unit employees

Permanent staff Fixed-term/contracted staff (internship, grant holders) Part-time collaborators

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	1	8 medical staff
Nurse		10
Monitor or CRA		1
Pharmacist		1
Biometry		
Data management		1
Medical writing		1
Pharmacokinetics		1
Quality assurance		1
Project Management		1
Finance		
Recruitment		1
IT (informatics)		
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician X Nurse

Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	No
The quality assurance activities are subcontracted by the Unit	Yes
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	No
Laminar flow chamber availability for preparation of parenteral treatments	No
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Physician (Dr. Garcia Luque) **Preparation**: Physician (Dr. Garcia Luque)
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification	

Labels with the code of the study and number of volunteer figure below, followed by number indicating the period, followed by the time of extraction

Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes
Number of centrifuges available	2
System for plasma/fluids samples storing	6 freezers at -30º and 2 at -80º
Fridges and freezers available in the Unit	6 freezers at -30º and 2 at -80º
The Unit has its owned Bioanalytical Department	No
Availability of genotyping or fenotyping methods for participants	No

Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

Services Capabilities

Data Management and software used (describe)	Microsoft Access
Biometry or Statistical Analysis and software used (describe)	WinNolin Professional Edition version 2.0 (Scientific Consulting, Inc, Cary USA)
Pharmacokinetic Analysis and software used (describe)	WinNolin Professional Edition version 2.0 (Scientific Consulting, Inc, Cary USA)
Medical Writing and skilled languages	Spanish and English
Owned archives in the same Unit building (describe)	Yes

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

The entire file of the investigator and CRDs is saved during 15 years

The study files are digitized and converted in a CD or web format	No
Project management	No

Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers	Yes	Patients	Yes
Other populations	No		

If the Unit has experience in oncology, detail kind of tumour and age groups

No	Solid tumour	No	Haematological tumour	Yes	Adults	No	Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Recruiting methods for healthy volunteers

Phoning and social networks volunteers

Recruting methods for patients

Phoning and social networks volunteers

Do you have sugery rooms available for screening (separated from the in-house area)? (number) Yes 2 rooms

Do you keep a paper or electronic database of volunteers? (describe)

Name, phone number (s), date of birth, sex, participation in previous trials

Have you implemented any measure for avoiding the over-volunteering? (describe) No

Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

Pharmacodynamic / Pharmacokinetic Capabilities

Digital blood pressure devices (number)	2	Pulsioximetry devices (number)	2	12-leads ECG devices (number)	2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Yes
Availability in the Unit of tests for assessing CNS drug effects	No
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	Yes
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes
Experience in other kind of PD or PK evaluations not formerly collected	No

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

No

Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						5
First single-dose administration in humans						
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)						
Own research lines						1
Others (specificying)						

Number of trials linked to a PEI (IND) submission | 2009 | 0 | 2010 | 0 | 2011 | 0 | 2012 | 0 | 2013 | 0 | 2014 | 0

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

NSAID, Calcio antagonist, antipsychotics, phosphodiesterase inhibitors

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 2 Number of trials promoted by multinational companies 3

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 30

Number of Early Stages trials performed in the Unit and published in the last 4 years 0

Unidad de Ensayos Clínicos del Hospital Central de la Defensa Gómez Ulla

Annexes Brochure

Hospital Central de la Defensa
"Gómez Ulla"

UNIDAD DE ENSAYOS CLÍNICOS

SERVICIO DE FARMACOLOGÍA CLÍNICA.

The Clinical Trials Unit, belonging to the Clinical Pharmacology Department, is located in the Gate B of the 9th floor of the central tower at the Hospital Central de la Defensa.

C/ Glorieta del Ejército, s/n 28047 Madrid (Spain)
Teléfono: +34 91 4228186
Fax: +34 91 4228203
E-mail: igaliciadepedro@ctv.es, mpuerrov@hotmail.com

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study Participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

General Information

Who filled in this survey	Antonio Portolés
E-mail contact (Phone number)	antonio.portoles@salud.madrid.org (+34 913303413)
Date of survey filling in	15/07/2015
Formal name of the unit	
Postal address	Servicio de Farmacología Clínica Hospital Clínico San Carlos C/ Prof. Martín Lagos s/n 28040 Madrid

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Location

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Ownership

Ownership	Hospital Clínico San Carlos
Established	1998
Linked hospital	Hospital Clínico San Carlos
Distance between linked hospital and Unit	Into Hospital Clínico San carlos
Linked Ethics Committee (CEIC)	CEIC - Hospital Clínico San Carlos

Unit Manager

First and last names	Dr. Antonio Portolés
Qualifications	MD, PhD, Clinical Pharmacologist
Medical specialty	Clinical Pharmacology
Manager since	1998
E-mail and phone	Antonio.portoles@salud.madrid.org (+34 913303413)

Short CV

Qualifications
MD, PhD
Specialised in Clinical Pharmacology
Design and statistics in Health Sciences
Health Institutions Managing
Quality assurance managing

Experience
Head of Section Clinical Pharmacology
Wide experience in design, evaluation, and developement of clinical research.
Development of all phases Clinical Trials, specially Phase I

Teaching and Investigation Experience
UCM lecturer.
High number of scientific publications and communications

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

Agencia de Vigilancia Sanitaria Brasileña (ANVISA): Bioequivalence Centre (2004-2005)
AENOR: Certification ISO9000:1994; 2003-
AENOR: Certification ISO9001:2000; 2006-
AENOR: Certification ISO9001:2008; 2009-
AENOR: Certification ISO9001:2008; 2014-
BPC compliance Acreditation (Government of Madrid) since 2011-

Audits by regulatory agencies (last 3 years)

AEMPyPS, 2014

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **yes**

Audits by sponsors (last 3 years)

2009, 2014

Do you follow your own Standard Operating Procedures (SOPs)? yes Do you supply with a SOP copy to a sponsor if requested? yes

Would you follow the sponsor SOPs if requested: if available

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: yes

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Yes (archaiving, data safety legislation compliance, etc)

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

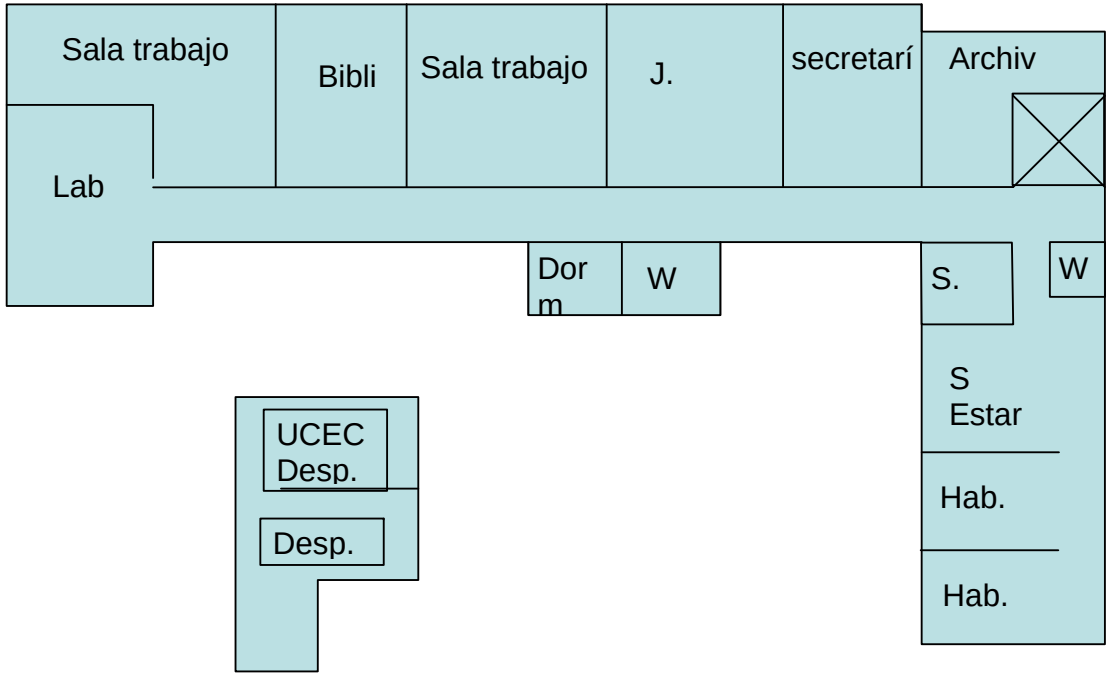
Facilities

Year of Unit building	1962	Last Unit reform	1998
Usable space	350m2	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	Depend on requirements	Number of beds	8
Beds distribution	2 rooms, 4 beds each		
Beds distribution allows a complete and continuous visual control by nurses			Yes (TV)
Number of bed with intensive or continuous monitoring	If needed	Number of armchairs suitable for subject monitoring	6
Owned kitchen	No	Meals supervision by dietitian	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Yes		
Distance and time to get the former services	Few meters		
Unit entrance/Exit door controlled	yes	Unit with Closed Circuit Television	Yes
Availability of an alternate electrical generating set that automatically works in case of a general system failure			No

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Facilities

Unit distribution plan



Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Staffing and Resources

Unit employees

Permanent staff 10 Fixed-term/contracted staff (internship, grant holders) 6 Part-time collaborators 10

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	2	
Co-investigator (physician)	3	4
Nurse	2	10
Monitor or CRA		1
Pharmacist		
Biometry		
Data management	2	1
Medical writing	1	
Pharmacokinetics	2	
Quality assurance	2	+services
Project Management	1	
Finance	1	
Recruitment	1	1
IT (informatics)		
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

x Physician **If needed** Nurse

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	yes
The quality assurance activities are subcontracted by the Unit	no
Availability of a specific area for drug storing and preparation of medications for the study	yes
The former area or room has restricted access by key or code	yes
Laminar flow chamber availability for preparation of parenteral treatments	In the Department of Pharmacy
Perfusion pumps for intravenous treatment	yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Nurse (under medical supervision) **Preparation**: Nurse (under medical supervision)
Drug accountability procedures, such as reception, preparation and dispensing forms	yes
SOPs available for drug preparation and dispensing	No
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification :	
Preprinted labels	
Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	No
Number of centrifuges available	2
System for plasma/fluids samples storing	yes
Fridges and freezers available in the Unit	-20ºC, -80ºC
The Unit has its owned Bioanalytical Department	yes
Availability of genotyping or fenotyping methods for participants	subcontracted

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Services Capabilities

Data Management and software used (describe)	yes
Own software based on Access, Excel, SPSS	
Biometry or Statistical Analysis and software used (describe)	yes
SPSS, WinNonLin (Pharsight)	
Pharmacokinetic Analysis and software used (describe)	yes
WinNonLin (Pharsight)	
Medical Writing and skilled languages	Yes, Spanish, English
Owned archives in the same Unit building (describe)	yes
Restricted access area, compliant with safety and antifire requirements	
Regarding a specific clinical trial what documents are sent to the archives and for long time are archived	
All the documents are long time archived	
The study files are digitized and converted in a CD or web format	partly
Project management	yes

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Study participants

Kind of participants included in clinical trials performed in the Unit

X Healthy volunteers X Patients

X Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour Haematological tumour X Adults Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Specific department, wide experience

Recruiting methods for healthy volunteers

Specific staff for recruitment. Healthy subjects Data Base. Advertising if required.

Recruting methods for patients

Coordination with specific departments as well as advertising if required

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	Yes (1)
Do you keep a paper or electronic database of volunteers? (describe)	Yes

Demographics, clinical history, allergies, etc

Have you implemented any measure for avoiding the over-volunteering? (describe)	Yes

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	Yes (3)	Pulsioximetry devices (number)	Yes	12-leads ECG devices (number)	Yes (2)

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	No
Availability in the Unit of tests for assessing CNS drug effects	Specific
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	Some
Familiarity with Electronic Data Capture –EDC applied to clinical trials	No
Experience in other kind of PD or PK evaluations not formerly collected	Interactions, PK Modelling
Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted	

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence	6	5	6	3	3	3
First single-dose administration in humans						
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)	2		4	6	1	1
Proof of concept (Phase Ib or I/II)					2	1
Own research lines			2		1	1
Others (specificying)						1

Number of trials linked to a PEI (IND) submission | 2009 | 1 | 2010 | 0 | 2011 | 4 | 2012 | 2 | 2013 | 2 | 2014 | 2

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Antidepressants, analgesics, monoclonal antibodies, antihypertensive, antitumour chemotherapy, antibiotics

Sponsor typology for Early Stages trials performed in the last 4 years (2003 to 2006)

Number of trials promoted by Spanish companies 25 Number of trials promoted by multinational companies 15

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 2 m

Number of Early Stages trials performed in the Unit and published in the last 4 years

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Experience Scientific publications

Papers

- Portolés A, Vargas E, García M, Terleira A, Rovira M, Caturla MC y Moreno A. Comparative single-dose bioavailability study of two oral formulations of ibuprofen in healthy volunteers.Clin Drug Invest 2001;21(5):383-9
- Portolés A, Vargas E, Burgos A, Moreno E, García M, Terleira A, Caturla MC, Moreno A . Pharmacokinetic Study of a New Ibuprofen 600mg plus Codeine 30mg Combination versus Ibuprofen or Codeine Alone in Single Oral Doses in Healthy Volunteers. Clin Drug Invest 2002;22(1):41-49
- Terleira A, Portolés A. Lisinato de ibuprofeno: una forma rápida de ibuprofeno. JANO sup. 2002
- Vargas E, Terleira A, Hernando F, Pérez E, Cordón C, Moreno A, Portolés A. Effect of adverse drug reactions on length of stay in surgical intensive care units. Crit Care Med 2003;31(3):694-8
- Portolés A, Puerro M, Terleira A, Todríguez A, Caturla MC, Fernandez N, Vargas E. A new High-absorption-rate paracetamol 500 mg formulation: A comparative bioavailability study in healthy volunteers. Curr Ther Res 2003; 64(7):401-11
- Portolés A, Terleira A, Almeida S, García-Arenillas M, Caturla MC, Filipe A, Vargas E. Bioequivalence study of two formulations of Enalapril, at a single oral dose of 20 mg (tablets): a randomized, two-way, open-label, crossover study in healthy volunteers. Curr Ther Res 2004;65(1):34-46
- Portolés A, Almeida S, Terleira A, de Pablo I, Filipe A, Caturla MC, Moreno A. Truncated AUC in the evaluation of fluconazol bioequivalence. ArzneimittelForschung Drug Research. 2004;54(11):752-6. ISSN:0064-4172
- Terleira A, Vargas E, Portolés A. El clopidogrel. Su uso de acuerdo a las guías clínicas. Cardiovascular Risk Factors 2004:13(3):167-175.
- Antonio Portolés, Augusto Filipe, Susana Almeida, Ana Terleira, François Vallée, Alexis Sampedro. Bioequivalence study of two formulations of carvedilol, at a single oral dose of 25mg tablets, in healthy volunteers. ArzneimittelForschung. Drug Res. 2005;55(4):212-17. ISSN:0064-4172
- Susana Almeida, Antonio Portolés, Ana Terleira, et al. Comparative bioavailability/bioequivalence of two sertraline 100 mg tablet formulations. A randomised, 2x2, cross-over, clinical trial in healthy volunteers. ArzneimittelForschung. Drug Res. 2005;55(4):191-7. ISSN:0064-4172
- Revuelta J, Jimenez NV, Portolés A, Lardinois R. A survey of Danish, German and Spanish Ethics Committees Prior to the 2004 Implementation of the European Directive Covering the International Conference of Harmonisation – Good Clinical Practices (ICH-GCP). Int J Pharm Med 2005;19(1):29-36. ISSN: 1364-9027
- Terleira A, Portolés A, Rojas A, Vargas E. Effect of Drug-Test interactions on length of hospital stay Pharmacoepidemiol Drug Safety 2007;16(1):39-45
- Portolés A, Terleira A, Calvo A, Martínez I, Resplandy G. Effect of Hypericum perforatum on Ivabradine pharmacokinetics in healthy volunteers. An open-label, pharmacokinetic interaction clinical trial. Clin Pharmacol Ther 2006;46:1188-1194
- Portolés A, Calvo A, Terleira A, Laredo L, Resplandy G, Gorostiaga C, Moreno A. Lack of pharmacokinetic interaction between omeprazole or lansoprazole and ivabradine in healthy volunteers. An open-label, randomised cross-over, pharmacokinetic interaction clinical trial. Clin Pharmacol Ther 2006;46:1195-1203

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Experience Published trials

Papers (cont.)

- Portolés A, Palau E, Puerro M, Vargas E, Picazo JJ. Health economics assesment study of teicoplanin versus vancomycin in gram-positive infections. Rev Esp Quimioterap, 2006;19(1):65-75
- Montejo AL1, Prieto N1, Terleira A2, Matias J1, Alonso S2, Paniagua G1, Naval S2, Gonzalez Parra D1, Gabriel C3, Mocaër E3, Portolés A2. Better sexual acceptability of agomelatine (25 and 50 mg) compared to paroxetine (20 mg) in healthy male volunteers. An 8-week, placebo controlled study using the PRSexDQ scale. J Psychopharm, 2008
- Portolés A, Prieto E, Calvo A, Laredo L, Fernández N, Vargas E Bioequivalence study on two alendronate formulations, 70 mg tablets, after a single oral dose, in healthy volunteers. ArzneimittelForschung. Drug Res. 2009

Communications in Congresses

- Portolés A, Vargas E, García M, Terleira M, Ruiz de Aguiar S, Gassent C, Cabrera L, Rojas A, Moreno A. Ensayo clínico aleatorizado, cruzado, de biodisponibilidad de dos formulaciones de ibuprofeno, a dosis única (lisinato 1025 mg y base 600 mg), por vía oral, en voluntarios sanos. V Reunión científica de la Sociedad Española del Dolor y Jornada de actualización en Dolor. Granada, 1-2 de marzo de 2001. Publicado en Revista de la Sociedad Española del Dolor 2001;8(I):77
- Puerro M, Rodriguez A, Terleira A, de Pablo I, Sanchez E, Portolés A. Estudio comparativo de farmacocinéticas de dos formulaciones de paracetamol, a dosis única, de 500 mg (comprimidos), por vía oral, en voluntarios sanos. XVIII Congreso Nacional de la Sociedad Española de Farmacología Clínica, Pamplona octubre 2002. Publicado en Revista de Medicina Universidad de Navarra, 2002;5(46):40.
- Pan M, Laredo L, Arroyo R, Portolés A, Vargas E. Utilización de interferón beta en esclerosis múltiple en el Hospital Clínico San Carlos de Madrid. XVIII congreso Nacional de la Sociedad Española de Farmacología Clínica, Pamplona, octubre 2002. Publicado en Revista de Medicina Universidad de Navarra, 2002;5(46):32.
- Portolés A, García-Arenillas M, Terleira A, Almeida S, Vargas E. Bioequivalence study of two Enalapril formulations (20 mg) in healthy volunteers. 6th Congress of the European Association for Clinical Pharmacology and Therapeutics. Istanbul, June 24-28, 2003 In: Tulunay FC & Orme M (Eds) European Collaboration: towards Drug Development and Rational Drug Therapy. Springer-Verlag. Berlin Heidelberg, 2003.
- Terleira A, García-Arenillas M, Martínez T, Plaza ML, Moreno A, y Portolés A. Actividad del Comité Etico de Investigación Clínica del Hospital Clínico San Carlos en los últimos 5 años. Utilidad de una base de datos. XIX congreso de la Sociedad Española de Farmacología Clínica, Santander, Octubre 2004.
- Sampedro A, Terleira A, Almeida S, Cea E, y Portolés A. Estudio de bioequivalencia de dos formulaciones de carvedilol en dosis única (25mg), en voluntarios sanos. XIX congreso de la Sociedad Española de Farmacología Clínica, Santander, Octubre 2004.

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Experience Published trials

Communications in Congresses (cont.)

- Cea E, Laredo L, Martín MC, Pan M, Herraiz MA y Portolés A. Estudio de utilización de atosiban. Resultados de la aplicación de un protocolo de uso. XIX congreso de la Sociedad Española de Farmacología Clínica, Santander, Octubre 2004.
- Colmenares F, Terleira A, Sampedro A y Portolés A. Estudio de utilización de antibióticos de uso restringido. XIX congreso de la Sociedad Española de Farmacología Clínica, Santander, Octubre 2004.
- Calvo A*, Terleira A*, Martínez I**, Lerebours G***, and Portolés A*. Effect of Hypericum perforatum on ivabradine pharmacokinetics in healthy volunteers. 7th Congress of the European Association for Clinical Pharmacology and Therapeutics. Poznan. Polonia. June-2005. In: Basic & Clinical Pharmacology & Toxicology 2005;97(I):44.
- Colmenares F, Terleira A, Sampedro A, Portolés A. Utilization study of restricted prescription antibiotics. 7th Congress of the European Association for Clinical Pharmacology and Therapeutics. Poznan. Polonia. June-2005. In: Basic & Clinical Pharmacology & Toxicology 2005;97(I):81.
- Almeida S, Portolés A, Terleira A, Filipe A, Cea E, Caturla MC. Truncated AUCs in the assessment of sertraline bioequivalence in healthy volunteers. Congreso Bioequivalencia. Barcelona, 2005.
- Portolés, A; Naval, S; Calvo, A; Martín, MC; Fernández, N*. Urinary bioequivalence study on two Alendronate formulations, 70 mg tablets, after single oral doses, in healthy volunteers. XX Congreso de la Sociedad Española de Farmacología Clínica. Tenerife 2006. Publicado en: Basic 6 Clinical Pharmacology & Toxicology. 2006;99(sup I):28-9.
- Terleira A., Cea E., Alonso S., Calvo A., Naval S., De Blas B., Portolés A Study to evaluate the hit rate of two vancomycin dosage adjustment methods (through vs peak-trough) XX Congreso de la Sociedad Española de Farmacología Clínica. Tenerife 2006. Seleccionado para presentación oral. Publicado en: Basic 6 Clinical Pharmacology & Toxicology. 2006;99(sup I):22
- Alonso S, Martín MC, Terleira A, Laredo L, Portolés A. Drug Utilization Study of systemic antifungal agents in the Hospital Clínico San Carlos. XX Congreso de la Sociedad Española de Farmacología Clínica. Tenerife 2006. Publicado en: Basic 6 Clinical Pharmacology & Toxicology. 2006;99(sup I):36
- Alonso S, Terleira A, Rojas A, Prieto E, Almeida S, Portolés A. Bioequivalence study of two bicalutamide formulations, at a single oral dose of 50 mg, in healthy male volunteers. 8th congress of the European Association for Clinical Pharmacology and Therapeutics. Amsterdam 2007. Publicado en: Basic & Clinical Pharmacology and Toxicology 2007;101(s1):140-141
- Alonso S, Terleira A, Rojas A, Prieto E, Portolés A. Bioequivalence study of two formulations of glimepiride, at a single oral dose of 2 mg (tablets), during breakfast in healthy volunteers. 8th congress of the European Association for Clinical Pharmacology and Therapeutics. Amsterdam 2007. Publicado en: Basic & Clinical Pharmacology and Toxicology 2007;101(s1):141
- Montejo AL, Prieto N, Terleira A, Matias J, Alonso S, Paniagua G, Gonzalez Parra D, Portoles A. Better sexual acceptability of agomelatine compared to paroxetine in healthy male volunteers using the PRSexDQ Scale. 20th European College of Neuropsychopharmacology (ECNP) Congress, 13 – 17 October 2007, Vienna, Austria.

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Experience Published trials

Communications in Congresses (cont.)

- Alonso S, Torres A, Terleira A, Laredo L, Martin MC, Portolés A. Adverse events in quetiapine bioequivalence studies. Are they safe?. XXI Congreso Sociedad Española de Farmacología Clínica. Barcelona, octubre 2008.
- Alonso S, Díaz B, Terleira A, García M, Rojas A, Portolés A. Pharmacodynamic effects of irbesartan/hydrochlorothiazide formulations in bioequivalence studies with healthy subjects. XXI Congreso Sociedad Española de Farmacología Clínica. Barcelona, octubre 2008.

Unidad de Estudios de Farmacología Clínica – Hospital Clínico San Carlos

Annexes

Brochure

CLINICAL PHARMACOLOGY STUDY UNIT
DEPARTMENT OF CLINICAL PHARMACOLOGY
HOSPITAL CLÍNICO SAN CARLOS
C/ Prof. Martín Lagos s/n 28040 Madrid
Phone: 00 34 91 3303413
Fax: 00 34 91 3303299
e-mail: aportoles.hcsc@salud.madrid.org
Coordinator: Dr. Antonio Portolés

Location:

The Unit is located in the Hospital Clínico San Carlos, a third-level hospital with 1200 beds, including all medical disciplines. A complete renovation was undertaken recently, which provided the hospital with the most modern facilities and technologies.

The hospital, with a strong research and teaching background, has provided complete support to the Unit since its creation, assisting the Unit and supplying the necessary resources and equipment. Research is essential to the Hospital; with an Independent Ethics Committee that supervises about 200 clinical trials a year, with biweekly meetings, and considered as one of the most efficient committees in Spain.

Facilities:

The Clinical Pharmacology Study Unit is part of the Department of Clinical Pharmacology. Located on the first floor, in direct connexion with Emergencies and the Intensive Care Unit, it offers the maximum safety guarantees for our volunteers.

The Unit comprises about 350 m2, which include laboratory, exploration room, archives, library, meeting room, offices, administrative area and subject's facilities (two rooms with three beds each, living room and dinning room).

Since its creation in 1985, the Clinical Pharmacology Department was certified for 1resident training, and undertook undergraduate and graduate education (including PhD studies and continuing education courses). As health care providers, our activity is part of the National Health system and the Hospital management plan.

The Clinical Pharmacology Study Unit was established in 1998 and since then our clinical research output has expanded rapidly.

Staff:

The Unit provides clinical research support services with experienced faculty and staff which include: 14 physicians (Head of Department, 5 specialists in Clinical Pharmacology and 8 residents in Clinical Pharmacology), 9 nurses (2 complete, 7 partial dedication) and 3 secretaries.

Recent research:

The Clinical Pharmacology department has participated in numerous research projects and has received public (DGF and FISS) and private funding. Fifteen PhD theses have been written over the last years.

Research has basically focused on Pharmacoepidemiology and Pharmacokinetics. More than ten pharmacoepidemiologic studies using advanced methodology, statistics and computing have been performed during the past five years.

The unit has also conducted over 70 clinical trials since 1998; mostly concerning pharmacokinetics, interactions, bioavailability, pharmacokinetic or pharmacodynamic bioequivalence and safety.

The research activity of the Department is completed with pharmacokinetic and drugutilization studies (generally as part of the prescription advising role within the Hospital), methodological counselling in numerous phase II, III and IV clinical trials, elaboration of expert reports or participation in drug evaluation programs.

Study subjects:

Our database is composed of more than 1500 volunteers, which allow us to perform an efficient recruitment in a short period of time.

Quality:

Our unit offers the best quality guarantees. In December 2002 we obtained the ISO9002, later converted to ISO9001/2000, presently certified under ISO9001/2008 rules. In 2004 we obtained the credential as Bioequivalence Centre (Clinical and Statistical Phase) by the National Health Surveillance Agency of Brazil.

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

- General Information
- Ownership
- Accreditations and Audits
- Facilities
- Staffing and Resources
- Services Capabilities
- Study participants
- Pharmacodynamic/Pharmacokinetic Capabilities
- Experience
- Annexes

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

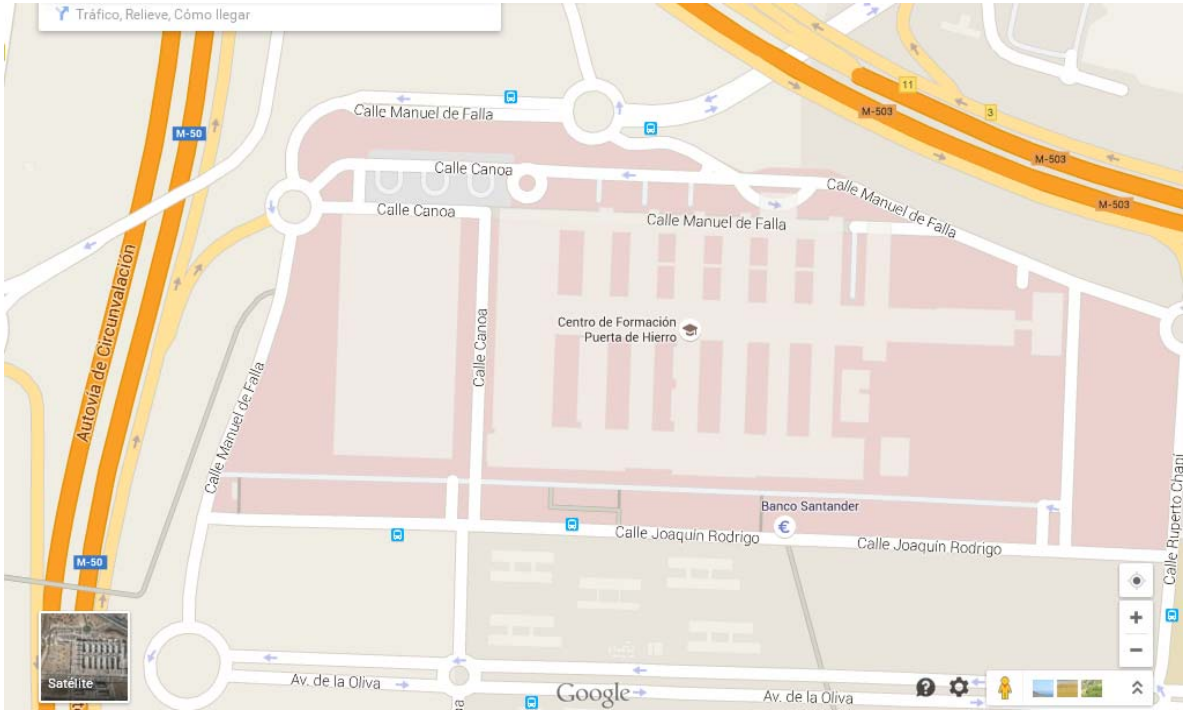
General Information

Who filled in this survey	Dr. Belen Ruiz-Antoran
E-mail contact (Phone number)	mariabelen.ruiz@salud.madrid.org (+34911916479)
Date of survey filling in	19-May-2015
Unit web address	N/A
Formal name of the unit	Clinical Pharmacology Reasearch Unit. University Hospital Puerta de Hierro-Majadahonda
Postal address	Hospital Universitario Puerta de Hierro Majadahonda Servicio de Farmacología Clínica C/ Manuel de Falla 1, planta baja, peine 2 Majadahonda 28220 Spain

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Location

https://www.google.es/maps/place/Hospital+Universitario+Puerta+de+Hierro/@40.449886,-3.871962,17z/data=!3m1!4b1!4m2!3m1!1s0xd4184535026e04b:0x22049d96375584b9



Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Ownership

Ownership	IIS PUERTA DE HIERRO
Established	1998
Linked hospital	UNIVERSITY HOSPITAL PUERTA DE HIERRO MAJADAHONDA
Distance between linked hospital and Unit	NONE, THE UNIT IS INSIDE THE HOSPITAL
Linked Ethics Committee (CEIC)	CEIC HOSPITAL PUERTA DE HIERRO MAJADAHONDA

Unit Manager

First and last names	BELEN RUIZ-ANTORAN
Qualifications	MD
Medical specialty	CLINICAL PHARMACOLOGY
Manager since	2006
E-mail and phone	mariabelen.ruiz@salud.madrid.org (+34911916479)

Short CV

PROFESSIONAL EXPERIENCE

Since - 2000: Clinical Pharmacology Consultant in University Hospital "Puerta de Hierro".
1997 - 2000. Clinical Pharmacology Service in Hospital "La Paz" Clinical Pharmacokinetic. Monitoring medicinal products. Hospital pharmacovigilance. Therapeutic consultations. Drug utilisation research studies. Pharmacoeconomic studies. Collaboration in the methodological and ethics assessment of Clinical trials phase I-IV, which were evaluated in the Ethic Committee of the Hospital "La Paz" Clinical trials Unity: Clinical investigator Performance of phase I-IV clinical trials, including design and analysis of data.
1996 - 1997. Internal medicine, Haematology, Intensive care, Nefrology Services, in Hospital "La Paz" Clinical activity with hospitalised patients in the different service above cited.
1996 - 2000. Emergency Service in Hospital "La Paz" Between four and seven sessions per month in the mentioned service.

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Ownership

Unit Manager

First and last names BELEN RUIZ-ANTORAN

Short CV (cont.)

ACADEMIC ACTIVITY

1998-2000 Collaboration as professor in doctorate course imparted by Clinical Pharmacology Service of Hospital "La Paz", belong to program doctorate of Pharmacology and Therapeutics of Autonoma University.

1999-2002 Collaboration as professor in several courses related to Clinical and General Pharmacology (3º - 6º course)

2002-2006 Professor in the Course of European Procedure of Registry of Drugs, organizated by The Official College of Pharmacist of Madrid.

OTHER RELEVANT INFORMATION

EMEA expert. Member of the Spanish Society of Clinical Pharmacology. Trained yearly in Good Clinical Practice

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

None

Audits by regulatory agencies (last 3 years)

None

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **N/A**

Audits by sponsors (last 3 years)

Yes 2012/2013/2014

Do you follow your own Standard Operating Procedures (SOPs)? Y Do you supply with a SOP copy to a sponsor if requested? Y

Would you follow the sponsor SOPs if requested: Yes, if they fulfil our Unit requirements

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 4

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

In our Unit we work following Good Clinical Practice as well as the ethical principles subscribed at Helsinki Declaration and The Convention on Human Rights and Biomedicine (Oviedo Convention). The Royal Decree-Law 223/2004 for the regulation of clinical trials is enforced. The personal and clinical data of patients/volunteers who participate in clinical trials are kept locked at the Unit and only the staff involved in the study have access to this information. Patient/volunteers personal data are codified according to sponsor requirements. The name of the volunteers/patients will only be shown at clinical notes, informed consent and volunteers/patients logs which will be kept at the Unit.

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

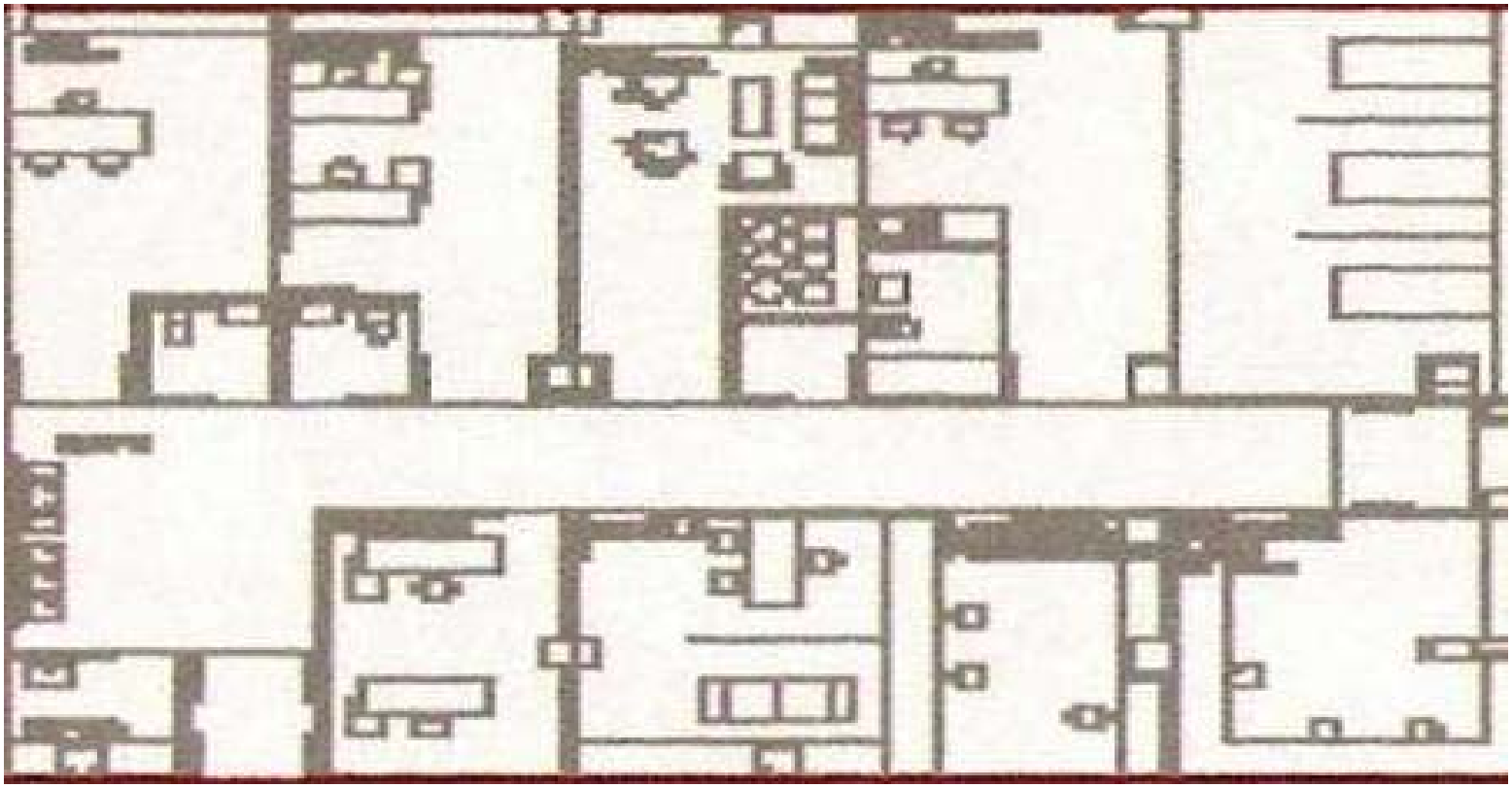
Facilities

Year of Unit building	2007	Last Unit reform	None
Usable space	150m2	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultaneously	4	Number of beds	2
Beds distribution	1 room with 2 beds		
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	2	Number of armchairs suitable for subject monitoring	6
Owned kitchen	No	Meals supervision by dietician	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emergency trolley for cardiopulmonary resuscitation			Yes
The emergency trolley has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes/ALS		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	A+E, ICU, OR, as required		
Distance and time to get the former services	In site		
Unit entrance/Exit door controlled	Yes, key	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Facilities

Unit distribution plan



Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Staffing and Resources

Unit employees

Permanent staff 8 Fixed-term/contracted staff (internship, grant holders) 2 Part-time collaborators varies

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	3	
Co-investigator (physician)	3	
Nurse	3	
Monitor or CRA	1	
Pharmacist	1	
Biometry		
Data management	1	
Medical writing	1	
Pharmacokinetics		
Quality assurance		
Project Management	1	
Finance	1	
Recruitment	2	
IT (informatics)		
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit:

1 Physician **1** Nurse

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameters)	Yes
The quality assurance activities are subcontracted by the Unit	Yes
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	Yes
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** pharmacist/nurses depending on the trial requirements **Preparation**: pharmacist/nurses depending on the trial requirements
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification	
Bar codes stickers with name and ID number	
Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes
Number of centrifuges available	2
System for plasma/fluids samples storing	freezer
Fridges and freezers available in the Unit	3
The Unit has its owned Bioanalytical Department	No
Availability of genotyping or fenotyping methods for participants	No at site, subcontracting is possible

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Services Capabilities

Data Management and software used (describe)	Yes if software is provided by sponsor. Otherwise, it is subcontracted at Universidad Autonoma de Barcelona
Biometry or Statistical Analysis and software used (describe)	SPSS
Pharmacokinetic Analysis and software used (describe)	WinNolin
Medical Writing and skilled languages	Yes, English
Owned archives in the same Unit building (describe)	Yes. Aprox 15-20 clinical trials archives can be stored at site in locked cabinets. If more space is required, it is subcontracted with Iron Mountain, external archive.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

ISF with all the documents within: informed consent forms, contracts, SUSARs, protocols, IB, CRF at least for 15 years or as required by sponsor.

The study files are digitized and converted in a CD or web format	Yes
Project management	Yes

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Study participants

Kind of participants included in clinical trials performed in the Unit

X Healthy volunteers X Patients

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

Solid tumour Haematological tumour X Adults X Paediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Recruiting methods for healthy volunteers

Recruiting it is done according to the Unit SOPs and the specific protocol. Most of the volunteers are Medicine/Nursing students.

Recruiting methods for patients

In collaboration with other clinical departments at the hospital, through the principal investigator of every trial, according to the Unit SOPs

Do you have surgery rooms available for screening (separated from the in-house area)? (number) Yes, 1

Do you keep a paper or electronic database of volunteers? (describe) No

Have you implemented any measure for avoiding the over-volunteering? (describe) Yes

According to Royal Decree-Law 223/2004, no more than 3 trials/year. The data will be checked through the clinical notes of the volunteer/patient.

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	4	Pulsioximetry devices (number)	2	12-leads ECG devices (number)	2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Yes, 1(2005), 2 (2008), 1 (2013)
Availability in the Unit of tests for assessing CNS drug effects	
Familiarity in poblational analysis and PK/PD modelling, including writing of clinical reports	Subcontratad at Universidad Autonoma de Madrid
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes
Experience in other kind of PD or PK evaluations not formerly collected	

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Regular collaborations with pharmaceutical companies and independent researches

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence				1		
First single-dose administration in humans		2		1	1	
First multiple-dose administration in humans					1	
Drug interaction						1
Food interaction						
Special populations (Renal or liver impairment, elderly)						1
Proof of concept (Phase Ib or I/II)	3	2	3	4	5	4
Own research lines	2	1	1	1	3	4
Others (specificying)	5	4	7	10	11	8

Number of trials linked to a PEI (IND) submission 2009 2010 2 2011 1 2012 3 2013 2 2014 2

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 6 Number of trials promoted by multinational companies 68

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60

Number of Early Stages trials performed in the Unit and published in the last 4 years 4

Unidad de Investigación Farmacológica. Hospital Universitario Puerta de Hierro Majadahonda

Annexes

Brochure not available in English

Unidad de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

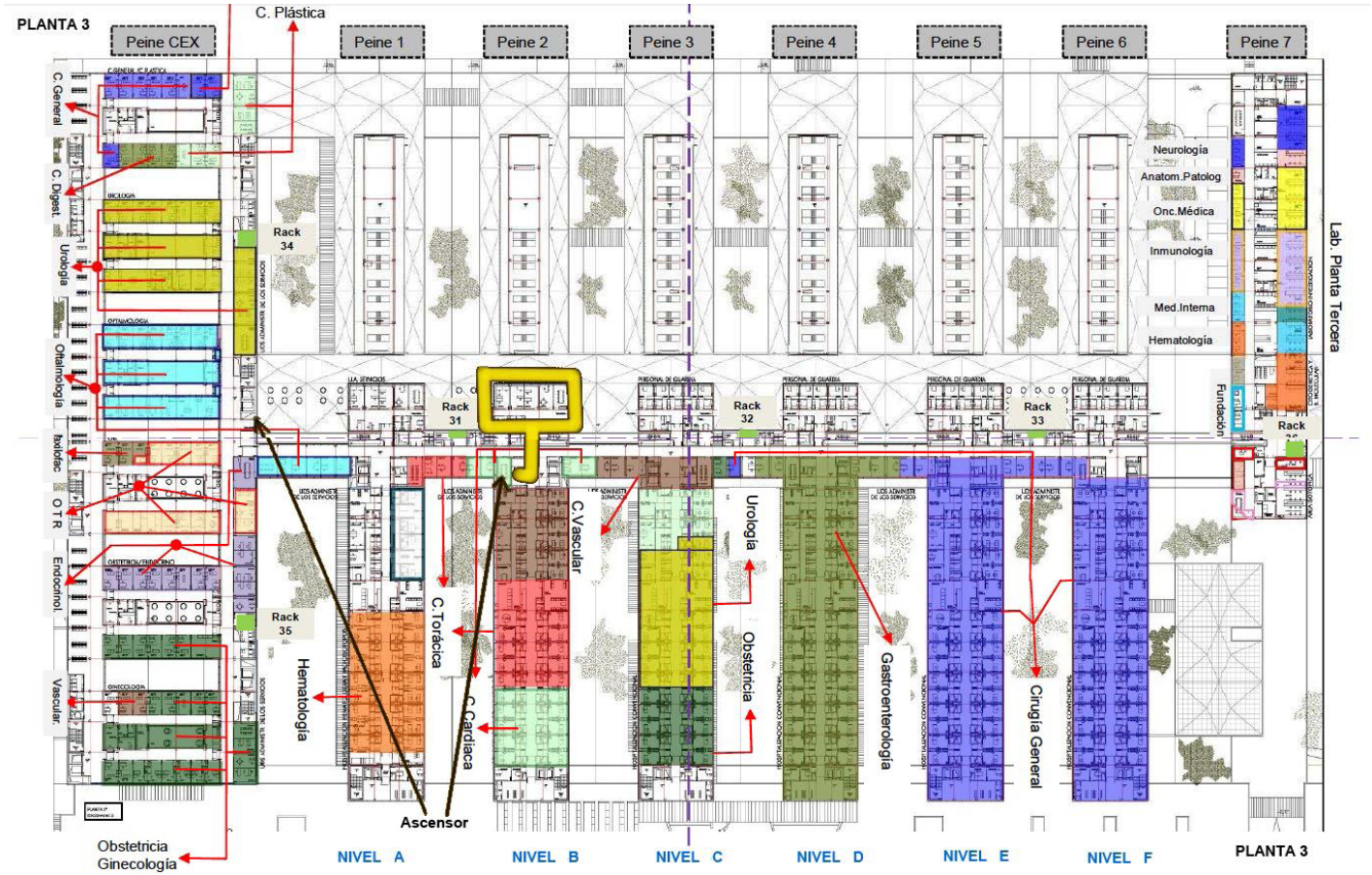
Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

General Information

Who filled in this survey	SANDRA CERDEIRA
E-mail contact (Phone number)	scerdeira.hpth@salud.madrid.org
Date of survey filling in	20/05/2015
Unit web address	www.oncologiapuertadehierro.com
Formal name of the unit	EARLY PHASE DRUGS UNIT ONCO-FI
Postal address	Puerta de Hierro University Hospital Calle Manuel de Falla 1 28222- Majadahonda Madrid. Spain

Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

Location



Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

Ownership

Ownership	MEDICAL ONCOLOGY DEPARTMENT
Established	2014
Linked hospital	PUERTA DE HIERRO UNIVERSITY HOSPITAL
Distance between linked hospital and Unit	SAME BUILDING
Linked Ethics Committee (CEIC)	PUERTA DE HIERRO UNIVERSITY HOSPITAL´S CEIC

Unit Manager

First and last names	DR. MARIANO PROVENCIO
Qualifications	MD, Ph D
Medical specialty	MEDICAL ONCOLOGY
Manager since	2014
E-mail and phone	mariano.provencio@salud.madrid.org 91 191 6280

Short CV

- 2011-present: Head of Medical Oncology Department at Puerta de Hierro University Hospital
- 2011-present: Full professor, School of Medicine, Autonoma University of Madrid
- 2012-present: Board member of the Research Institute of Puerta de Hierro University Hospital
- 2012-present: Scientific director of the Research Institute of Puerta de Hierro University Hospital
- 2007-present: President of the Spanish Lymphoma Oncology Group
- 2014-present: President of the Spanish Society of Lung Cancer
- 2010-present: Board of the Pblishing Committee of the European Society of Medical Oncology

Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

Accreditations and audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

Health Council, Community of Madrid

Audits by regulatory agencies (last 3 years) None

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? Yes

Audits by sponsors (last 3 years)

None

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? Yes

Would you follow the sponsor SOPs if requested: The unit could follow the SOPs of the sponsor assuming they do not conflict with those of the unit.

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial:

The internal audit plan of the unit is 1 year and may increase its frequency depending on the number of trials and patients recruited.

Audits for a clinical trial would be the ones indicated by the promoter.

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

In compliance with the Data Protection Act, we have developed a security document in which are collected, among other things, all technical procedures that have been adopted and implemented at the Institute of Health Research Puerta de Hierro for proper use of the information systems as required by the rules of data protection as well as correct treatment of personal data as warranty of its confidentiality and integrity. Specifically, we have defined the following procedures and standards:

- Delegation of authorizations
- Access data over communications networks
- Working outside local files
- Temporary files
- Backup & Recovery
- Physical Access Control
- Tests with real data
- Incident Record
- Support and Document Management
- Identification and Authentication
- Creating and Using Passwords
- Custom treatment

Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

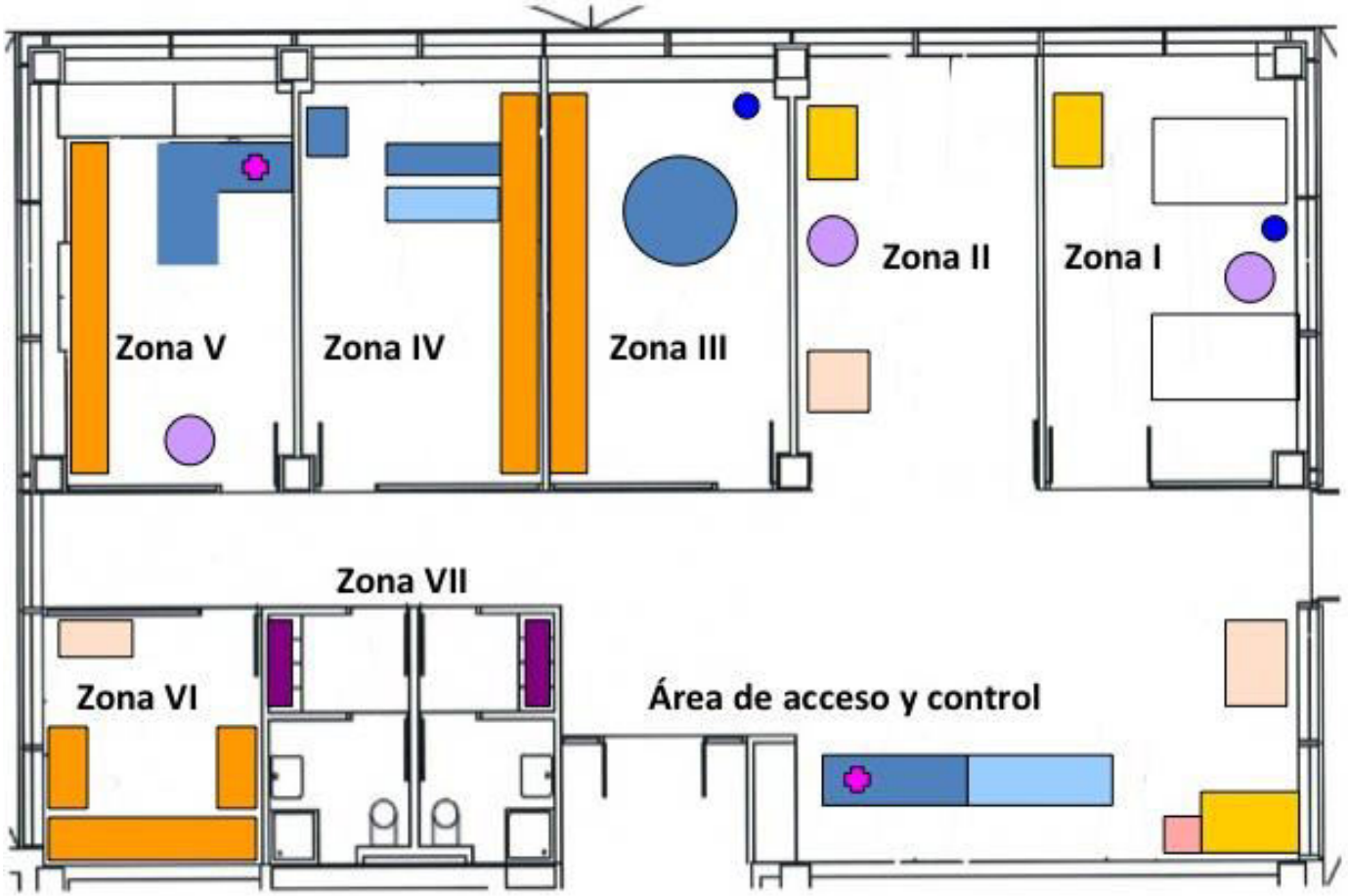
Facilities

Year of Unit building	2008	Last Unit reform	
Usable space	143m2	The Unit building is separate from the linked hospital	NO
Number of CTs the unit could perform simultanously	2	Number of beds	2
Beds distribution	TWO BEDS PER ROOM		
Beds distribution allows a complete and continuous visual control by nurses			YES
Number of bed with intensive or continuous monitoring	1	Number of armchairs suitable for subject monitoring	2
Owned kitchen	NO	Meals supervision by dietitian	YES
Dining-room available for volunteers	YES	Individual lockers available for volunteers	YES
Relaxing room available for volunteers independent from the beds area			YES
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			YES
The emergency trolly has available suitable medications with immediate by controlled access			YES
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	YES		
Unit availability of an evacuation plan for volunteers in emergency situations			YES
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			YES
Volunteers/patients healthcare would be covered by the national or the regional health system if required			
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	EMERGENCY DEPARTMENT AND INTENSIVE CARE UNIT		
Distance and time to get the former services	3mins to emergency room, 140m far away 1min 35 seconds to Intensive Care Unit (72m to module C, 143m to module D)		
Unit entrance/Exit door controlled	YES	Unit with Closed Circuit Television	YES
Availability of an alternate electrical generating set that automatically works in case of a general system failure			YES

Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

Facilities

Unit distribution plan:



Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

Staffing and Resources

Unit employees

Permanent staff 20 Fixed-term/contracted staff (internship, grant holders) 3 Part-time collaborators 1

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	8	
Co-investigator (physician)	3	
Nurse	2	
Monitor or CRA	4	
Pharmacist		
Biometry		
Data management		
Medical writing		
Pharmacokinetics		
Quality assurance	1	
Project Management		
Finance		
Recruitment		
IT (informatics)	1	
Other (specify): CTA, psychologist, etc	1 CTA and 1 LABORATORY TECHNICIAN	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician X Nurse

Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	YES
The quality assurance activities are subcontracted by the Unit	NO
Availability of a specific area for drug storing and preparation of medications for the study	YES
The former area or room has restricted access by key or code	YES
Laminar flow chamber availability for preparation of parenteral treatments	NO
Perfusion pumps for intravenous treatment	YES
Who is the responsible for drug preparation and dispensing	**Dispensing:** NURSE **Preparation**: PHARMACY DEPARTMENT
Drug accountability procedures, such as reception, preparation and dispensing forms	YES
SOPs available for drug preparation and dispensing	YES
SOPs available for drawing and managing of biological fluids	NO
System or procedure used for samples identification	Identification sticker with barcode
Availability of a specific area for blood samples managing	YES
The former area or room has restricted access by key or code	YES
Number of centrifuges available	1
System for plasma/fluids samples storing	Unit´s own fridge and freezer
Fridges and freezers available in the Unit	2
The Unit has its owned Bioanalytical Department	NO
Availability of genotyping or fenotyping methods for participants	NO

Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

Services Capabilities

Data Management and software used (describe)	NO
Biometry or Statistical Analysis and software used (describe)	NO
Pharmacokinetic Analysis and software used (describe)	NO

Medical Writing and skilled languages

Owned archives in the same Unit building (describe) YES

The hospital has an active file with an approximate area of 1000 m2́ and a capacity of 200,000 clinical records. Restricted access and registration of inputs and outputs available.

It also has a passive file where the documentation is kept indefinitely (IRON MOUNTAIN)

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Once the trial is completed, all documentation related is sent to the external file of the hospital IRON MOUNTAIN (Daganzo de Arriba) where it can be stored indefinitely so as to recover if necessary for any inspection or audit

The study files are digitized and converted in a CD or web format	NO
Project management	NO

Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

Study Participants

Kind of participants included in clinical trials performed in the Unit

	Healthy volunteers	X	Patients
	Other populations		

If the Unit has experience in oncology, detail kind of tumour and age groups

X	Solid tumour		Haematological tumour	X	Adults		Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

LUNG, BREAST, COLORECTAL, LYNPHOMA, GASTRIC…

Recruiting methods for healthy volunteers

THERE IS NO RECRUITMENT OF HEALTHY PATIENTS

Recruting methods for patients

Patients are recruited from our own service but can also be referred from other hospitals

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	YES
Do you keep a paper or electronic database of volunteers? (describe)	NO
Have you implemented any measure for avoiding the over-volunteering? (describe)	NO

Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	1	Pulsioximetry devices (number)	1	12-leads ECG devices (number)	1

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Cardiology department collaborates regularly and are responsible for such assessments
Availability in the Unit of tests for assessing CNS drug effects	YES
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	NO
Familiarity with Electronic Data Capture –EDC applied to clinical trials	YES (SINCE 2008, 50 STUDIES approximately)
Experience in other kind of PD or PK evaluations not formerly collected	NO

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

NO

Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence			1		1	
First single-dose administration in humans						
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)	9	9	11	12	11	20
Own research lines						
Others (specificying)	16	15	20	20	18	21

Number of trials linked to a PEI (IND) submission 2009 0 2010 0 2011 0 2012 0 2013 0 2014 0

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Antiangiogenics, TK inhibitors, ALK inhibitors, anti CD30, ROS inhibitors, PI3K, PDL1

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 1 Number of trials promoted by multinational companies 3

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 80 DAYS

Number of Early Stages trials performed in the Unit and published in the last 4 years 0

Unidad de de Estudios de Medicamentos en Fase Temprana ONCO-FI. HUPH Majadahonda

Anexos Brochure not available in English

Unidad de Estudios Clínicos en Fase Temprana en Oncología – UFTO. Hospital Universitario 12 de Octubre

English version not available

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

General Information

Who filled in this survey	Mª Ángeles Gálvez Múgica
E-mail contact (Phone number)	Mariaangeles.galvez@salud.madrid.org
Date of survey filling in	2015-April-30th
Unit web address	http://www.irycis.org/
Formal name of the unit	Clinical Trial Unit, Ramón y Cajal Hospital
Postal address	Carretera de Colmenar Viejo, Km 9,100, 28034 Madrid

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Location

Clinical Trial Unit, Ramón y Cajal Hospital

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Ownership

Ownership	Public. Ramon y Cajal Hospital
Established	2010, November
Linked hospital	Ramon y Cajal Hospital
Distance between linked hospital and Unit	Included in the hospital
Linked Ethics Committee (CEIC)	Ramon y Cajal Hospital Ethics Comitee

Unit Manager

First and last names	Mª Angeles Gálvez Múgica
Qualifications	Medical Doctor
Medical specialty	Clinica Pharmacology
Manager since	2009
E-mail and phone	Mariaangeles.galvez@salud.madrid.org/ 0034913368825 / 0034917291890

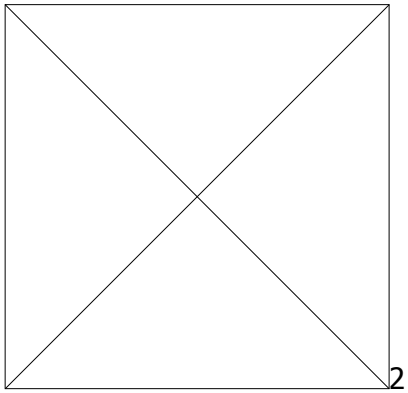
Short CV

Head of the Clinical Pharmacology Unit at the Ramon y Cajal Hospital since October 2003 and manager of the Clinical Trial Unit since 2009. Vice President of the Ethical committee of the hospital Ramon y Cajal. Executive Committee member and Training Manager of the Spanish platform of clinical trials (SCReN)

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Accreditations and audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years



2 accreditations by the Council of Health of the Community of Madrid. The first in October 2012 for two years. In October 2013 it was re-accredited for a period of four years

Audits by regulatory agencies (last 3 years)

None

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? Yes

Audits by sponsors (last 3 years)

Yes

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? Yes

Would you follow the sponsor SOPs if requested: Yes

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: One per year by the quality manager

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

We have specific SOPs and Data are included in the hospital Clinical Investigation File

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Facilities

Year of Unit building	1980	Last Unit reform	2009
Usable space	200m2	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	4-5	Number of beds	4/8
Beds distribution	2 per room		
Beds distribution allows a complete and continuous visual control by nurses			
Number of bed with intensive or continuous monitoring	4	Number of armchairs suitable for subject monitoring	8
Owned kitchen	yes	Meals supervision by dietitian	yes
Dining-room available for volunteers	yes	Individual lockers available for volunteers	yes
Relaxing room available for volunteers independent from the beds area			yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			yes
The emergency trolly has available suitable medications with immediate by controlled access			yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	yes		
Unit availability of an evacuation plan for volunteers in emergency situations			yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Intensive Care Unit		
Distance and time to get the former services	Several floors below (5 minutes taking the elevator) but the intensivist physician attends the unit to the emergency call		
Unit entrance/Exit door controlled	yes	Unit with Closed Circuit Television	yes
Availability of an alternate electrical generating set that automatically works in case of a general system failure			yes

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Facilities

Unit distribution plan

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Staffing and Resources

Unit employees

Permanent staff Fixed-term/contracted staff (internship, grant holders) Part-time collaborators

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	1	1
Nurse		2
Monitor or CRA		2
Pharmacist	1	
Biometry		
Data management		1
Medical writing		
Pharmacokinetics		
Quality assurance	1 (the Co-investigator)	
Project Management		
Finance	1	
Recruitment		1 (Nurse)
IT (informatics)		
Other (specify): CTA, psychologist, etc	CTA	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

Physician Nurse

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	yes
The quality assurance activities are subcontracted by the Unit	no
Availability of a specific area for drug storing and preparation of medications for the study	yes
The former area or room has restricted access by key or code	yes
Laminar flow chamber availability for preparation of parenteral treatments	No, it is available in the Pharmacy
Perfusion pumps for intravenous treatment	yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Nurse or MD **Preparation**: pharmacist and nurse
Drug accountability procedures, such as reception, preparation and dispensing forms	yes
SOPs available for drug preparation and dispensing	yes
SOPs available for drawing and managing of biological fluids	Yes (still in preparation)
System or procedure used for samples identification	still in preparation
Availability of a specific area for blood samples managing	yes
The former area or room has restricted access by key or code	yes
Number of centrifuges available	one
System for plasma/fluids samples storing	yes
Fridges and freezers available in the Unit	One fridge and two freezers (-80ºC and -20ºC)
The Unit has its owned Bioanalytical Department	no
Availability of genotyping or fenotyping methods for participants	No but we collaborate closely with the laboratory that performs the analysis

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Services Capabilities

Data Management and software used (describe)	CTMS (Clinical Trial Management System), Pharmacovigilance database (PcV manager "excedo")
Biometry or Statistical Analysis and software used (describe)	yes
MACRO	
Pharmacokinetic Analysis and software used (describe)	yes
Winnonlin	
Medical Writing and skilled languages	yes
Owned archives in the same Unit building (describe)	
locked cabinets, which is controlled by the Unit Manager	
Regarding a specific clinical trial what documents are sent to the archives and for long time are archived	
All documents are archived for 15 years in an specific file after trial completion	
The study files are digitized and converted in a CD or web format	Not yet
Project management	yes

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers x Patients x

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

Solid tumour x Haematological tumour x Adults x Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Any type of tumor. There are currently trials on different type of cancer

Recruiting methods for healthy volunteers

We have a database

Recruting methods for patients

Doctors who are part of the research team recruited patients who visit the clinic

Do you have sugery rooms available for screening (separated from the in-house area)? (number) Yes

Do you keep a paper or electronic database of volunteers? (describe) Yes

Yes, a database with minimal information: ID number card, age, gender, contact address and phone number

Have you implemented any measure for avoiding the over-volunteering? (describe)

Internal control. In addition, the subject is asked about their participation in clinical trials in other units

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Pharmacodynamic / Pharmacokinetic Capabilities

Digital blood pressure devices (number)	Yes, 6	Pulsioximetry devices (number)	6	12-leads ECG devices (number)	Yes, 1

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	yes
Availability in the Unit of tests for assessing CNS drug effects	hospital resources
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	yes
Familiarity with Electronic Data Capture –EDC applied to clinical trials	yes
Experience in other kind of PD or PK evaluations not formerly collected	no

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

some collaborations with the pharmaceutical industry

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence			1		1	
First single-dose administration in humans						1
First multiple-dose administration in humans					2	3
Drug interaction			1	1		
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)			6	12	17	13
Own research lines			2		1	
Others (specificying) fase III			6	12	10	13

Number of trials linked to a PEI (IND) submission	2009	2010	2011	2012	2013	2014

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Antineoplastic agents, antiretrovirals, anti-HCV

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 7 Number of trials promoted by multinational companies 85

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 3

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Annexes Brochure

SERVICES PORTFOLIO

The CTU is prepared for the admission of patients or healthy volunteers in phase I studies. Phase II to IV studies are conducted in a collaboration with several other clinical services which can include , but are not limited to nursing support and specific visits according to protocol, this may include studies with medical products, medical devices, diagnostic techniques, etc.

Furthermore, CTU staff assits in:

1. Support to the investigator/sponsor in design of the protocol, CRF and/or informed consent form and implementation of different clinical studies.
2. Monitoring of clinical trials and observational studies.
3. Analysis of results and elaboration of final and annual reports.
4. Support in the process to submit the request of the clinical study to EC and AEMPS according to the current legislation.
5. Pharmacovigilance activities: assessment of serious adverse events and reporting if applicable

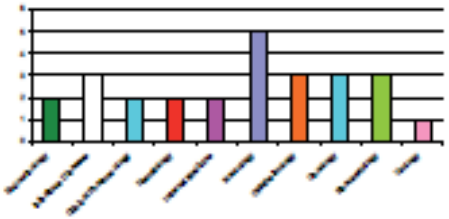


Figure 1. Number of Clinical Trials (CT) with hospital admissions in the CT Unit, by Service, during 2012

In addition, the CTU has assisted in the implementation, administrative procedures, and monitoring of 27 CT from different Hospital Services

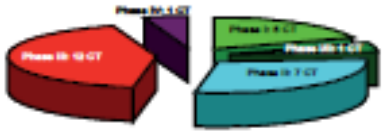


Figure 2. Phase of CT performed in the CT Unit during 2012

Hospital Universitario Ramón y Cajal

CTU CONTACT

Hospital Universitario Ramón y Cajal
Ctra. de Colmenar Viejo, Km. 9,100 Planta 7ª Izda.
28034 Madrid
Tel. 91 336 88 25 / 91 729 18 90
Fax 91 336 88 25

CTU Responsible
Dra. Mª Ángeles Gálvez Múgica
mariaangeles.galvez@salud.madrid.org

www.irycis.org

Unidad de Ensayos Clínicos. Hospital Ramón y Cajal

Annexes Brochure

Contribute to innovation in the field of biosciences is our main objective. Clinical research with medicinal products is a paradigm of this innovation. We consistenly wish to participate in the creation in Spain of a platform of excellence. Therefore, we present this new set of goals that aim to improve our efficiency and competitiveness.

COMMITMENT WITH THE DEADLINES IN CLINICAL TRIALS

Before the aproval of the Ethics Commitee (EC)

- Will not exceed **60 days**, since the validation of the documentation, when the Hospital Universitario Ramón y Cajal (HURYC) is the Reference EC.
- Will give an expert report **within 30 days** when the HURYC acts as the local EC.
- For single-center phase I clinical trials (CT), a clinical pharmacologist will make an assessment prior to the evaluation by the EC and the deadline for approval will be in **30-45 days.**

Time to aproval of the Center

Aproval will be released at the same time that the opinion of the EC.

Time of execution of the contract

In this case, it is a commintment shared with the sponsors, which can only be be met if there are no delays by part of sponsor

- Contract management in parallel with the presentation of the CT to the EC.
- Signature of the Contract made before the CT has obtained relevant authorizations but with a clause stating that the CT will not start until the corresponding authorizations have been sent to the Centre.

COMMITMENT WHIT THE RECRUITMENT OF THE PATIENTS

- The principal investigator (PI) performs a pre-selection of patients coinciding with the entry of the CT for its assessment by the EC of the Center.
- The PI is informed in time to sign the contract and bearing in mind the start date and deadline of the trial.
- Certain measure have been established for researchers to comply with the deadlines and for the inclusion of the first patient as well as anticipated recruitment of patients.

COMMITMENT WITH THE RESEARCH IN EARLY PHASES

The Phase I Clinical Trials Unit (CTU) of the Hospital Universitario Ramón y Cajal has been certified by the General Department of Evaluation and Control of the Ministry of Health of the Community of Madrid in September 2012.

COMMITMENT WITH THE PATIENTS AND THE HEALTY VOLUNTEERS INVOLVED IN CT

The creation of the CTU has improved the comfort and well-being of patients. Until now, the CTU has been used by 181 patients and 24 healthy volunteers. In a recently conducted survey, 97% of our users would return to participate in a clinical trial. The assessment about our facilities received a "very good" and "excellent" valuation by 82% of respondents and the personal attention was considereded "very good" and "excellent" by 94%

PHASE I CLINICAL TRIAL UNIT OF HOSPITAL RAMÓN Y CAJAL. IRYCIS

The Clinical Research Unit (CRU) is located in the hospital itself, on the 7th floor, but in an independent area with a private entrance. It has easy access to the emergency services.

STAFF: All personel in the Unit are specialized in clinical research. The current staff is as follows:

- Three Clinical Pharmacologists
- One Clinical Research Associate (CRA).
- One Research Nurse and Laboratory Technician
- One Technical Specialist in economic management of clinical trials

INFRASTRUCTURE:

Hospital ward. Four beds and eight fully reclining chairs, oxygen uptake, vital signs monitors, central monitoring system, synchronized clocks, security cameras, continuous monitoring system defibrillator and resuscitation equipment.

Laboratory. Equipment for processing biological samples, refrigerated centrifuge, refrigerator and freezers (-20ºC and -80ºC) to store biological samples gifted with temperature control and alarm system.

Multipurpose room. Conference room with TV, Internet, Bed-sofa, Lockers and can also be utilized as a waiting area.

Medical Office. a separate area for medical examination to ensure privacy. It includes: a scale to measure weight, height and BMI; electrocardiograph and viewbox.

Nursing control

Staff office. A computer connected to the hospital intranet with access to patient files and file cabinets for documents relating to the clinical trial.

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

General Information

Who filled in this survey	Jesús Frías Iniesta / Alberto M. Borobia
E-mail contact (Phone number)	alberto.borobia@salud.madrid.org +34-91 207 14 66
Date of survey filling in	21/01/2015
Unit web address	http://www.idipaz.es/PaginaDinamica.aspx?IdPag=187&Lang=EN
Formal name of the unit	La Paz Central Research and Clinical Trials Unit
Postal address	Hospital Universitario La Paz Hospital Maternal, 2ª planta Pº de la Castellana, 261 28046 Madrid

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Location

Metro

Station: Begoña; Line 10 (Fuencarral-Puerta del Sur)

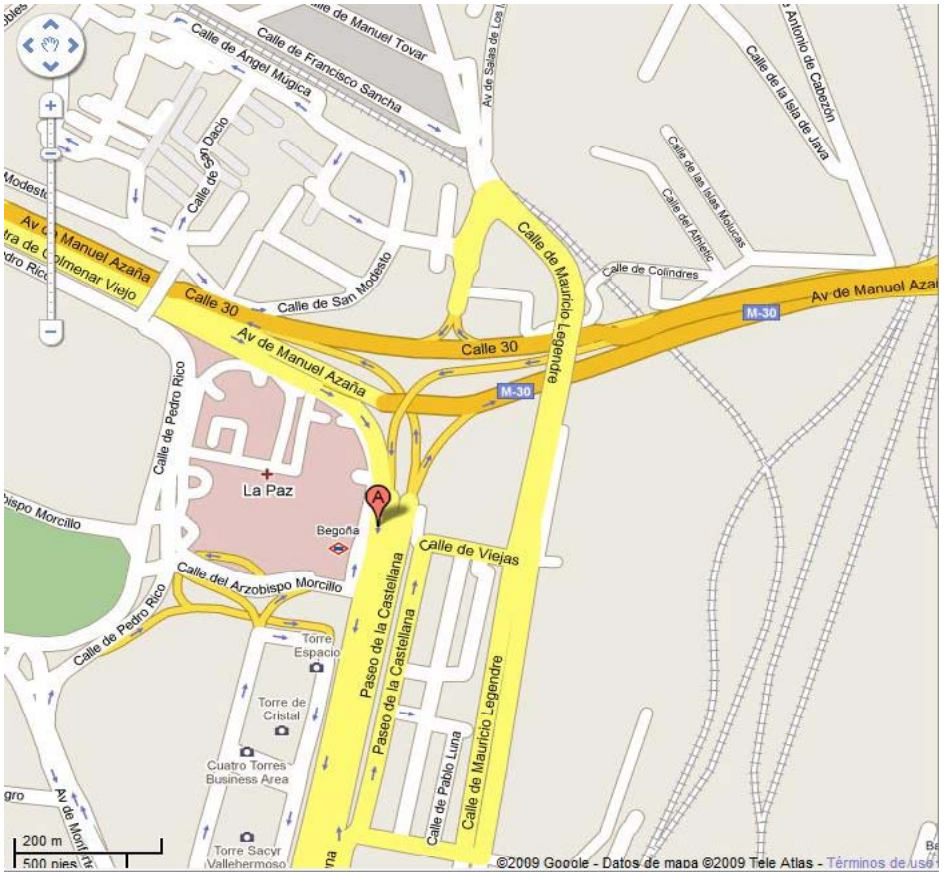
City Buses

Lines: 67, 124, 132, 134, 135, 137 y 173.

Interurban Buses

Main bus lines that reach La Paz University Hospital from the 5th basic area of health:

- Alcobendas: 151, 153, 157, 159, 171, 191, 194, 196 y 197.
- Algete: 171, 181, 182 y 185.
- Buitrago de Lozoya: 191 y 196
- Colmenar Viejo: 154 C, 191,721, 722, 724, 725 y 726
- El Molar: 191, 194, 195 y 196
- La Cabrera: 191, 194, 195 y 196
- La Moraleja: 155
- Manzanares el Real: 724
- Miraflores: 725
- Rascafría: 194
- SS de los Reyes: 152 C, 154 C, 161, 172, 191, 194, 196 y 197
- Soto del Real: 725 y 726
- Torrelaguna: 197
- Tres Cantos: 712, 713, 716, 717, 721, 722, 724 y 726.



Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Ownership

Ownership	Public (La Paz University Hospital. Autonomous Region of Madrid)
Established	Phase I Unit since 2009
Linked hospital	La Paz University Hospital
Distance between linked hospital and Unit	The Unit is inside the hospital
Linked Ethics Committee (CEIC)	La Paz University Hospital Ethics Committee

Unit Manager

First and last names	Alberto M. Borobia
Qualifications	MD. PhD
Medical specialty	Specialist in Clinical Pharmacology
Manager since	2014
E-mail and phone	alberto.borobia@salud.madrid.org +34-91.207.14.66

Short CV

Medical Degree. Universidad Autónoma of Madrid
PhD. (Special award). Universidad Autónoma of Madrid
Specialist in Clinical Pharmacology. La Paz University Hospital

Professional experience:

Associate Physician. Clinical Pharmacology Department (2010-present). La Paz University Hospital
Clinical Pharmacology Intern (2005-2010). La Paz University Hospital.

Teaching and research experience:

Associate Professor of Faculty of Medicine, Universidad Autónoma of Madrid (2010-present)
Participation as investigator in more than 50 clinical trials
Participation as investigator in more than 10 public funded by official agencies research projects
More than 30 publications in national and international scientific journals

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Accreditations and audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

Accredited in 2011 by Madrid Autonomous Region Authorities (Good Clinical Practices accomplishment)

Audits by regulatory agencies (last 3 years)

None

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? Yes

Audits by sponsors (last 3 years)

2011 (1), 2013 (1), 2014 (3). Total audits: 5

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? Yes

Would you follow the sponsor SOPs if requested: Yes

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 0

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

There is a confidenciality SOP. Filing room: key-locked, double door, fireproof. Personal access computers. Electronic file: centralized with limited and differenciated access.

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

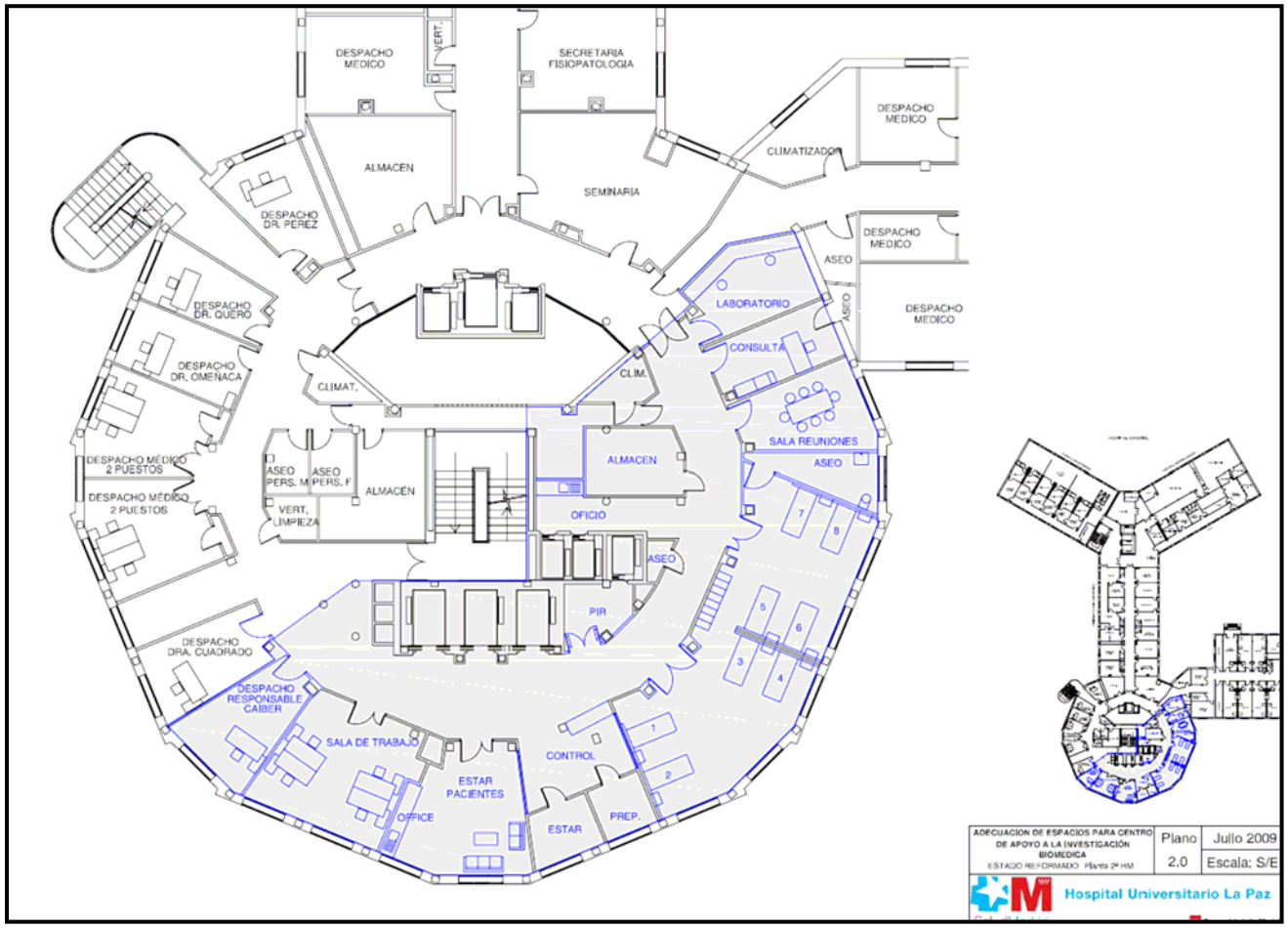
Facilities

Year of Unit building	1964	Last Unit reform	2009
Usable space	450 m^2	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	Depends on the number of patients	Number of beds	8 (+ 4 armchairs)
Beds distribution	8 beds and 4 armchairs distributed in 2 communicated rooms (4 beds-2 armchairs in each room)		
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	4	Number of armchairs suitable for subject monitoring	0
Owned kitchen	Yes	Meals supervision by dietitian	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes, both		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Intensive Care Unit and Resucitation Unit		
Distance and time to get the former services	Those are located in the Hospital as well		
Unit entrance/Exit door controlled	Yes (magnetic ID cards)	Unit with Closed Circuit Television	Yes
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Facilities

Unit distribution plan:



Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Unit Staffing and Resources

Unit employees

Permanent staff 7 Fixed-term/contracted staff (internship, grant holders) 6 Part-time collaborators 15

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	4	1
Co-investigator (physician)	4	2
Nurse	2	2
Monitor or CRA	1	5
Pharmacist	0	1
Biometry	2	1
Data management	1	5
Medical writing	4	2
Pharmacokinetics	4	1
Quality assurance	0	1
Project Management	0	1
Finance	2	0
Recruitment	4	2
IT (informatics)	0	0
Other (specify): CTA, psychologist, etc	1 CTA	3 CTA

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician X Nurse

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	Yes (ISO 9001.2008)
The quality assurance activities are subcontracted by the Unit	Yes (Clinical Pharmacology Center-Phase I Unit of Universidad Autónoma of Madrid)
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	No
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Unit´s Pharmacist and Nurses **Preparation**: Unit´s Pharmacist and Nurses
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification	Samples are labelled specifying study code and volunteer code, followed by the sample extraction number. Sponsor´s requirements are followed if needed
Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes
Number of centrifuges available	2 (both refrigerated)
System for plasma/fluids samples storing	Kept in transparent bags or boxes for each volunteer labeled with protocol code and volunteer number
Fridges and freezers available in the Unit	1 fridge, 2 (-20)ºC freezers and also 2 (-80)ºC freezers

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Services Capabilities

The Unit has its owned Bioanalytical Department	No
Availability of genotyping or fenotyping methods for participants	Yes (PharmArray®, in collaboration with Medical and Molecular Institute of La Paz University Hospital-INGEMM)
Data Management and software used (describe)	Microsoft Access, CRDataX®
Biometry or Statistical Analysis and software used (describe)	IBM Statistics SPSS, IBM Modeler, Stata, R
Pharmacokinetic Analysis and software used (describe)	Phoenix™ WinNonlin® 6.3 and R
Medical Writing and skilled languages	Yes, Spanish and English
Owned archives in the same Unit building (describe)	Key-controlled acces, fireproof doors

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

After a study closure, the whole Investigator File and CRFs are sent to a central archiving repository (IronMountain), and keeped for 15 years

The study files are digitized and converted in a CD or web format	No
Project management	Yes

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers Yes Patients Yes

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour X Haematological tumour X Adults X Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All kind of tumors, as our Unit is in contact with La Paz Hospital Medical Oncology Department

Recruiting methods for healthy volunteers

Informative meetings at our Unit

Recruting methods for patients

Information given by Hospital medical specialists and at informative meetings at our Unit

Do you have sugery rooms available for screening (separated from the in-house area)? (number) Yes (1)

Do you keep a paper or electronic database of volunteers? (describe) No

Have you implemented any measure for avoiding the over-volunteering? (describe) Yes

Previous studies data (volunteers participation) is checked in order to prevent a volunteer participation to be repeated in less than 3 months

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	4	Pulsioximetry devices (number)	5	12-leads ECG devices (number)	1

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Yes, during the last 4 years, in about 5 studies/year
Availability in the Unit of tests for assessing CNS drug effects	No
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	Yes, 2 per year (Nonmen® y R)
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes, in about 7 studies/year for the last 7 years
Experience in other kind of PD or PK evaluations not formerly collected	
Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted	

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence	4	2	2	1	2	1
First single-dose administration in humans	1					
First multiple-dose administration in humans			1			
Drug interaction						
Food interaction						1
Special populations (Renal or liver impairment, elderly)			3	5	5	7
Proof of concept (Phase Ib or I/II)			2	3	4	3
Own research lines				2	1	4
Others (specificying)						

Number of trials linked to a PEI (IND) submission	2009	2010	2011	2012	2013	2014

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

For all therapeutic areas

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 15% Number of trials promoted by multinational companies 85%

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 11

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Annexes

Early Stages trials Publications:

López-Rodríguez R, Cabaleiro T, Ochoa D, Román M, Borobia AM, Carcas AJ, Ayuso C, Novalbos J, Abad-Santos F. Pharmacodynamic genetic variants related to antipsychotic adverse reactions in healthy volunteers. Pharmacogenomics. 2013 Jul;14(10):1203-14. doi: 10.2217/pgs.13.106. Factor de Impacto: 3.857 (Q1)

Ramírez E, Abraira V, Guerra P, Borobia AM, Duque B, López JL, Mosquera B, Lubomirov R, Carcas AJ, Frías J. A preliminary model to avoid the overestimation of sample size in bioequivalence studies. Drug Res (Stuttg). 2013 Feb;63(2):98-103. doi: 10.1055/s-0032-1333296

Borobia AM, Lubomirov R, Ramírez E, Lorenzo A, Campos A, Muñoz-Romo R, Fernández-Capitán C, Frías J,Carcas AJ. An acenocoumarol dosing algorithm using clinical and pharmacogenetic data in spanish patients with thromboembolic disease. PLoS One. 2012;7(7):e41360. Epub 2012 Jul 20. Factor de Impacto: 4.092 (Q1)

Carcas AJ, Borobia AM, Velasco M, Abad-Santos F, Díaz MQ, Fernández-Capitán C, Ruiz-Giménez N, Madridano O, Sillero PL; PGX-ACE Spanish Investigators Group. Efficiency and effectiveness of the use of an acenocoumarol pharmacogenetic dosing algorithm versus usual care in patients with venous thromboembolic disease initiating oral anticoagulation: study protocol for a randomized controlled trial. Trials. 2012 Dec 13;13:239. doi: 10.1186/1745-6215-13-239. Factor de impacto: 2.5 (Q2)

Ramirez E, Laosa P, Guerra P, Duque B, Mosquera B, Borobia AM, Lei SH, Carcas AJ, Frias J. Acceptability and characteristics of 124 human bioequivalence studies with active Substances classified according to BCS. Br J Clin Pharmacol. 2010 Nov;70(5):694-702. Factor de Impacto: 2.958 (Q2)

S. Fudio; A.M. Borobia; E. Piñana; E. Ramírez; B. Tabarés; P. Guerra; A.J. Carcas; J. Frías. Evaluation of the influence of sex and cyp2c19 and cyp2d6 polymorphisms in the Disposition of citalopram Eur J Pharmacol. 2010 Jan 25;626(2-3):200-4. Factor de Impacto: 2.516 (Q2)

Borobia AM, Novalbos J, Guerra-López P, López-Rodríguez R, Tabares B, Rodríguez B, Abad-Santos F, Carcas AJ. Influence of sex and cyp2d6 genotype on mirtazapine disposition, evaluated in spanish healthy volunteers. Pharmacological Research. 2009 Jun;59(6):393-8 Factor de Impacto: 4.436 (Q1)

Unidad Central de Investigación Clínica y Ensayos Clínicos. Hospital Universitario La Paz

Annexes

Early Stages trials Publications (cont.):

L. Alonso, G. Nuno-Almeida, A. Campos, L. Hierro, L. Espinosa, P. Jara, A. Alonso-Melgar, M. García-Mesequer, HY Tong, E. Ramírez, AJ. Carcas. A limited sampling strategy (LSS) for tacrolimus monitoring after Advagraf administration in children with stable renal and liver transplantation. Basic & Clinical Pharmacology & Toxicology, 109(3). Impact Factor: 2.371 (Q3).

A. Campos, L. Espinosa, N. Medrano, A. Alonso Melgar, L. Alonso, G. Nino-Almeida, HY Tong, E. Ramírez, J. Frías Iniesta, AJ Carcas-Sansuán. Relative bioavailability of two tacrolimus formulations: Prograf (normal release) in children with kidney transplant. Basic & Clinical Pharmacology & Toxicology 2011;109(Suppl.3):33. Impact Factor: 2.371 (Q3).

Carcas-Sansuán AJ, Hierro L, Almeida-Paulo G, Frauca E, Tong HY, Díaz C, Piñana-Efire E, Frías J, Jara P. Conversion from Prograf to Advagraf in adolescents with stable liver transplants: comparative pharmacokinetics and one-year follow-up. Liver Transplantation. Impact Factor: 3.944 (Q1).

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

General Information

Who filled in this survey	Emiliano Calvo
E-mail contact (Phone number)	Emiliano.calvo@start.stoh.com 0034 91 756 78 25
Date of survey filling in	05-may-2015
Unit web address	www.startmadrid.com
Formal name of the unit	START Madrid-CIOCC
Postal address	START Madrid-CIOCC Oncology Phase I Unit_Floor 3 Hospital HM Universitario Sanchinarro Calle Oña 10, 28050 Madrid Spain

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Location

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Ownership

Ownership	START (South Texas Accelerated Research Therapeutics)
Established	2008
Linked hospital	Hospital HM Universitario Sanchinarro
Distance between linked hospital and Unit	Unit inside Hospital
Linked Ethics Committee (CEIC)	

Unit Manager

First and last names	Emiliano Calvo
Qualifications	MD, PhD
Medical specialty	Oncologist
Manager since	2008
E-mail and phone	Emiliano.calvo@start.stoh.com 0034 91 756 78 25

Short CV

Director of Clinical Research and Head of the START Madrid Programme of Early Clinical Development in Madrid, Spain, as well as Associate Professor of Oncology at the University CEU San Pablo, Madrid, and co-founder and president of Foundation Intheos (Investigational Therapeutics in Oncological Sciences)
He earned his M.D. in 1993 at the Universidad Autónoma de Madrid in Madrid, Spain and his Ph.D. in 2003 at the Universidad de Navarra in Pamplona, Spain, with highest commendation. He trained in Medical Oncology at the Clínica Universitaria de Navarra in Pamplona, Spain. He completed his Advanced Fellowship in Drug Development at the Cancer Therapy & Research Center's Institute for Drug Development in San Antonio, Texas, from 2003 to 2005, where he was a Senior Fellow and Clinical Investigator.
While working in the Medical Oncology Department at the Hospital Vall d'Hebron in Barcelona, Spain, Dr. Calvo headed the Brain Tumors Area from 2007 until 2008, the Genitourinary Tumor and Sarcoma Area from 2006 until 2008, the Pharmacokinetics Unit from 2005 until 2008, and was Co-Director and Senior Researcher of the Phase I Unit.

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Ownership

Unit Manager

Nombre y apellidos	Emiliano Calvo Aller

Short CV (cont.)

Dr. Calvo's major interests are the early clinical development of novel anticancer drugs, and pharmacokinetics.
Dr. Calvo has co-authored more than 100 scientific articles, abstracts and oncology book chapters, and is an international lecturer on drug development in multiple conferences and meetings, and a reviewer for several oncology journals He has also participated in approximately 90 clinical trials, two thirds of them in Phase I international studies, as an investigator. He serves as an ad-hoc reviewer of various oncology journals.
He is a faculty member of the Educational Committee of ESMO and a member of the Scientific Committee of the ESMO-ECCO (European CanCer Organisation) Multidisciplinary Congress, for the Drug Development track committee, and the non-prostate genitourinary committee, and is also currently a member of the Scientific Program Committee on the Developmental Therapeutics - Clinical Pharmacology & Experim Track of ASCO, and an international member of the peer review panel for the National Cancer Research Institute of Renal Clinical Studies Group of the United Kingdom. Also, he serves as a member of the Scientific Committee of the EORTC-NCI-AACR annual Symposium on Molecular Targets and Cancer Therapeutics on early clinical drug development in Oncology
Dr. Calvo is a member of the European Organization for Research and Treatment of Cancer, American Society of Clinical Oncology, the Sociedad Española de Oncología Médica, and the European Society of Medical Oncology.

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

January 2013, Certificate of Excellence in ICH GCP Guidelines and Oncology Phase I Unit Requirements by Comunidad Autónoma de Madrid (CAM).

Audits by regulatory agencies (last 3 years)

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **Yes**

Audits by sponsors (last 3 years)

March 2012, Roche by Covance (CRO)

June 2012, Pharmamar

August 2014, Janssen-Cilag

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? No

Would you follow the sponsor SOPs if requested: Yes

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 2

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Electronic Medical Records restricted access by user and password. Paper source documentation and study files are stored in a secure and restricted area of the Unit.

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Facilities

Year of Unit building	2008	Last Unit reform	2011
Usable space	250	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	6 treatment chairs	Number of beds	40
Beds distribution			
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	6 chairs	Number of armchairs suitable for subject monitoring	6
Owned kitchen	Hospital kitchen	Meals supervision by dietitian	yes
Dining-room available for volunteers	yes	Individual lockers available for volunteers	No, only at bedrooms
Relaxing room available for volunteers independent from the beds area			yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			yes
The emergency trolly has available suitable medications with immediate by controlled access			yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes, advanced		
Unit availability of an evacuation plan for volunteers in emergency situations			yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required	Private insurance		
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers			yes
Distance and time to get the former services	Unit inside the hospital		
Unit entrance/Exit door controlled	yes	Unit with Closed Circuit Television	no
Availability of an alternate electrical generating set that automatically works in case of a general system failure			yes

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Facilities

Unit distribution plan: Not available

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Staffing and Resources

Unit employees

Permanent staff 20 Fixed-term/contracted staff (internship, grant holders) Part-time collaborators

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1, 2, 3, 4, 5	
Co-investigator (physician)	2, 3, 4, 5	
Nurse	6, 7, 8, 9, 10, 11, 12,	
Monitor or CRA		
Pharmacist	18	
Biometry		
Data management	13, 14, 15, 16, 17	
Medical writing		
Pharmacokinetics		
Quality assurance	1, 6, 13, 18	
Project Management		
Finance		
Recruitment		
IT (informatics)		
Other (specify): Pharmacy technician, and Scheduler	19, 20	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician **X** Nurse

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	yes
The quality assurance activities are subcontracted by the Unit	sponsor
Availability of a specific area for drug storing and preparation of medications for the study	yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	yes
Perfusion pumps for intravenous treatment	yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Pharmacist, and Nursing for IV treatment **Preparation**: Pharmacist
Drug accountability procedures, such as reception, preparation and dispensing forms	yes
SOPs available for drug preparation and dispensing	yes
SOPs available for drawing and managing of biological fluids	yes
System or procedure used for samples identification	Identification according to SOP of local lab or central lab
Availability of a specific area for blood samples managing	yes
The former area or room has restricted access by key or code	yes
Number of centrifuges available	2
System for plasma/fluids samples storing	Freezer or refrigerator
Fridges and freezers available in the Unit	3
The Unit has its owned Bioanalytical Department	no
Availability of genotyping or fenotyping methods for participants	yes

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Services Capabilities

Data Management and software used (describe)	sponsor
Biometry or Statistical Analysis and software used (describe)	sponsor
Pharmacokinetic Analysis and software used (describe)	sponsor
Medical Writing and skilled languages	English and spanish

Owned archives in the same Unit building (describe)

Storage restricted area for owned archives

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

The company "Recall Management" is used to store archives for long period of time (the years required by law)

The study files are digitized and converted in a CD or web format	no
Project management	sponsor

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers	Patients	Yes, all tumor types
Other populations		

If the Unit has experience in oncology, detail kind of tumour and age groups

All	Solid tumour	All	Haematological tumour	X	Adults		Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All tumor types

Recruiting methods for healthy volunteers

Recruting methods for patients

We are a highly specialized Early Clinical Anticancer Drug Development Program (www.startmadrid.com), with experience in all type of early Phase 1 trials (FIH, FIC, Phase 1b, Phase 1b/2, DDI, Mass Balance, molecular-based selection targeted drugs, tumor type specific expansion cohorts, etc), and fully dedicated and trained/experienced staff for these type of studies, in all the required specialized positions.

We are integrated in the Centro Integral Oncologuico Clara Campal (CIOCC), an oncology center that sees 2500 new patients per year. 80% of our patients are reffered from CIOCC, and 20 % are reffered from other private hospitals in Spain or around the world.

We perform weekly phase I meetings to inform about availability of these studies to Oncologists Head of each tumor type in the Hospital

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	Yes (4)
Do you keep a paper or electronic database of volunteers? (describe)	no

Have you implemented any measure for avoiding the over-volunteering? (describe)

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	1	Pulsioximetry devices (number)	1	12-leads ECG devices (number)	2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	yes
Availability in the Unit of tests for assessing CNS drug effects	no
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	yes
Familiarity with Electronic Data Capture –EDC applied to clinical trials	yes
Experience in other kind of PD or PK evaluations not formerly collected	yes

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence				1		
First single-dose administration in humans	4	6	3	5	7	5
First multiple-dose administration in humans						
Drug interaction					3	
Food interaction					1	1
Special populations (Renal or liver impairment, elderly)		1				1
Proof of concept (Phase Ib or I/II)	8	9		5	6	8
Own research lines						
Others (specificying)			1			

Number of trials linked to a PEI (IND) submission | 2009 | 4 | 2010 | 6 | 2011 | 3 | 2012 | 5 | 2013 | 7 | 2014 | 5

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Small molecules, antibodies, virus, nanoparticules

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014): 75

Number of trials promoted by Spanish companies 4 Number of trials promoted by multinational companies 71

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 70 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 27

Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Annexes References of clinical trials publications

1. Lin C*, Calvo E*, Papadopoulos K, Patnaik A, Sarantopoulos J, Mita AC, Preston G, Mita M, Yeh I, O'Rourke P, Takimoto C, Tolcher A. Phase I Study of Cetuximab, Erlotinib, and Bevacizumab in Patients with Advanced Solid Tumors. Cancer Chemotherapy and Pharmacology. 2008 Sep 16 [Epub ahead of print] (*Both authors contributed equally to this article).

2. Lockhart AC, Calvo E, Tolcher AW, Rowinsky EK, Shackleton G, Morrison J-G, Rafi R, VerMeulen W, Rothenberg ML. A Phase I dose-escalation study of SR271425, an intravenously dosed thioxanthone analog, administered weekly in patients with refractory solid tumors. American Journal of Clinical Oncology Am J Clin Oncol. 2009 Feb;32(1):9-14, 2009.

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Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

Annexes References of clinical trials publications

9. Morelli MP, Calvo E, Ordoñez E, Wick MJ, Viqueira BR, Lopez-Casas PP, Bruckheimer E, Calles-Blanco A, Sidransky D, Hidalgo M. Prioritizing Phase I Treatment Options Through Preclinical Testing on Personalized Tumorgraft. J Clin Oncol. 2012 Feb 1;30(4):e45-8. Epub 2011 Dec 19.

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11. Larkin J, Esser N, Calvo E, Tsuchihashi Z, Fiedler U, Graeser R, Kim D.Efficacy of sequential treatment with sunitinib-everolimus in an orthotopic mouse model of renal cell carcinoma. Anticancer Res. 2012 Jul;32(7):2399-406

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(*Both authors contributed equally to this article)

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19. Brana I, Calles A, LoRusso PM, Yee LK, Puchalski TA, Seetharam S, Zhong B, de Boer CJ, Tabernero J, Calvo E. Carlumab, an anti-C-C chemokine ligand 2 monoclonal antibody, in combination with four chemotherapy regimens for the treatment of patients with solid tumors: an open-label, multicenter phase 1b study. Target Oncol. 2014 Jun 15

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Unidad de Ensayos START Madrid-CIOCC. Hospital HM Universitario Sanchinarro

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Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

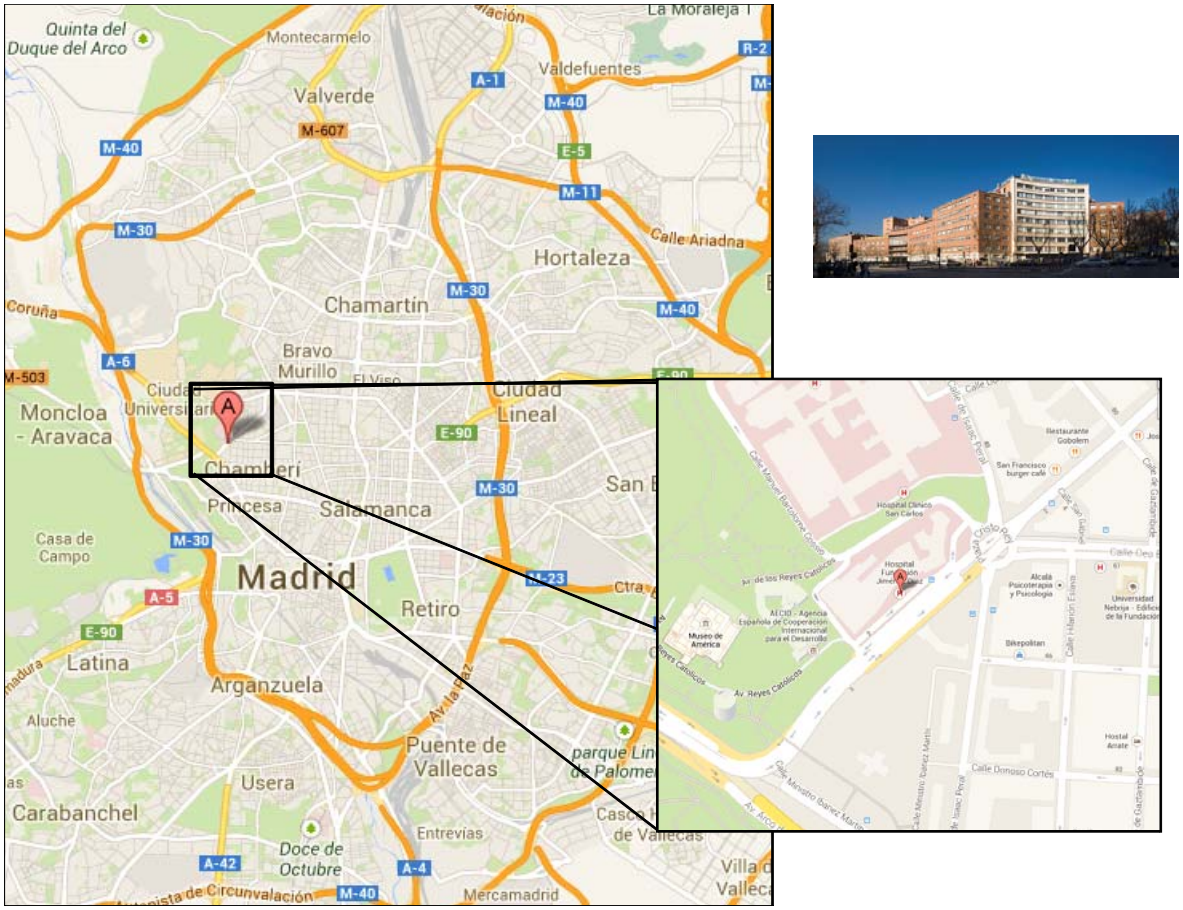
General Information

Who filled in this survey	Victor Moreno
E-mail contact (Phone number)	Victor.moreno@start.stoh.com
Date of survey filling in	25/05/2015
Unit web address	www.startmadrid.com
Formal name of the unit	START Madrid-FJD
Postal address	Av. Reyes Católicos, 2 28020 Madrid

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Location

START Madrid-FJD is located at the Fundación Jiménez Díaz, a National Public Health System general hospital



Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Ownership

Ownership	START Madrid-FJD
Established	2013
Linked hospital	Fundación Jiménez Díaz
Distance between linked hospital and Unit	Within.
Linked Ethics Committee (CEIC)	Comité Ético de Investigación Clínica del Instituto de Investigación Sanitaria Fundación Jiménez Díaz

Unit Manager

First and last names	Victor Moreno
Qualifications	MD, PhD
Medical specialty	Medical Oncology
Manager since	October 2013
E-mail and phone	Victor.moreno@start.stoh.com

Short CV

2013- Current :Director Clinical Researcher Phase I Clinical Trials Unit
START-Madrid Fundación Jiménez Díaz.
CNIO Clinical Researcher, Gastrointestinal Tumors Unit.

Jun 2011- Sept 2013: Consultant in Medical Oncology.
Gastrointestinal Cancer, Neuro-oncology and Phase I Clinical Trials.
La Paz University Hospital. Medical Oncology Service. Madrid. Spain

Jan 2010 - May 2011: Clinical Fellow at Drug Development Unit.
Royal Marsden Hospital, Sutton, Surrey. United Kingdom.
GMC reference number: 7053371

May 2009- Dec 2009: Consultant in Medical Oncology
Hospital La Paz. Medical Oncology Service. Madrid. Spain

May 2005-May 2009: Medical Oncology Residency program.
Hospital La Paz. Medical Oncology Service. Madrid. Spain

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

Consejería de Sanidad de la Comunidad de Madrid. May 2014 and May 2015.

Audits by regulatory agencies (last 3 years)

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? Yes

Audits by sponsors (last 3 years)

Do you follow your own Standard Operating Procedures (SOPs)? Yes Do you supply with a SOP copy to a sponsor if requested? No

Would you follow the sponsor SOPs if requested: Yes

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 1

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Facilities

Year of Unit building	1964	Last Unit reform	2013
Usable space	331 m^2	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	30-40	Number of beds	3
Beds distribution	Beds are located in the Oncology ward if needed.		
Beds distribution allows a complete and continuous visual control by nurses			No
Number of bed with intensive or continuous monitoring	0	Number of armchairs suitable for subject monitoring	6
Owned kitchen	Yes	Meals supervision by dietitian	Yes
Dining-room available for volunteers	No	Individual lockers available for volunteers	No
Relaxing room available for volunteers independent from the beds area			No
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Yes		
Distance and time to get the former services	2 floors away		
Unit entrance/Exit door controlled	Yes	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Facilities

Unit distribution plan:

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Staffing and Resources

Unit employees

Permanent staff Fixed-term/contracted staff (internship, grant holders) Part-time collaborators

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)		4
Nurse	3	
Monitor or CRA		
Pharmacist	1	1
Biometry		
Data management	2	1
Medical writing	0	
Pharmacokinetics	0	
Quality assurance	0	
Project Management	1	
Finance	2	
Recruitment		
IT (informatics)	1	
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

THIS UNIT IS ONLY FOR ONCOLOGY PATIENTS.

Physician Nurse

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	YES
The quality assurance activities are subcontracted by the Unit	NO
Availability of a specific area for drug storing and preparation of medications for the study	YES
The former area or room has restricted access by key or code	YES
Laminar flow chamber availability for preparation of parenteral treatments	YES
Perfusion pumps for intravenous treatment	YES
Who is the responsible for drug preparation and dispensing	**Dispensing:** PHARAMCIST/NURSE **Preparation**: PHARMACIST
Drug accountability procedures, such as reception, preparation and dispensing forms	YES
SOPs available for drug preparation and dispensing	YES
SOPs available for drawing and managing of biological fluids	YES
System or procedure used for samples identification	
Availability of a specific area for blood samples managing	YES
The former area or room has restricted access by key or code	YES
Number of centrifuges available	2
System for plasma/fluids samples storing	YES
Fridges and freezers available in the Unit	2 FRIDGES ONE -20 AND ONE -80
The Unit has its owned Bioanalytical Department	NO
Availability of genotyping or fenotyping methods for participants	YES. MOLECULAR DIAGNOSIS FOR CANCER

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Services Capabilities

Data Management and software used (describe)

EMR Varian. Part 11 compliant.

Biometry or Statistical Analysis and software used (describe)

No

Pharmacokinetic Analysis and software used (describe)

No

Medical Writing and skilled languages

Owned archives in the same Unit building (describe)

No

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

The study files are digitized and converted in a CD or web format	YES
Project management	YES

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers Patients Oncology Patients

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

YES Solid tumour YES Haematological tumour YES Adults NO Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

ALL SOLID TUMORS AND HEMATOLOGICAL MALIGNANCIES

Recruiting methods for healthy volunteers

NO

Recruting methods for patients

LOCAL PATIENTS AND REFERRALS FROM ANY PUBLIC HOSPITAL IN MADRID

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	3
Do you keep a paper or electronic database of volunteers? (describe)	YES. All medical records are electronic.
Have you implemented any measure for avoiding the over-volunteering? (describe)	Only cancer patients are treated in the Unit.

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	2	Pulsioximetry devices (number)	2	12-leads ECG devices (number)	2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	YES
Availability in the Unit of tests for assessing CNS drug effects	YES
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	YES
Familiarity with Electronic Data Capture –EDC applied to clinical trials	YES
Experience in other kind of PD or PK evaluations not formerly collected	YES

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						
First multiple-dose administration in humans					1	3
Drug interaction						2
Food interaction						1
Special populations (Renal or liver impairment, elderly)						1
Proof of concept (Phase Ib or I/II)						8
Own research lines						1
Others (specificying)						

Number of trials linked to a PEI (IND) submission 2009 2010 2011 2012 2013 1 2014 15

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

New chemotherapeutic agents. New molecularly targeted agents. Immunooncology agents. Antibody drug conjugates. Nanoparticles.

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 1 Number of trials promoted by multinational companies 14

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 8 weeks

Number of Early Stages trials performed in the Unit and published in the last 4 years 2

Unidad de Fase I Oncología FJD-START. Hospital Universitario Fundación Jiménez Díaz

Annexes

START (South Texas Accelerated Research Therapeutics) Madrid refers to the international program START of Oncology Early Clinical Drug Development, located in Madrid, Spain.
The mission of START is to accelerate the development of new anticancer drugs with the purpose of improving quality of life and survival for patients with cancer. With increased international presence, START has taken the first step toward establishing an around-the-clock presence in its development of anticancer agents.
START Madrid shares the same SOPs, highly specialized organization, central budgeting, efficient and proactive IRBs, IT systems, expert and fully dedicated staff, as it occurs in the original START in San Antonio (USA).
START Madrid has currently two sites located in Madrid, Spain's capital city of six million residents: START Madrid-CIOCC, since 2008, and START Madrid-FJD, launched in 2013. START Madrid-FJD is located in a National Health Public System Hospital, and START Madrid-CIOCC is located in a Private Hospital. Both sites are synergistic, because while START Madrid-CIOCC treats patients that belong to the private health system, START Madrid-FJD treat those from the public health system, and, all together, provide us with a total population base of around 5,000 new Oncology patients taking together the Medical Oncology departments of both Cancer Centers where our START Madrid units are located, which potentiate recruitment possibilities in any indication within our excellence quality environment for Ph1 studies.
This way, START Madrid is able to provide all patients from Madrid and abroad with access to our innovative drugs, regardless of their health coverage system, without exceptions.
START Madrid is an institutional priority of Fundación Jiménez Díaz (FJD), integrated within the Center's major Oncology Group. As a consequence, START Madrid-FJD is able to obtain daily referrals from these Oncologists consistent with selection criteria of our active studies. In addition, there are weekly Phase 1 meetings with the general oncology group, at which time available slots are noted and recruitment of eligible patients is promoted.
About two thousand new cancer patients come to the Oncology Department of FJD every year. Furthermore, **FJD is a referral Hospital for two other Centres located in Madrid surrounding areas (Rey Juan Carlos Hospital at Mosotoles and Infanta Elena at Valdemoro) that share common management by IDC-Salud.** In addition, START Madrid-FJD sees patients referred directly from other public hospitals of Spain to be considered for phase I clinical trials.

FOR MORE INFORMATION PLEASE VISIT: www.startmadrid.com

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

General Information

Who filled in this survey	Tatiana Massarrah Sanchez
E-mail contact (Phone number)	tatiana.massarrah@salud.madrid.org// +34 91 4269395
Date of survey filling in	03/06/2015
Unit web address	
Formal name of the unit	Clinical&Traslational Medical Oncology Research Unit
Postal address	C/Maiquez 7. Pabellón Oncológico Principe de Asturias. Planta -1 Madrid 28.009

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Location

Clinical&Traslational Medical Oncology Research Unit

The Unit is divided in two areas:
Zone A: Study Coordinators, Data Entries, Data protection and Medical records custody, Investigators Offices, Clinical Trial Nursing Offices, Monitoring room. Located floor -1
Zone B: Patients area (drug administration, blood samples, vital signals monitoring, ECG, etc), waitning-dinning room, Toilets, assessment room. Located floor B.

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Ownership

Ownership	Public Institution
Established	2011
Linked hospital	Hospital General Universitario Gregorio Marañón/Universidad Complutense de Madrid
Distance between linked hospital and Unit	At the same Hospital
Linked Ethics Committee (CEIC)	CEIC. Fundación para la Investigación Biomédica.Hospital Gregorio Marañón.

Unit Manager

First and last names	Dr.Miguel Martín Jimenez
Qualifications	Professor of Medicine Head, Medical Oncology Service
Medical specialty	Medical Oncology
Manager since	Since 2010
E-mail and phone	mmartin@geicam.org +34 91 586 8115

Short CV

Prof. Miguel Martin is currently Head of the Medical Oncology Service at the Hospital General Universitario Gregorio Marañón in Madrid (Spain).
He is also a Professor of Medical Oncology at the Complutense University of Madrid.
Since 1990, Prof. Martin is fully devoted to breast cancer research and treatment.
His main areas of research are systemic treatment of breast cancer, where he has led m national and and international clinical trials, and genomic/molecular characterization of breast cancer.
Prof. Martin is the Chairman of GEICAM (Spanish Group for Breast Cancer Research), a cooperative network involving more than 170 Spanish institutions.
He is a founder member of CIRG -Cancer International Research Group-, an International Cooperative Group (now named TRIO).

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Ownership

Unit Manager

First and last names	Dr.Miguel Martín Jimenez

Short CV (cont.)

Since 2001, Prof. Martin serves as a member of the Board of Directors and of the Scien Steering Committee of
TRIO (Translational Research In Oncology), an international not-for-profit clinical research organization of 2000 investigators and 450 cancer centers in over 45 differ countries.
Prof. Martin has published more than 250 articles in peer- reviewed medical journals.
He is a full member of several scientific societies, including ASCO (American Society of Medical Oncology), ESMO (European Society for Medical Oncology), SEOM (Sociedad Española de Oncología Médica), ASBD (American Society of Breast Diseases), among others.

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

netGEICAM, Novartis, Comunidad de Madrid acreditation on going

Audits by regulatory agencies (last 3 years)

NO

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **YES**

Audits by sponsors (last 3 years)

NO

Do you follow your own Standard Operating Procedures (SOPs)? YES Do you supply with a SOP copy to a sponsor if requested? YES

Would you follow the sponsor SOPs if requested: YES

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 3-4

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

GCP regulations are followed. Protected data from patients are safe under the law "Ley Orgánica 15/99 de 13 de diciembre"

All docs are kept at the Unit, locked into cupboards and classified by pathologies

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

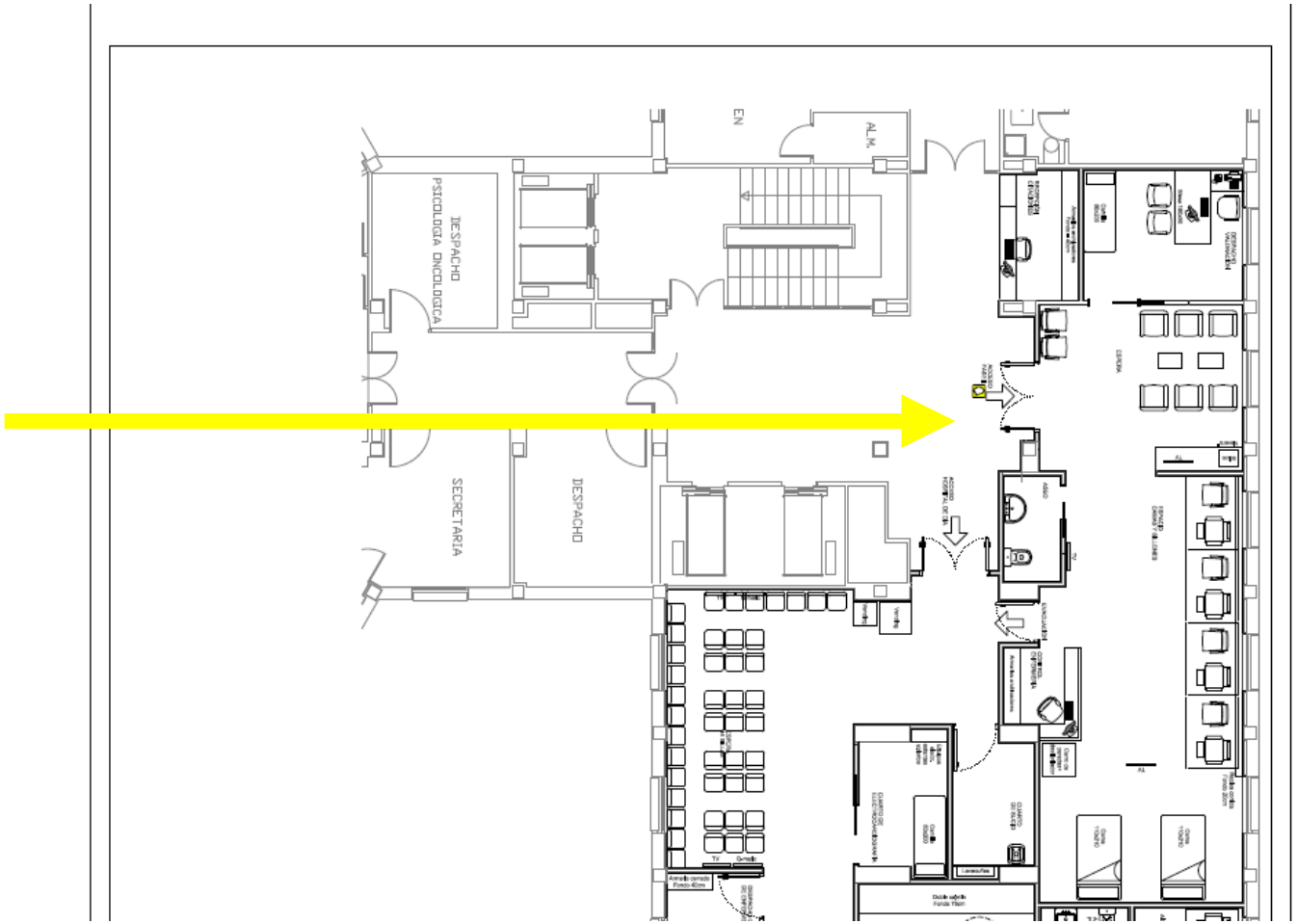
Facilities

Year of Unit building	1968	Last Unit reform Bulding (2013-14), Unit on going	
Usable space	250m2	The Unit building is separate from the linked hospital	NO
Number of CTs the unit could perform simultanously	20	Number of beds	6
Beds distribution	1 room with 4 recliners chairs and an enclosed room with two beds. There are 4 additional beds in case of hospitalitation.		
Beds distribution allows a complete and continuous visual control by nurses			YES
Number of bed with intensive or continuous monitoring	2	Number of armchairs suitable for subject monitoring	4
Owned kitchen	YES	Meals supervision by dietitian	NO
Dining-room available for volunteers	YES	Individual lockers available for volunteers	NO
Relaxing room available for volunteers independent from the beds area			YES
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			YES
The emergency trolly has available suitable medications with immediate by controlled access			YES
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)			
Unit availability of an evacuation plan for volunteers in emergency situations			YES
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			NO
Volunteers/patients healthcare would be covered by the national or the regional health system if required			YES
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	ICU, AND INTERMEDATE CARE UNIT		
Distance and time to get the former services	5-7’		
Unit entrance/Exit door controlled	NO	Unit with Closed Circuit Television	YES
Availability of an alternate electrical generating set that automatically works in case of a general system failure			

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Facilities

Unit distribution plan:



Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Staffing and Resources

Unit employees

Permanent staff 12 Fixed-term/contracted staff (internship, grant holders) 8 Part-time collaborators

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	3	0
Co-investigator (physician)	7	
Nurse	7	
Monitor or CRA		
Pharmacist		
Biometry	3	
Data management		
Medical writing	0	
Pharmacokinetics	1	
Quality assurance	1	
Project Management	1	
Finance	1	
Recruitment	9	
IT (informatics)	2	
Other (specify): CTA, psychologist, etc	Psychologist	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

Physician Nurse

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	YES
The quality assurance activities are subcontracted by the Unit	NO
Availability of a specific area for drug storing and preparation of medications for the study	YES
The former area or room has restricted access by key or code	YES
Laminar flow chamber availability for preparation of parenteral treatments	YES
Perfusion pumps for intravenous treatment	YES
Who is the responsible for drug preparation and dispensing	**Dispensing:** PHARMACY **Administration**: Nursing **Preparation**: PHARMACU
Drug accountability procedures, such as reception, preparation and dispensing forms	YES
SOPs available for drug preparation and dispensing	YES
SOPs available for drawing and managing of biological fluids	YES
System or procedure used for samples identification	ID AND STUDY CODE
Availability of a specific area for blood samples managing	YES
The former area or room has restricted access by key or code	YES
Number of centrifuges available	4
System for plasma/fluids samples storing	FREEZERS
Fridges and freezers available in the Unit	1 AND 4
The Unit has its owned Bioanalytical Department	YES IHQ
Availability of genotyping or fenotyping methods for participants	YES PAM50

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Services Capabilities

Data Management and software used (describe)	SPSS
Biometry or Statistical Analysis and software used (describe)	YES
Pharmacokinetic Analysis and software used (describe)	NO
Medical Writing and skilled languages	YES. ENGLISH
Owned archives in the same Unit building (describe)	YES.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

All documents will be kept for 15 years

The study files are digitized and converted in a CD or web format	NO
Project management	YES

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Study Participants

Kind of participants included in clinical trials performed in the Unit

	Healthy volunteers	Patients	X
	Other populations		

If the Unit has experience in oncology, detail kind of tumour and age groups

X	Solid tumour	Haematological tumour	Adults	Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Breast, Lung, Ovary, Cervical, Próstate, Urotelial, Colorrectal, esofagus, gástric, hepátic, páncreas, Neuroendocrine, Head-Neck, Melanoma,Basocelular, CNS, Sarcoma.

Recruiting methods for healthy volunteers

Recruting methods for patients

From consulting at the hospital, and referral from other hospitals

Do you have sugery rooms available for screening (separated from the in-house area)? (number) YES

Do you keep a paper or electronic database of volunteers? (describe)

Have you implemented any measure for avoiding the over-volunteering? (describe)

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	2	Pulsioximetry devices (number)	3	12-leads ECG devices (number)	2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	YES
Availability in the Unit of tests for assessing CNS drug effects	NO
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	NO
Familiarity with Electronic Data Capture –EDC applied to clinical trials	YES
Experience in other kind of PD or PK evaluations not formerly collected	YES
Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted	NO

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence					1	
First single-dose administration in humans						0
First multiple-dose administration in humans						2
Drug interaction						2
Food interaction					1	
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)			1	2	2	3
Own research lines						
Others (specificying)						

Number of trials linked to a PEI (IND) submission	2009	2010	2011	2012	2013	2014	2

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

EGFR Inhibitors, ANTI-HER 2, SMO Inhibitors, CXCR4 inhibitor, anti-NaPi2b

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies

Number of trials promoted by multinational companies 11

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60 days

Number of Early Stages trials performed in the Unit and published in the last 4 years

Unidad de Investigación Clínica y Traslacional de Oncología Médica. HGU Gregorio Marañón

Annexes References of clinical trials publications

"A phase I study of LDE225 in combination with docetaxel in patients with triple negative (TN) advanced breast cancer (ABC): GEICAM/2012-12 (EDALINE study)**"** Miguel Martín et al., **San Antonio Breast Cancer Symposium, December 9- 13, 2014 in San Antonio, Texas**.

Interim Results from a Phase 1b/2a Study of Trastuzumab Emtansine and Docetaxel, With and Without Pertuzumab, in Patients With HER2-Positive Locally Advanced or Metastatic Breast Cancer . Martin M,[1] Garcia-Sáenz JA,[2] Dewar JA,[3] Albanell J,[4] Limentani SA,[5] Strasak A,[6] Patre M,[6] Branle F,[6] Fumoleau P[7] San Antonio breast cancer Symposium 2012

Unidad de Investigación Clínica - Clínica Universitaria de Navarra CUN

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

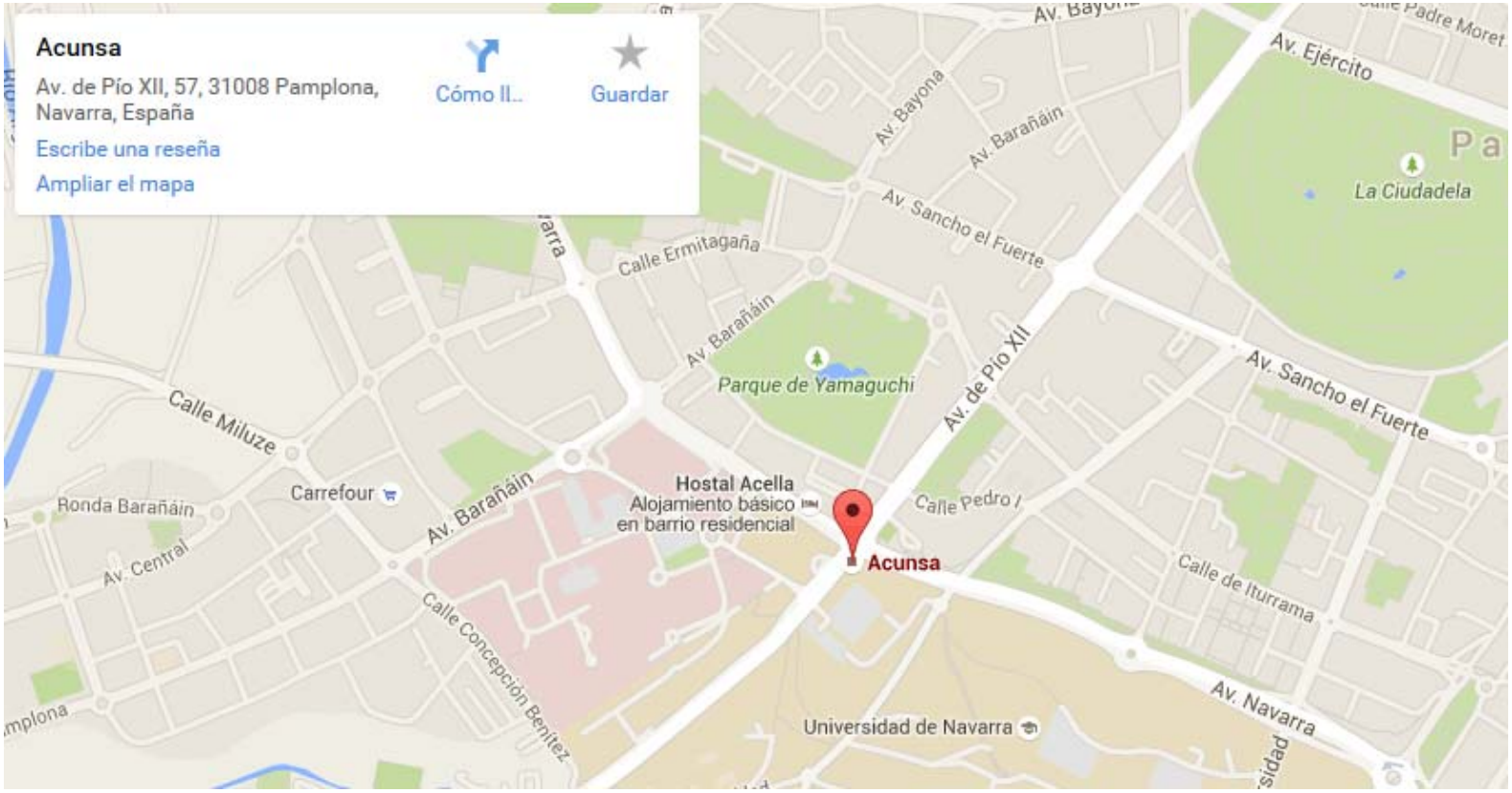
General Information

Who filled in this survey	Belén Sádaba
E-mail contact (Phone number)	bsadaba@unav.es (34 948 296 695)
Date of survey filling in	15/05/2015
Unit web address	http://www.cun.es/nuestros-profesionales/servicios-medicos/unidad-investigacion-clinica
Formal name of the unit	Clinical Research Unit – Clínica Universidad de Navarra
Postal address	Avda. Pío XII 36 31008 Pamplona (Spain)

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Location

Clínica Universidad de Navarra
7º floor – Phase II
Avda. Pío XII 36
31008 Pamplona (Spain)



Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Ownership

Ownership	Clínica Universidad de Navarra
Established	1988
Linked hospital	Clínica Universidad de Navarra
Distance between linked hospital and Unit	It is located in the same hospital
Linked Ethics Committee (CEIC)	CEIC de Navarra

Unit Manager

First and last names	JOSE R. AZANZA
Qualifications	Doctor in Medicine
Medical specialty	Clinical Pharmacology
Manager since	1999
E-mail and phone	jrazanza@unav.es (34 948 296 695)

Short CV

Head of Clinical Pharmacology Service (Clínica Universidad de Navarra)

Director of Clinical Research Unit (Clínica Universidad de Navarra)

Professor of Clinical Pharmacology (School of Medicine and School of Nursing), University of Navarra. Pamplona, Spain. Acredited by the Ministry of Education (Spanish National Agency for Quality Assessment and Accreditation - ANECA).

Academic Division President of Official School of Doctors of Navarra.

President of Continued Medical Training Commission. Government of Navarra.

He has been a part of a work-team in some financed research projects in competitive calls.

As a researcher, he has also participated in more than 100 clinical trial, especially in phases I in healthy volunteers and in phases III in patients.

Director of 7 doctoral dissertations and examiner of more than 25 ones.

311 scientific articles, 106 communications presented to National and International Medical Congresses, 35 books, 115 chapters of books written in collaboration.

400 lectures and 70 practical university teaching courses.

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

No the Clinical Research Unit by itself, but the hospital (Clinica Universitaria de Navarra) as a Research Centre is recognised by the "Joint Commission International".

Audits by regulatory agencies (last 3 years)

Government of Navarra - 2013

Spanish Agency for Medications and Healthcare Products (AEMPS) - 2010

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? **YES**

Audits by sponsors (last 3 years)

YES - 2013

Do you follow your own Standard Operating Procedures (SOPs)? YES Do you supply with a SOP copy to a sponsor if requested? NO

Would you follow the sponsor SOPs if requested: YES

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: It depends on the CTs

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

The Clinica Universidad de Navarra uses a process on protection of personal data in accordance with the Organic Law 15/99. There is a medical history computerized system with sign-in register using a individual code. Everybody has a profile, according to which a clearly defined access is allowed. On-line user can only Access the medical history of his patients.
Personal data which are in a specific server (out of the medical history computerized system) also have a sign-in register with a set profile depending on the accessible information. Anonymous personal data are in Clinical Research Unit (CRU) location or CRU computers which are accessed by password. Label samples don't have personal data. Archived documentation is identified by a code.

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Facilities

Year of Unit building	1977	Last Unit reform	2012
Usable space	265 m^2	The Unit building is separate from the linked hospital	NO
Number of CTs the unit could perform simultanously	3-4	Number of beds	8

Beds distribution: A big room with 8 beds. It would be possible to use hospitalization room or exploratory room if necessary.

Beds distribution allows a complete and continuous visual control by nurses			YES
Number of bed with intensive or continuous monitoring	8	Number of armchairs suitable for subject monitoring	6
Owned kitchen	NO	Meals supervision by dietitian	YES
Dining-room available for volunteers	YES	Individual lockers available for volunteers	YES
Relaxing room available for volunteers independent from the beds area			YES
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			YES
The emergency trolly has available suitable medications with immediate by controlled access			YES
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)			BASIC LIFE SUPPORT
Unit availability of an evacuation plan for volunteers in emergency situations			YES
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			YES
Volunteers/patients healthcare would be covered by the national or the regional health system if required			UNKNOWN

Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers: Clínica Universidad de Navarra services (Emergency department, ICU)

Distance and time to get the former services: ICU is in the 3rd floor, Emergency department is in the ground floor. There is a emergency system through beeper and emergency intervention team on duty.

Unit entrance/Exit door controlled	YES	Unit with Closed Circuit Television	NO
Availability of an alternate electrical generating set that automatically works in case of a general system failure			YES

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Facilities

Photo-book of facilities

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Staffing and Resources

Unit employees

Permanent staff 6 Fixed-term/contracted staff (internship, grant holders) Part-time collaborators 4

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	2	
Co-investigator (physician)	If necessary	
Nurse	1	
Monitor or CRA	1	
Pharmacist	1 (collaborator)	
Biometry	1	
Data management	2	
Medical writing	1	
Pharmacokinetics	1	
Quality assurance	1	
Project Management	1	
Finance	1 (collaborator)	
Recruitment	2	
IT (informatics)	2 (collaborator)	
Other (specify): CTA, psychologist, etc	If necessary	

The same person can carry out more than a task

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

Physician **X** Nurse

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	YES, Joint Commission International
The quality assurance activities are subcontracted by the Unit	YES
Availability of a specific area for drug storing and preparation of medications for the study	YES
The former area or room has restricted access by key or code	YES
Laminar flow chamber availability for preparation of parenteral treatments	YES (Pharmacy Service)
Perfusion pumps for intravenous treatment	YES
Who is the responsible for drug preparation and dispensing	**Dispensing:** If necessary, Pharmacy Service is used. When pharmaceutical products don't need special conditions the investigator is responsible for preparation and dispensation. **Preparation**:
Drug accountability procedures, such as reception, preparation and dispensing forms	YES
SOPs available for drug preparation and dispensing	YES
SOPs available for drawing and managing of biological fluids	YES

System or procedure used for samples identification

Clinical analysis samples (biochemistry, haematology …) are identified by a barcode and CUN central laboratory process them through the medical history computerized system. Other biological analysis samples (drug quantification ….) are identified by the volunteer code, study code, and blood draw date/hour.

Availability of a specific area for blood samples managing	YES
The former area or room has restricted access by key or code	YES
Number of centrifuges available	1, no cool – 3, cool
System for plasma/fluids samples storing	Aliquoted samples are frozen in boxes
Fridges and freezers available in the Unit	FRIDGES: 2 – FREEZERS: 5 (3 of them until -70ºC)
The Unit has its owned Bioanalytical Department	NO. The sponsor chooses clinical analysis laboratory.
Availability of genotyping or fenotyping methods for participants	NO. The Universidad de Navarra have the methods.

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Services Capabilities

Data Management and software used (describe)	YES. Excell, SPSS, Stata, Phoenix Winnonlin.
Biometry or Statistical Analysis and software used (describe)	YES. SPSS, Stata.
Pharmacokinetic Analysis and software used (describe)	YES. Non-compartmental, Phoenix Winnonlin.
Medical Writing and skilled languages	Spanish and English.
Owned archives in the same Unit building (describe)	NO. CRU only stores documentation of studies which are being held at the moment and electronic documentation. The main storage is subcontracted to ATECNA.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Investigator archive, CRF copies, final report, clinical patients data and analytical data are sent to the subcontracted archive.

The study files are digitized and converted in a CD or web format	YES
Project management	NO in particular. It is a task that depends on the CRU's Director.

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Study Participants

Kind of participants included in clinical trials performed in the Unit

X Healthy volunteers X Patients

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour X Haematological tumour X Adults X Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

Working together with the Oncology and Haematology Departments, the CRU could access any kind of cancer.

Recruiting methods for healthy volunteers

The CRU has a specific database, with personal data given by volunteers, when fullfilling a CRU card. CRU activity become known by volunteers word of mouth. Up to now it hasn't been necessary advertise for recruitment process. Using the database according to the needs of each study, volunteers are contacted by phone.

Recruting methods for patients

CRU collaborates with different medical departments, depending on patients needs.

Do you have sugery rooms available for screening (separated from the in-house area)? (number)	YES, 4 (1 in the CRU and 3 in the central investigation area)
Do you keep a paper or electronic database of volunteers? (describe)	YES

Name, surname, age, date of birth, telephone, health history (smoker, allergies, blood donation, weight, height, regular medication….), previous studies as a volunteer, update database.

Have you implemented any measure for avoiding the over-volunteering? (describe)	YES

It is the only CRU in the autonomous community, so we have no problems because in the database is stated every clinical research and the dates.

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	9	Pulsioximetry devices (number)	8	12-leads ECG devices (number)	1 + 8 monitors

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules: NO, count on Cardiology Department

Availability in the Unit of tests for assessing CNS drug effects

Sometimes we have worked with Neurology, Neurophysiology and Nuclear Medicine Departments, with whom the CRU could do these kind of studies. We also have experience on collaborations with Psychiatry Department.

Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports: NO, the Universidad de Navarra could take over this activity.

Familiarity with Electronic Data Capture –EDC applied to clinical trials: NO

Experience in other kind of PD or PK evaluations not formerly collected

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence	5	6	6	3	3	6
First single-dose administration in humans			1	1		
First multiple-dose administration in humans						1
Drug interaction						
Food interaction			1	1		
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)	1					
Own research lines						
Others (specificying)		2	2	2	1	

Number of trials linked to a PEI (IND) submission	2009	2010	2011	2012	2013	2014
				2		1

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Mesenchymal stem cells, anti-inflammatory, zinc, cough suppressant, analogous to interleukin, antihistamines, synthetic oligonucleotide double–stranded RNA (dsRNA), benzodiazepines, memantine, donepezil.

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies

Number of trials promoted by multinational companies

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 45 days

Number of Early Stages trials performed in the Unit and published in the last 4 years 4

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Experience

Published trials

ORIGINALS

Sangro B, Mazzolini G, Ruiz M, Ruiz J, Quiroga J, Herrero I, Qian C, Benito A, Larrache J, Olagüe C, Boan J, Peñuelas I, Sádaba B, Prieto J. A phase I clinical trial of thymidine kinase-based gene therapy in advanced hepatocellular carcinoma. Cancer Gene Ther 2010; 17 (12): 837-43

Moreno-Montañés J, Sádaba B, Ruz V, Gómez-Guiu A, Zarranz J, González MV, Pañeda C, Jimenez AI. Phase I clinical trial of SYL040012, a small interfering RNA targeting β-adrenergic receptor 2, for lowering intraocular pressure. Mol Ther. 2014; 22(1): 226-232. doi: 10.1038/mt.2013.217. Epub 2013 Sep 12.

Sadaba B, Barrio A, Campanero MA, Azanza JR, Gomez-Guiu A, Lopez-Picazo JM, Martin Algarra S, Guillen Grima F, Blanco Prieto M, Perez-Gracia JL, Gurpide A. Randomized Pharmacokinetic Study Comparing Subcutaneous and Intravenous Palonosetron in Cancer Patients Treated with Platinum Based Chemotherapy. Plosone: 2014; 9 (2): e89747; Doi: 10.1371/journal.pone.0089747

Sádaba B, Gómez-Guiu A, Azanza J.R. Ortega I, Valiente R. Oral availability of Bilastine. Clin Drug Invest 2013, 33(5): 375-81 DOI: 10.1007/s40261-013-0076-y

POSTER

Sádaba B, Ruiz B, Ruiz J, Insa R. A phase I clinical trial of topical peptide P144 TGF-□1 inhibitor in healthy volunteers. 67th Annual Meeting of the American Academy of Dermatology. San Francisco. CA. 6-10 marzo 2009. Poster 1201.

González V, Sádaba B, Moreno-Montañes J, Velázquez A, Gómez-Guiu A, Ruz V, Jiménez AI. SYL1001 for treatment of ocular discomfort in dry eye. Safety and tolerance phase I study. 2012 ARVO Annual Meeting (Association for Research in Vision and Ophthalmology) May 6-10, 2012. Fort Lauderdale, Florida (USA). Poster A43.

Arévalo E, Del Barrio A, Sádaba B, Campanero MA, Azanza JR, Gúrpide A, López-Picazo JM, Martín Algarra S, Pérez Gracia JL. Evaluation of subcutaneous (SC) versus intravenous (IV) palonosetron in cancer patients treated with platinum-based chemotherapy: a randomized pharmacokinetic assay. 37th ESMO Congress. Viena (Austria), 28 septiembre – 2 octubre 2012. Póster: 1577P. Publicado en Annals of Oncology 2012; 23 (Supl. 9).

Unidad de Investigación Clínica - Clínica Universitaria de Navarra

Annexes

Unidad de Ensayos Clínicos IIS Bioaraba. Hospital Universitario de Araba

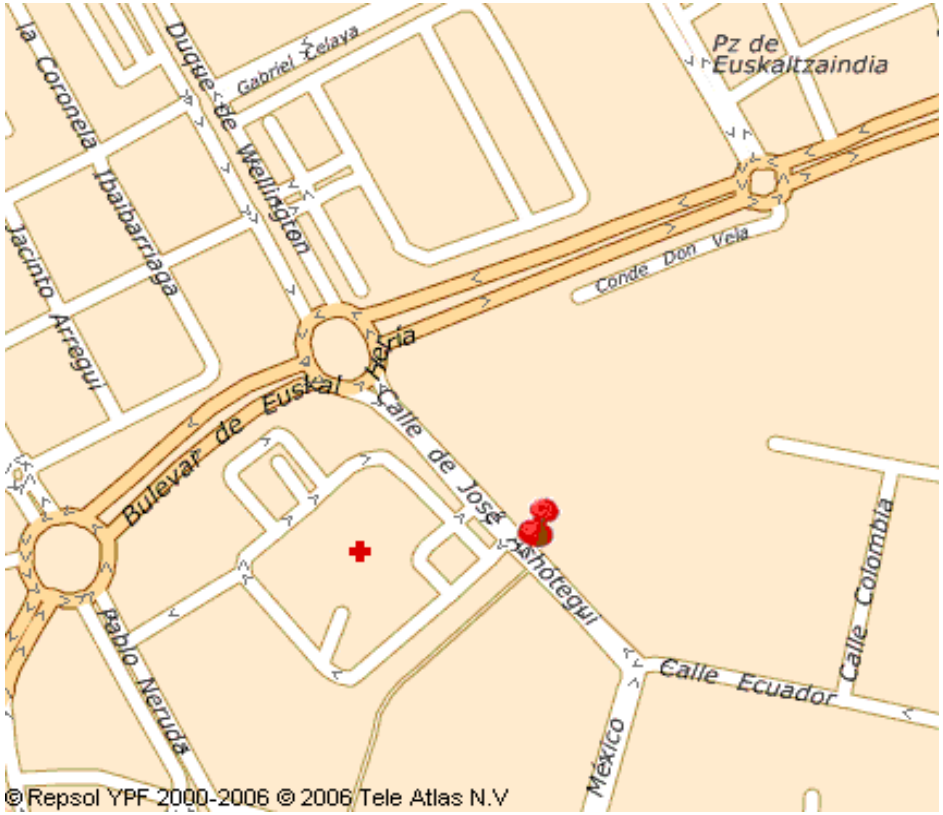
Unidad de Ensayos Clínicos I I S Bioaraba. Hospital Universitario de Araba

General Information

Who filled in this survey	Jose Medrano Laporte
E-mail contact (Phone number)	Jose.medranolaporte@osakidetza.eus Phone number: +34 945007437
Date of survey filling in	10/06/2015
Unit web address	www.bioaraba.org
Formal name of the unit	Health Research Institute Bioaraba Clinical Trials Unit
Postal address	Hospital Universitario Araba (HUA)-Sede Txagorritxu, 4ºC C/José Atxotegui 01009 Vitoria-Gasteiz

Unidad de Ensayos Clínicos IIS Bioaraba. Hospital Universitario de Araba

Location



Unidad de Ensayos Clínicos I I S Bioaraba. Hospital Universitario de Araba

Ownership

Ownership	Health Research Institute Bioaraba: formed by Universitary Hospital of Araba; Tecnalia Corporation and University of the Basque Country.
Established	1997
Linked hospital	Universitary Hospital of Araba (HUA)
Distance between linked hospital and Unit	The unit is included in the hospital
Linked Ethics Committee (CEIC)	CREC of HUA and CREC-Euskadi

Unit Manager

First and last names	Jose Medrano Laporte
Qualifications	Physician
Medical specialty	Internal medicine
Manager since	2015
E-mail and phone	Jose.medranolaporte@osakidetza.eus Phone number: +34 945007437

Short CV

Jose Medrano is a physician specialist in Internal Medicine by the "Universidad Autónoma de Madrid" and specialist in Infectious Diseases and tropical medicine by the "Université ParisYvellines" (France). He mainly acquired clinical experience in infectious diseases and clinical virology at Hospital Paris Bichat (France) and Hospital Carlos III (Madrid). In these centres, he took care of patients and had teaching responsibilities, mainly at Université ParisBichat. He is currently in charge of 2 student´s PhD. His clinical research skills are proved by more than 20 publications in peer reviews journals and by the following degrees: Diplôme Universitaire (DU) Methodes en recherche cliniques (Methods in clinical research) at International school of public health (ISPED) Bordeaux; DU Gestion des bases de données en santé (data management in health sciences), ISPED; DU Méthodes statitisques en epidemiologie et recherche clinique (biostatistics), ISPED;

Unidad de Ensayos Clínicos IIS Bioaraba. Hospital Universitario de Araba

Ownership

Unit Manager

First and last names	Jose Medrano Laporte

Short CV (cont.)

Diploma de Aplicaciones Web Dinámicas Aplicadas a la Enseñanza (web programing), Distance Educational National University (UNED) and Máster en Sida y Hepatitis V ricas, Universidad Complutense de Madrid. PUBLICATIONS: Principal Investigator has published during the last 4 years a dozen of prognostic studies at Hospital Carlos III concerning liver fibrosis progression and HCV clearance in HIVHCV coinfected patients. These studies led to an original approach to reliably predict SVR in HIVHCV coinfected patients, through webbased tools freely available and taking into account host genetics and noninvasive techniques of liver fibrosis assessment. These tools allow tailored therapy taking into account host and viral genetics, which may help decision making with new DAA.

Unit Manager

First and last names	Eider Larrarte Lazaro
Qualifications	Pharmacist
Medical specialty	
Manager since	2010 and co-manager since 2015
E-mail and phone	Eider.larrarte@tecnalia.com 677152891

Short CV

Eider Larrarte Lazaro holds a PhD in Pharmacy. Health and Quality of Life Director, She did a postdoctoral stage at the Surgery Department in the University of Liverpool. She is experienced in the management and direction of numerous research projects. She is director of Health and Quality of Life Area in TECNALIA.

Unidad de Ensayos Clínicos IIS Bioaraba. Hospital Universitario de Araba

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

No

Audits by regulatory agencies (last 3 years)

No

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies? -

Audits by sponsors (last 3 years)

Yes, November 2012, June 2013 and July 2014

Do you follow your own Standard Operating Procedures (SOPs)? yes Do you supply with a SOP copy to a sponsor if requested? no

Would you follow the sponsor SOPs if requested: Yes, in case those SOPs follow an audited system and they conform to the good clinical practices of the unit

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial: 1 general audit and 6 specific audits

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

The computer database with personal data of the subjects is under key and only unit staff has access to it. This database is registered in both the State Data Protection Agency and the agency of the Basque Country.

Once subjects are included in a study are given a unique number of recruitment. This number and the number of the subject once is randomized, are registered in the study documentation. The initials of the subjects are never included.

The file of ongoing studies is in locked cabinets in the same medical office and under constant visual control of the unit staff. In the unit there is an archive with controlled access under a personal code. Only the responsible for the file has access to it.

Unidad de Ensayos Clínicos I IS Bioaraba. Hospital Universitario de Araba

Facilities

Year of Unit building	1979	Last Unit reform	2002
Usable space	308 m2	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	2-3	Number of beds	12
Beds distribution	4 rooms with 3 beds each		
Beds distribution allows a complete and continuous visual control by nurses			No
Number of bed with intensive or continuous monitoring	4	Number of armchairs suitable for subject monitoring	0
Owned kitchen	Yes	Meals supervision by dietitian	Yes
Dining-room available for volunteers	Yes	Individual lockers available for volunteers	Yes
Relaxing room available for volunteers independent from the beds area			Yes
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	Yes/ALS		
Unit availability of an evacuation plan for volunteers in emergency situations			Yes
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes

Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers

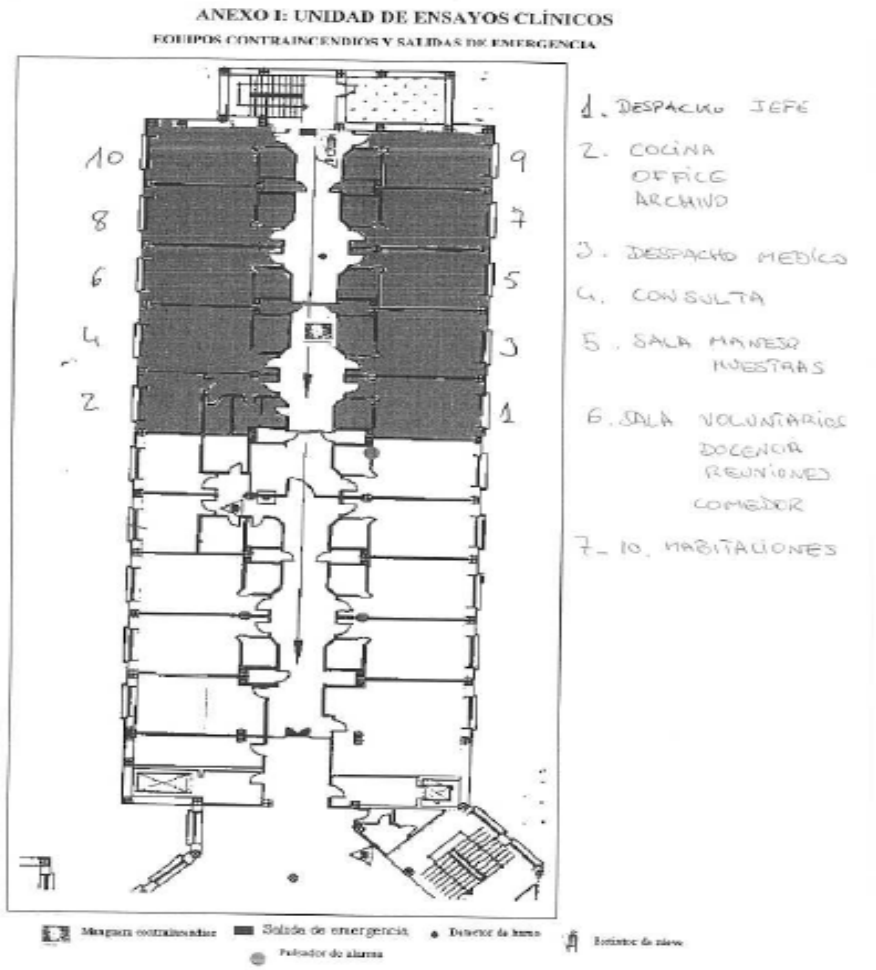
The unit has emergency trolly and medication. The Hospital provides care plan protocol to life-threatening situations "Stops". In addition, the hospital has emergency room, intensive care unit (ICU) and hospital wards.

Distance and time to get the former services	The ICU is located in 5th floor, 2 min from the unit. The emergency service is in the -1 floor.		
Unit entrance/Exit door controlled	Yes/individual password	Unit with Closed Circuit Television	No
Availability of an alternate electrical generating set that automatically works in case of a general system failure			Yes

Unidad de Ensayos Clínicos IIS Bioaraba. Hospital Universitario de Araba

Facilities

Unit distribution plan



Unidad de Ensayos Clínicos I IS Bioaraba. Hospital Universitario de Araba

Staffing and Resources

Unit employees

Permanent staff 8 Fixed-term/contracted staff (internship, grant holders) 0 Part-time collaborators 5

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	1	
Nurse	2,3	
Monitor or CRA	5,6	
Pharmacist	5,7	
Biometry	6	
Data management	2,3,4,6	
Medical writing	1	
Pharmacokinetics	1	
Quality assurance	5,6	
Project Management	6	
Finance	7,8	
Recruitment	1,2,3	
IT (informatics)	0	
Other (specify): CTA, psychologist, etc	Nutritionist:3, Lab technician: 4, Marketing: 8	

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

Yes

X Physician X Nurse

Unidad de Ensayos Clínicos I IS Bioaraba. Hospital Universitario de Araba

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	Yes

The Unit has the laboratory of biochemistry and hematology of the hospital which works under standard quality procedures.

The quality assurance activities are subcontracted by the Unit	No
Availability of a specific area for drug storing and preparation of medications for the study	Yes
The former area or room has restricted access by key or code	Yes
Laminar flow chamber availability for preparation of parenteral treatments	Yes
Perfusion pumps for intravenous treatment	Yes
Who is the responsible for drug preparation and dispensing	**Dispensing:** Pharmacist of the hospital; principal investigator; nursery **Preparation**: Pharmacist of the hospital; principal investigator; nursery
Drug accountability procedures, such as reception, preparation and dispensing forms	Yes
SOPs available for drug preparation and dispensing	Yes
SOPs available for drawing and managing of biological fluids	Yes
System or procedure used for samples identification	Labelling
Availability of a specific area for blood samples managing	Yes
The former area or room has restricted access by key or code	Yes
Number of centrifuges available	2
System for plasma/fluids samples storing	Preparation of aliquots and storage at -80ºC
Fridges and freezers available in the Unit	1 fridge and 3 freezers
The Unit has its owned Bioanalytical Department	No
Availability of genotyping or fenotyping methods for participants	Arrays platform (Amplichip of Roche) y Real time PCR, Genetic analyzer ABI 3500, Quantitative PCR ABI PRISM 7500 and C-1000-HRM, 1 pirosequencer PYROMARK Q24

Unidad de Ensayos Clínicos IIS Bioaraba. Hospital Universitario de Araba

Services Capabilities

Data Management and software used (describe)

Specific software: SPSS statistical analysis, EXCEL spreadsheet, ACCESS database

Biometry or Statistical Analysis and software used (describe)

SPSS and WinNollin

Pharmacokinetic Analysis and software used (describe)

No compartmental analysis. Software: WinNonlin

Medical Writing and skilled languages	Yes, Spanish and English
Owned archives in the same Unit building (describe)	Yes. Capacity: 300 files with controlled access to authorized personnel with individual password and fireproof door.

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

At the end of a study the Trial Master File is sent to the archive, together with medical history and Case Report Form, for 15 years

The study files are digitized and converted in a CD or web format	Yes
Project management	Yes

Unidad de Ensayos Clínicos I I S Bioaraba. Hospital Universitario de Araba

Study participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers Yes Patients Yes

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour X Haematological tumour X Adults X Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

The protocol would be studied and oncology specialists would be contacted in each case

Recruiting methods for healthy volunteers

Database, ads, websites, twitter

Recruting methods for patients

Patient recruitment is done from services of Specialized care, Primary care and Emergency Unit.

Do you have sugery rooms available for screening (separated from the in-house area)? (number) Yes (1)

Do you keep a paper or electronic database of volunteers? (describe) Yes

N^{o} of recruitment, name, 1st surname , 2nd surname , initials , sex, phone number, ID, address , Account Number , CIC, code of the last study in which he has participated, date of end of last study, comments.

Have you implemented any measure for avoiding the over-volunteering? (describe)

Yes, against overvoluntarism within the unit itself, through the records of each volunteer in the database, but not in relation to other units.

Unidad de Ensayos Clínicos IIS Bioaraba. Hospital Universitario de Araba

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	3	Pulsioximetry devices (number)	3	12-leads ECG devices (number)	3

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Yes, four studies: 1 (2004-2005), 1 in 2005 and 2 in 2006
Availability in the Unit of tests for assessing CNS drug effects	Startle electromyography test and PPI (prepulse inhibition) and psychomotor performance tests
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	No
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes, 1 in 2008
Experience in other kind of PD or PK evaluations not formerly collected	No

Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted

No

Unidad de Ensayos Clínicos IIS Bioaraba. Hospital Universitario de Araba

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence	3	5	4	2	3	4
First single-dose administration in humans	1	0	0	0	0	1
First multiple-dose administration in humans	0	0	0	0	0	0
Drug interaction	0	0	0	0	0	0
Food interaction	0	0	0	1	1	0
Special populations (Renal or liver impairment, elderly)	4	4	1	1	1	4
Proof of concept (Phase Ib or I/II)	4	1	0	1	10	6
Own research lines	1	0	0	0	0	0
Others (specificying):Phase III	1	0	0	1	9	11
Others (specificying): Nutritionals	3	1	1	1	1	4
Others (specificying): Research projects	0	1	0	3	5	4

Number of trials linked to a PEI (IND) submission | 2009 | 0 | 2010 | 0 | 2011 | 0 | 2012 | 0 | 2013 | 0 | 2014 | 1

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Allergens , inhaled gluco/corticosteroids, analgesics, inhaled anticholinergics, inhibitors of acetylcholinesterase, angiotensin II antagonists, progestins, estrogens, hormones, flavonoids, ...

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 30 Number of trials promoted by multinational companies 6

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60

Number of Early Stages trials performed in the Unit and published in the last 4 years 0

Unidad de Ensayos Clínicos IIS Bioaraba. Hospital Universitario de Araba

Annexes

Unidad de Terapias Avanzadas – Onkologikoa Donostia

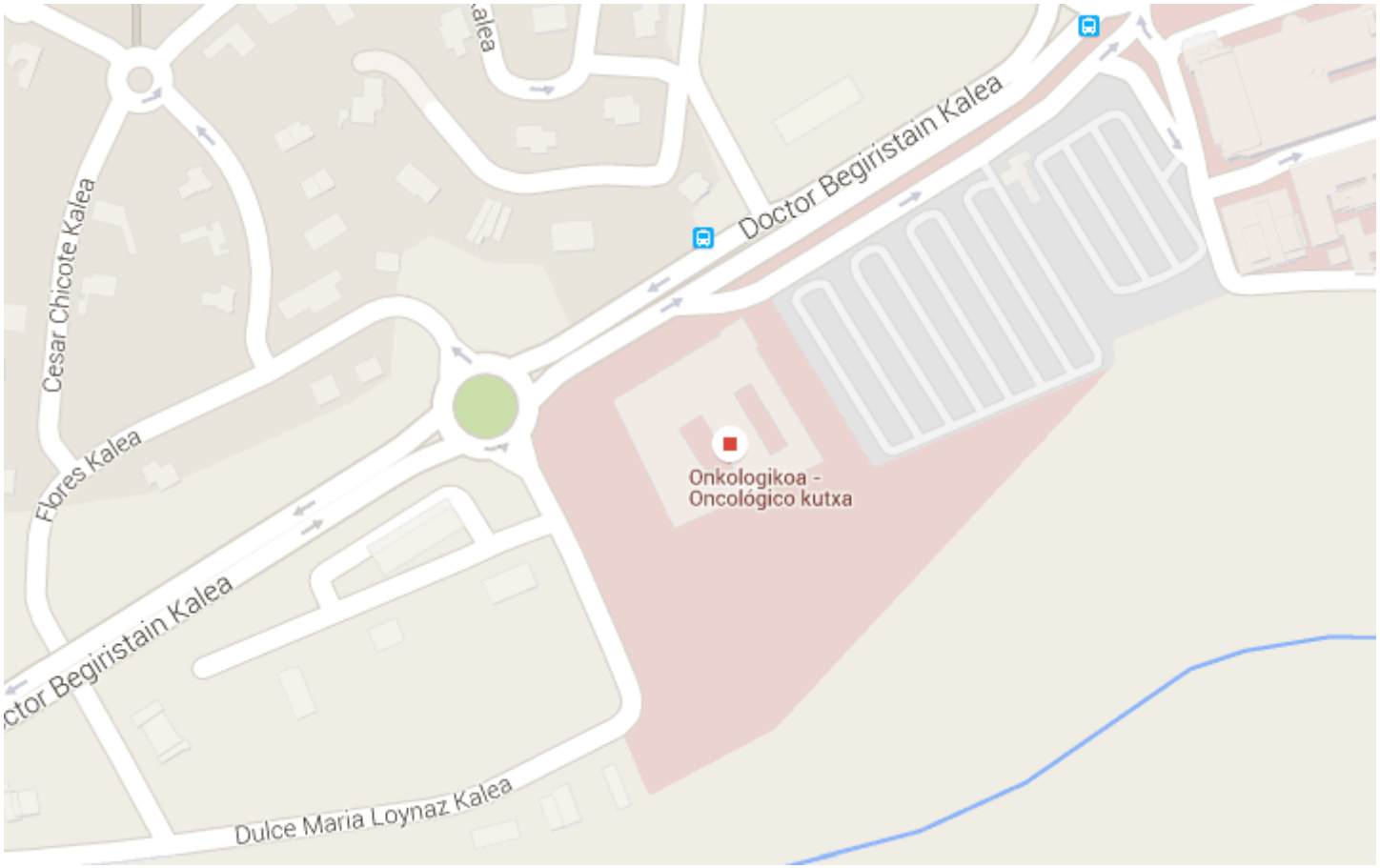
Unidad de Terapias Avanzadas – Onkologikoa Donostia

General Information

Who filled in this survey	Ander Urruticoechea Ribate
E-mail contact (Phone number)	anderu@onkologikoa.org 0034 943328311
Date of survey filling in	18. May. 2015
Unit web address	
Formal name of the unit	Advanced Therapy Unit -- Onkologikoa
Postal address	Pº Dr Beguiristain 121, 20014 San Sebastián (Guipúzcoa). Spain

Unidad de Terapias Avanzadas – Onkologikoa Donostia

Location



Unidad de Terapias Avanzadas – Onkologikoa Donostia

Ownership

Ownership	Fundación Onkologikoa
Established	2013
Linked hospital	Fundación Onkologikoa
Distance between linked hospital and Unit	Unit within the Hospital
Linked Ethics Committee (CEIC)	CEIC Euskadi

Unit Manager

First and last names	Ander Urruticoechea
Qualifications	MD, PhD
Medical specialty	Medical Oncology
Manager since	2013
E-mail and phone	anderu@onkologikoa.org 0034 943328311

Short CV

Ander Urruticoechea is a physician specialised in medical oncology since 2002. He has a PhD in cancer research. Following his specialist training in the Catalan Institute of Oncology (ICO) he moved to the Royal Marsden Hopspital/Institute of Cancer Research in London for two years in order to develop a research fellowship in breast cancer biology and treatment. Back to ICO in Barcelona he worked as consultant in breast oncology between 2004 and 2010. From 2010 he was in charge of the breast cancer programme with the view to integrate patient cancer and research in a multidisciplinary team. From 2013 to date he moved to San Sebastian (Spain) to work as scientific director in a Cancer centre (Onkologikoa Fundation).

Unidad de Terapias Avanzadas – Onkologikoa Donostia

Accreditations and Audits

Accreditations by the regions' administration o any other local, national or international organization in the last 3 years

Audits by regulatory agencies (last 3 years)

Would you provide to a sponsor if requested the result of the audits by the regulatory agencies?

Audits by sponsors (last 3 years)

Do you follow your own Standard Operating Procedures (SOPs)? YES Do you supply with a SOP copy to a sponsor if requested? YES

Would you follow the sponsor SOPs if requested: YES

Internal audits performed per year, including the general audits and the audits related to a specific clinical trial:

Unit policy and procedures to guarantee the safety and confidentiality of volunteers and study data:

All subjects Clinical unit is under the same level of security that the general clinical information center , namely :
- Electronic Medical history (paperless hospital) .
- Electronic medical records system security level HIMSS 6 .
- Access to information fully traceable , according to custom profiles of access to information .
- The monitorings are conducted with staff monitoring access to specific codes , restricted access and always under supervision of unit staff .
- Monitoring records followed by specific SOP .

Unidad de Terapias Avanzadas – Onkologikoa Donostia

Facilities

Year of Unit building	2009	Last Unit reform	
Usable space	70	The Unit building is separate from the linked hospital	No
Number of CTs the unit could perform simultanously	5-8	Number of beds	3
Beds distribution: 1 room with 1 bed, 1 room with 2 beds			
Beds distribution allows a complete and continuous visual control by nurses			Yes
Number of bed with intensive or continuous monitoring	3	Number of armchairs suitable for subject monitoring	1
Owned kitchen	no	Meals supervision by dietitian	Yes
Dining-room available for volunteers		Individual lockers available for volunteers	
Relaxing room available for volunteers independent from the beds area			
Availability in the unit of an emegency trolly for cardiopulmonary resuscitation			Yes
The emergency trolly has available suitable medications with immediate by controlled access			Yes
The medical and paramedical staff are trained and skilled to provide (Basic Life Support or/and Advanced LS)	ALS		
Unit availability of an evacuation plan for volunteers in emergency situations			
There is an official agreement with a hospital for the volunteers/patients hospitalisation and treatment if required			Yes
Volunteers/patients healthcare would be covered by the national or the regional health system if required			Yes
Suitable services or departments of the linked hospital for management of emergencies and critical care of volunteers	Intensive Care Unit		
Distance and time to get the former services	200 m, 2 min		
Unit entrance/Exit door controlled	Yes	Unit with Closed Circuit Television	no
Availability of an alternate electrical generating set that automatically works in case of a general system failure			

Unidad de Terapias Avanzadas – Onkologikoa Donostia

Staffing and Resources

Unit employees

Permanent staff 2 Fixed-term/contracted staff (internship, grant holders) Part-time collaborators 2

Distribution of Unit staff by functions

Function	Permanent staff	Contracted or part-time staff
Principal Investigator	1	
Co-investigator (physician)	1	
Nurse	1.5	
Monitor or CRA	1.5	
Pharmacist	0.5	
Biometry		
Data management		
Medical writing		
Pharmacokinetics		
Quality assurance		
Project Management		
Finance		
Recruitment		
IT (informatics)		
Other (specify): CTA, psychologist, etc		

In case of clinical trial requires the overnight stay of volunteers, what kind of healthcare providers will remain in the Unit

X Physician **X** Nurse

Unidad de Terapias Avanzadas – Onkologikoa Donostia

Services Capabilities

Availability of Central laboratory for safety analysis (biochemical and haematological parameteres)	X
The quality assurance activities are subcontracted by the Unit	
Availability of a specific area for drug storing and preparation of medications for the study	X
The former area or room has restricted access by key or code	X
Laminar flow chamber availability for preparation of parenteral treatments	X
Perfusion pumps for intravenous treatment	X
Who is the responsible for drug preparation and dispensing	**Dispensing:** Nurse (Investigator) **Preparation**: Pharmacist
Drug accountability procedures, such as reception, preparation and dispensing forms	X
SOPs available for drug preparation and dispensing	X
SOPs available for drawing and managing of biological fluids	X
System or procedure used for samples identification	
Coding	
Availability of a specific area for blood samples managing	X
The former area or room has restricted access by key or code	X
Number of centrifuges available	2
System for plasma/fluids samples storing	X
Fridges and freezers available in the Unit	4
The Unit has its owned Bioanalytical Department	
Availability of genotyping or fenotyping methods for participants	Subcontracted

Unidad de Terapias Avanzadas – Onkologikoa Donostia

Services Capabilities

Data Management and software used (describe)

Biometry or Statistical Analysis and software used (describe)

Pharmacokinetic Analysis and software used (describe)

Medical Writing and skilled languages

Owned archives in the same Unit building (describe)

Regarding a specific clinical trial what documents are sent to the archives and for long time are archived

Test material not immediately necessary, paper files for ongoing trials

The study files are digitized and converted in a CD or web format No

Project management

Unidad de Terapias Avanzadas – Onkologikoa Donostia

Study Participants

Kind of participants included in clinical trials performed in the Unit

Healthy volunteers | Patients X

Other populations

If the Unit has experience in oncology, detail kind of tumour and age groups

X Solid tumour | Haematological tumour | X Adults | Pediatrics

What kind of cancer (by organ) patients could be recruited by the Unit

All solid tumours

Recruiting methods for healthy volunteers

Recruting methods for patients

Consent inform in the medical oncology department

Do you have sugery rooms available for screening (separated from the in-house area)? (number)

Do you keep a paper or electronic database of volunteers? (describe)

Have you implemented any measure for avoiding the over-volunteering? (describe)

Unidad de Terapias Avanzadas – Onkologikoa Donostia

Pharmacodynamic/Pharmacokinetic Capabilities

Digital blood pressure devices (number)	2	Pulsioximetry devices (number)	1	12-leads ECG devices (number)	2

Familiarity with evaluation of the QTc interval prolongation accordingly with current rules	Yes
Availability in the Unit of tests for assessing CNS drug effects	
Familiarity in poblational analysis and PK/PD modeling, including writing of clinical reports	
Familiarity with Electronic Data Capture –EDC applied to clinical trials	Yes
Experience in other kind of PD or PK evaluations not formerly collected	Tumor biomarkers
Collaborations during the last 4 years with external departments related to efficacy, PD or PK evaluations not previously depicted	

Unidad de Terapias Avanzadas – Onkologikoa Donostia

Experience

Number of clinical trials per year and type of study	Year					
Type of study	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**
Bioequivalence						
First single-dose administration in humans						
First multiple-dose administration in humans						
Drug interaction						
Food interaction						
Special populations (Renal or liver impairment, elderly)						
Proof of concept (Phase Ib or I/II)					1	1
Own research lines						
Others (specificying)						

Number of trials linked to a PEI (IND) submission | 2009 | 2010 | 2011 | 2012 | 2013 | 1 | 2014 | 1

Type of drugs (pharmacological group or mechanism of action) tested in the trials performed in the last 4 years

Sponsor typology for Early Stages trials performed in the last 4 years (2011 to 2014)

Number of trials promoted by Spanish companies 1 Number of trials promoted by multinational companies 1

Median time for approval by the Ethics Committee and the Spanish Agency for the Early Stages trials 60

Number of Early Stages trials performed in the Unit and published in the last 4 years

Unidad de Terapias Avanzadas – Onkologikoa Donostia

Annexes

net GEICAM Grupo de Investigación

netGEicam
net of early trialists

Introduction

GEICAM is a non-profit scientific group founded in 1995 with an ambitious and innovative objective: to develop the Breast Cancer Clinical Research initiatives of our members:

- Has performed 102 clinical trials in which more than 44.300 patients with breast cancer have participated.
- Has collaboration agreements with 184 Spanish centre's.
- Collaborates with international cooperative groups (TRIO, BIG, GBG, ICORG, SOWG, ECOG-ACRIN, etc), as well as with other scientific institutions (CNIO, CIC,…).
- Has also the mission to disseminate the acquired knowledge within and outside the group, through the organization of scientific meetings and educational programs at the national level.
- Collaborates with cancer patients associations (FECMA, GEPAC).

What is net GEICAM?

A selected group of research sites meeting excellence criteria in the conduction of early clinical research: Phase I y Phase IIA.

OUR AIM
The delivery of optimal early clinical research data working towards the cure of cancer.

OUR COMMITMENT
Conducting early stage trials with quality and excellence.

net GEICAM Grupo de Investigación

netGEICAM
net of early trialists

The net of early trialists GEICAM (netGEICAM) has been created with the intention to perform early phase studies with the same quality standards, taking advantage of a group with a strong trajectory in trials design, implementation and conduction, together with the high standards and expertise of a well-known collaborative group.

Our commitment is to **collaborate with the sponsors**, helping them in the design and conduction of early phase trials with the ultimate intention of helping patients. We will focus on phase I and IB as well as phase IIA studies with new drug combinations. For this purpose we have created a **collaborative group** or net of hospitals with a long history in conducting clinical trials, and with strong expertise.

Although GEICAM has primarily focused on the development of phase II and III studies in breast cancer, netGEICAM is open to the development of drugs in other tumor types, following standard approaches for phase I studies.

How do we achieve our objectives?

TRAINING PROGRAM

A trained team is synonymous of excellence in clinical research. Our objective in netGEICAM is to perform routine educational and training programs for all the team members including oncologists, nurses and study coordinators. For this purpose we have created a training program to assist all the teams on a routine basis.

STANDARD OPERATING PROCEDURES:

When conducting clinical trials it is exceptionally important to follow the principles of good clinical practice. To this end a key component in our policy is the definition of standard operating procedures (SOPs) among all the member units, with a close and routinely evaluation of such SOPs. Our intention is to secure the maximum standard of excellence performing clinical research.

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SITES SELECTION:
Based on the in-depth knowledge of the research capacities of our centers and the investigator teams, we perform a selection process on the basis of the characteristics defining each trial. We reach agreement with the trial sponsors on the particularities of each protocol and select those of our centers that meet the optimal characteristics to deliver high quality research data. In this manner we guarantee rapid patient inclusion and quality of research output.

KEYS TO SUCCESS:
• Rapid center selection process
• Optimal patient inclusion rates
• High quality research data

The different units in each hospital have been selected from all over Spain, based on the group experience. Currently we comprise **9** hospitals that are coordinated by the experts of the netGEICAM central leading team.

Cetral Leading Team:

- Dr. Miguel Martín. netGEICAM Director and GEICAM Chairman.
- Dr. Ander Urruticoechea. netGEICAM Scientific Coordinator.
- Dr. Alberto Ocaña. netGEICAM Scientific Coordinator.
- Dra. Eva Carrasco. GEICAM Scientific Director.
- Andrés Hernando. GEICAM Project Manager.

In each hospital there is a group of people including oncologists, nurses and study coordinators, that has been selected by netGEICAM. All the units in each hospital follow standard operating procedures (SOPs) approved by netGEICAM. With this approach, we aim to establish a global consensus and guarantee abidance with the principles of good clinical practice (GCP).
In this context, netGEICAM will always guarantee a high standard in the conduction of the studies. It is also our obligation to closely monitor each unit and implement continuing educational programs for all the teams.

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netGEICAM Affiliated Hospitals

Are the following:

1. **Hospital Universitario Virgen de la Victoria, Málaga**
2. **Hospital Clínico Universitario, Barcelona**
3. **Hospital del Mar, Barcelona**
4. **Instituto Catalán de Oncología (ICO), Barcelona**
5. **Complejo Hospitalario Universitario, A Coruña**
6. **Instituto Valenciano de Oncología (IVO), Valencia**
7. **Hospital Universitario Virgen del Rocío, Sevilla**
8. **Hospital General Universitario Gregorio Marañón, Madrid**
9. **Hospital Clínico San Carlos, Madrid**

Detailed information of each of these units can be found in this directory

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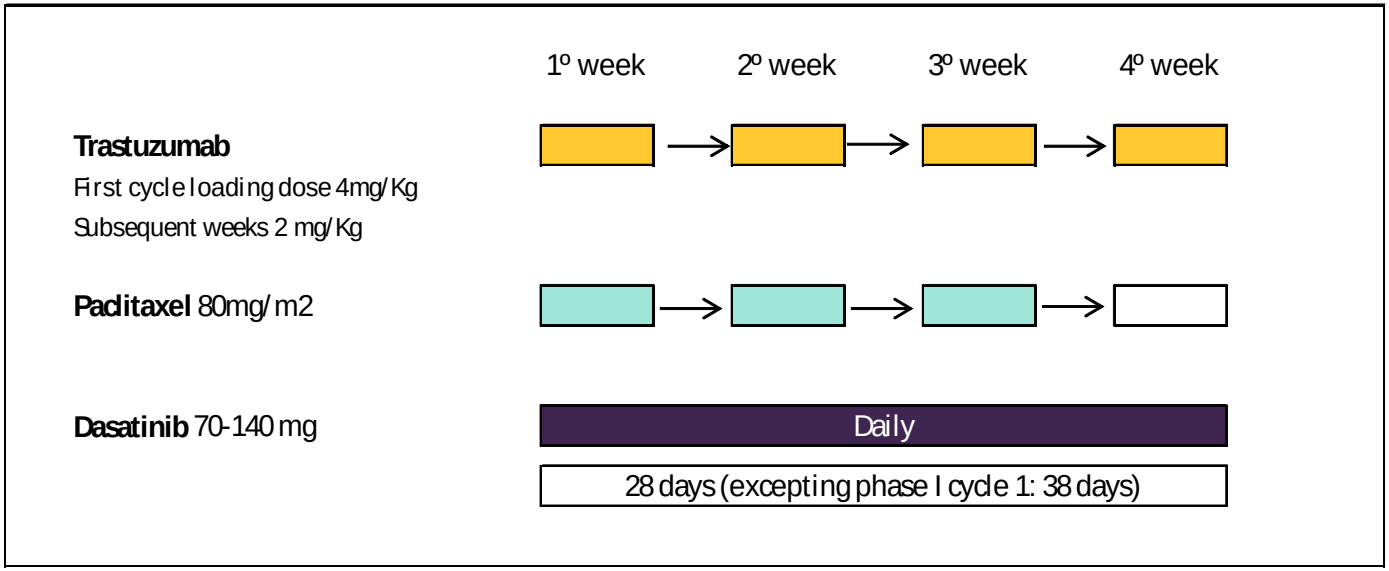
CLINICAL TRIALS in netGEICAM

GEICAM/2010-04. Phase I closed, now Phase II on recruitment.

Title: "A phase I/II trial of dasatinib in combination with trastuzumab and paclitaxel in the first line treatment of HER2-positive Metastatic Breast Cancer (MBC) patients."

Phase I recruitment period: from March 2011 to May 2013
Number of sites: 6
Enroll patients: 16
Patients included: 10
Screening Failure: 6

Study design



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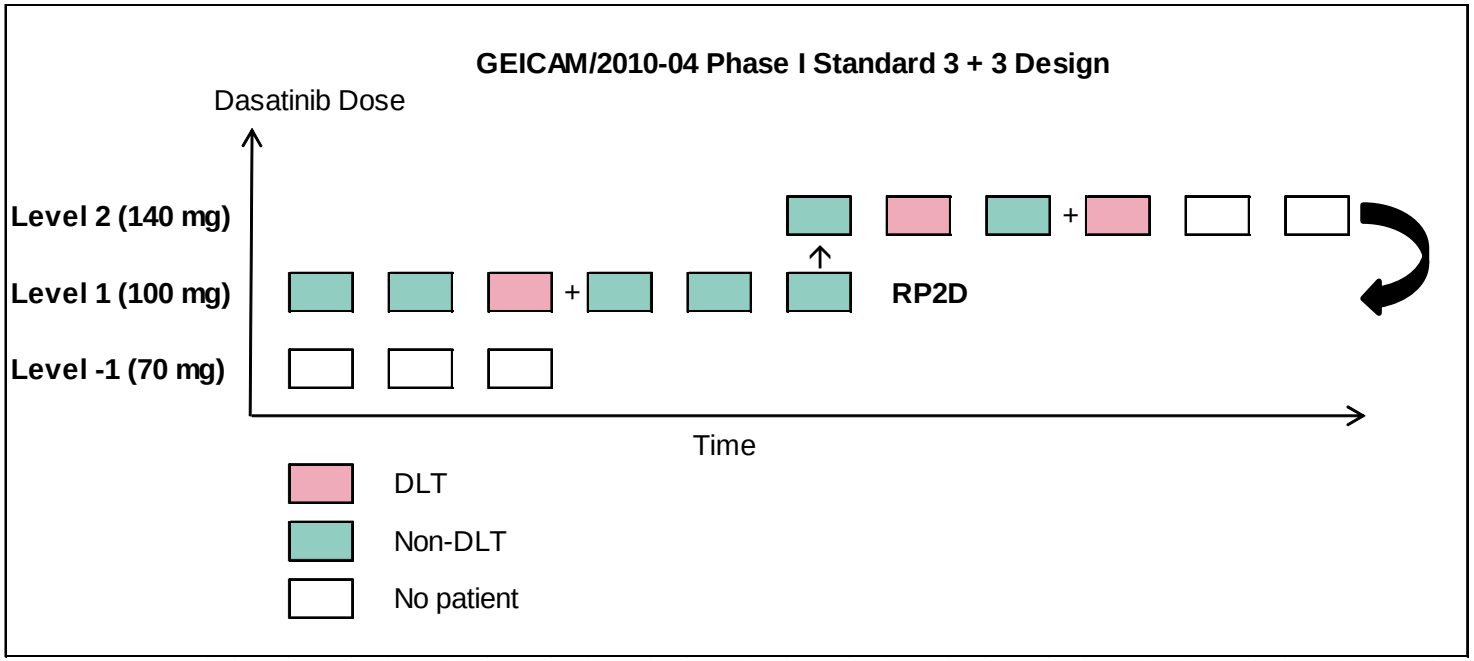

Poster submitted in EBCC 2014
Gil-Martin M, Martin M, Antolin S, Trigo JM, Guerrero A, Vidal L, Urruticoechea A, Pandiella A, Hernando A and Ocaña A. **Phase I study of dasatinib in combination with trastuzumab (T) and paclitaxel (P) in patients (pts) with HER2 positive Metastatic Breast Cancer (MBC).** Poster presentado en el European Breast Cancer Conference. 19 al 21 de Marzo 2014. Glasgow

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GEICAM/2012-12. On recruitment.

Título "A Phase Ib dose escalation, open label, multi-center study evaluating LDE225 in combination with docetaxel in Triple Negative (TN) Advanced Breast Cancer (ABC) patients.."

Recruitment period: from May 2014 (real) to May 2016 (planned)
Number of patients to be included: minimum 9 and maximum 18
Number of sites: 5
Status:
Enrol patients: 13
Patients included: 12
Screening failure: 1

Study design: