

BEST PROJECT

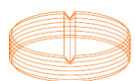
Medicine clinical investigation

Paediatric Clinical Investigation Guide In Spain

September 2017



The Spanish Technological Platform Medicamentos Innovadores is financially supported by the Ministry of Economy, Industry and Competitiveness (PTR-2016-0740)



MEDICAMENTOS INNOVADORES
Plataforma Tecnológica Española

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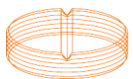
INTRODUCTION



GENERAL OVERVIEW



UNITS





INTRODUCTION



This is the first edition of the **Paediatric Clinical Investigation Guide** in Spain. This guide is the result of **30 Paediatric Investigation Units** working under the BEST project.

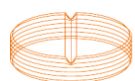
BEST is a project moved forward by the pharmaceutical industry. There are public and private stakeholders who participate in this project pursuing to build a Platform for Excellence for **Medicine Clinical Investigation** in Spain. The BEST project is part of the area of Clinical Investigation at the Spanish Technological Platform of Innovative Medicines.

The publication of this Guide seeks, among other goals, to stimulate the performance of clinical trials of paediatrics investigation and also to offer a useful working tool for **FARMAINDUSTRIA** associates.

The present Guide is published in the second semester of 2017 aiming to achieve a wide distribution among all the relevant organizations who are interested in Clinical Investigation.

The information was gathered among 30 Units between January and July 2017.

The first part of this Guide shows a global overview on the Paediatric Investigation Units included in it, and the second part contains the details of each unit.



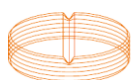


GENERAL OVERVIEW



The Units of Paediatric Investigation contained in the present Guide are the ones that appear in the next table (organized by the Spanish Autonomous Communities -AC-):

Units of Paediatric Investigation	Abbreviation	AC	Group*
Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC	R. SOFÍA	Andalucía	Group II
Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga	HRU MALAGA	Andalucía	Group II
Grupo Emergente de Pediatría Clínica - IBSAL	IBSAL	Castilla y León	Group III
Hospital Materno-Infantil de la Vall d'Hebron	V. HEBRON	Cataluña	Group II
Servei Pediatria - Hospital del Mar	H. MAR	Cataluña	Group III
Servicio de Pediatría - Hospital Parc Taulí	P. TAULÍ	Cataluña	Group II
Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu	S . J. DEU	Cataluña	Group I
Unidad de Investigación Clínica - Hospital Sanitas CIMA	H. S. CIMA	Cataluña	Group II
Grupo de Investigación de Nutrición Pediátrica de INCLIVA	INCLIVA	C. Valenciana	Group II
Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA)	HGU ALICANTE	C. Valenciana	Group II
Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General	HG ELCHE	C. Valenciana	Group III
Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset	DR. PESET	C. Valenciana	Group III
Servicio de Pediatría del Hospital La Fe	H. LA FE	C. Valenciana	Group II
Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela	H. SANTIAGO	Galicia	Group I





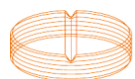
Units of Paediatric Investigation	Abbreviation	AC	Group*
Hospital General Universitario Gregorio Marañón	G. MARAÑÓN	Madrid	Group III
Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos	S. CARLOS	Madrid	Group II
Servicio de Pediatría - Hospital Universitario Severo Ochoa	S. OCHOA	Madrid	Group III
Servicio de Pediatría de la Fundación Jiménez Díaz	F. J. DÍAZ	Madrid	Group III
Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales	FI HM HOSP.	Madrid	Group II
Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz	H. LA PAZ	Madrid	Group I
Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ)	H. NIÑO JESÚS	Madrid	Group I
Unidad de Investigación Clínica - Hospital La Zarzuela	H. ZARZUELA	Madrid	Group II
Unidad de Investigación Clínica - Hospital Universitario de Torrejón	HU TORREJÓN	Madrid	Group II
Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria	IRYCIS	Madrid	Group II
Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid	HU QUIRONSM	Madrid	Group II
Unidad de Investigación Farmacológica (CTU) - Hospital Universitario Puerta de Hierro Majadahonda	P. H. MAJAD.	Madrid	Group II
Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre	HU 12O	Madrid	Group I
Unidad de Investigación Pediátrica - Clínica Universidad de Navarra	CU NAVARRA	Navarra	Group III
BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces	HU CRUCES	País Vasco	Group II
Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia	BIODONOSTIA	País Vasco	Group III

***Groups:**

Group I: Centres who have Specific Units for Paediatric Clinical Investigation

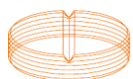
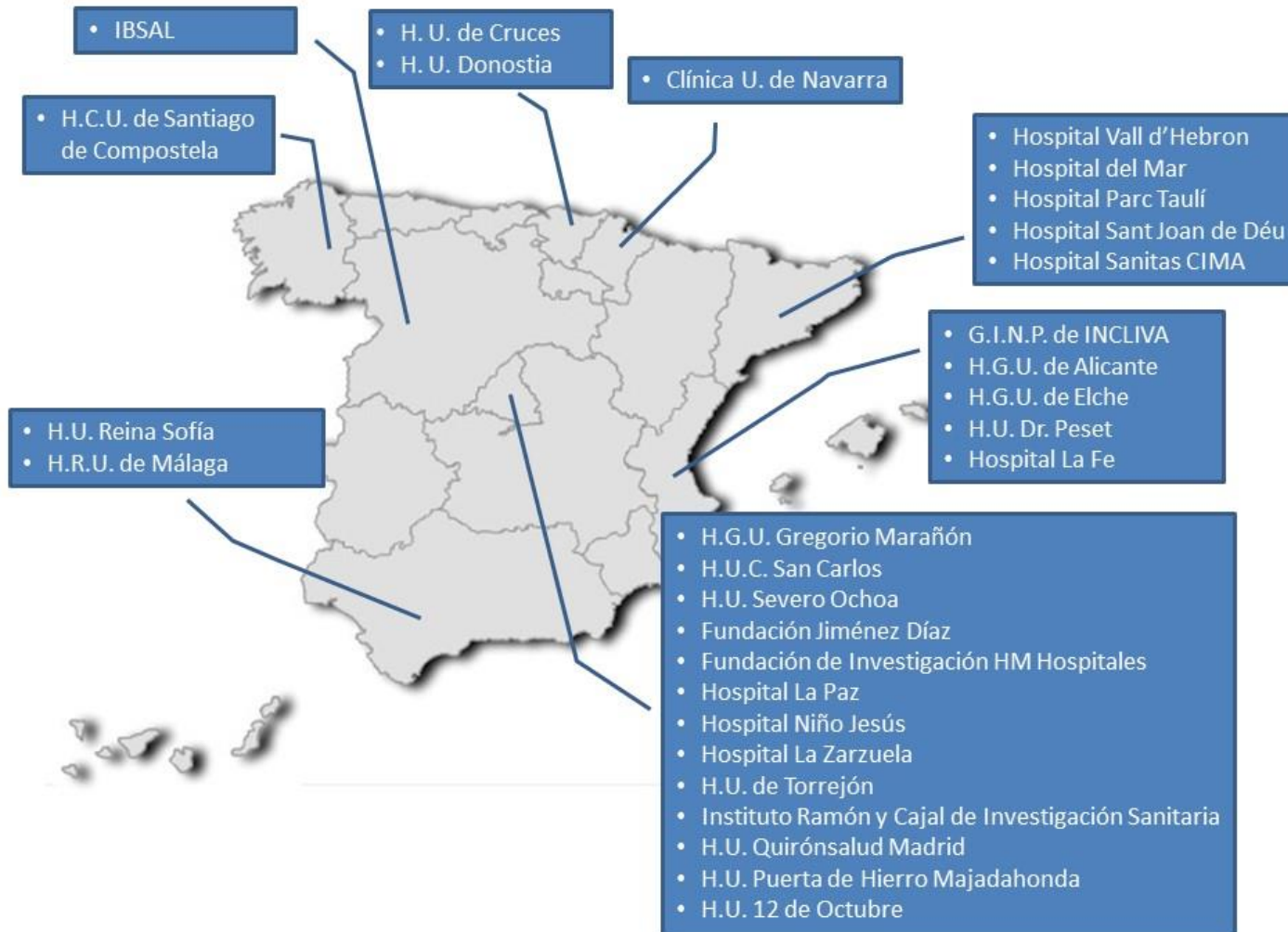
Group II: Centres who do not have a Specific Unit for paediatrics but they do have a Central Clinical Trials Unit to give support to this kind of service.

Group III: Paediatric Services that perform clinical trials in different areas.





Units Geographical Distribution





General Overview

There are several global data contained in the Guide in order to highlight the following:

- Out of the 30 Units contained by the guide, 21 belong to public **ownership**, 7 private ownership and two cases of public ownership under private management.
- All of the Units perform clinical trials with patients, and in 20 out of 30 healthy volunteers also participate in the trials.
- **Most of** the Units, 24 of them, **started paediatric research** in the ' **90 or after**. There are only 3 cases in which the investigation started in the '80, and one that started in 1965 (two of the Units haven't provided this information)
- The Units sum up a total of 1.730 **beds** with an average of 62 **beds** per Unit.
- As for the **personnel** involved, there are total of 1. 181 individuals participating in the clinical trials out of which 489 are permanent staff, 381 temporary and 311 part time collaborator personnel. As an average staff there are 16 permanent, 13 temporary and 10 collaborators per unit.
- On the other hand, **the number of clinical trials** performed by the Units in the last 5 years is **a total of 2.123**, an average 71 per Unit.





General Overview

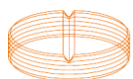
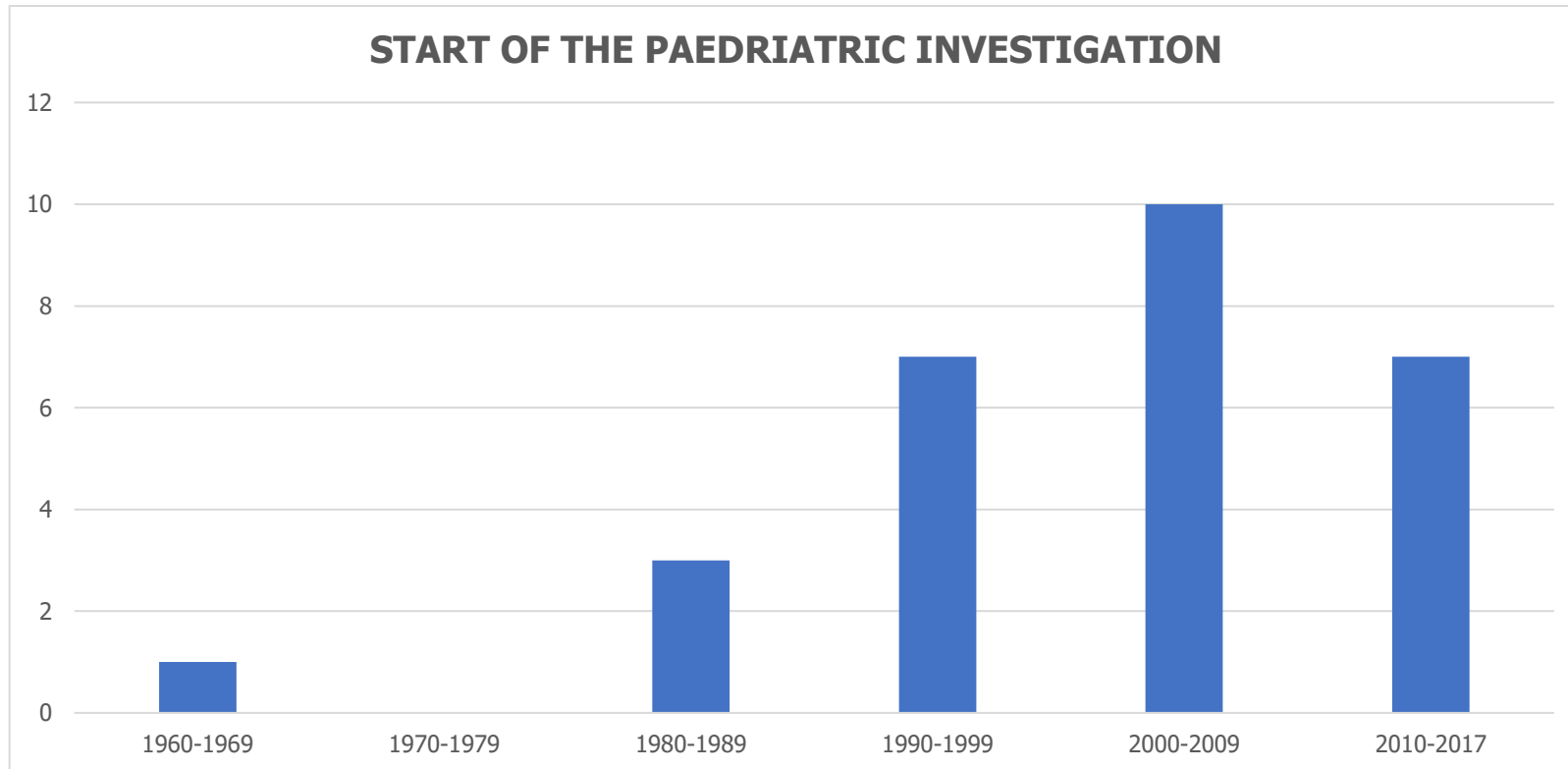
The following tables and graphics show the main synthesized features of each Unit of this Guide. This information has been organized according to **8 main sections**:

1. Adscription or Ownership
2. Audits
3. Facilities
4. Personnel
5. Services
6. Clinical Trial Subjects
7. Pharmacodynamic / pharmacokinetic Assesment
8. Experience



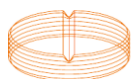
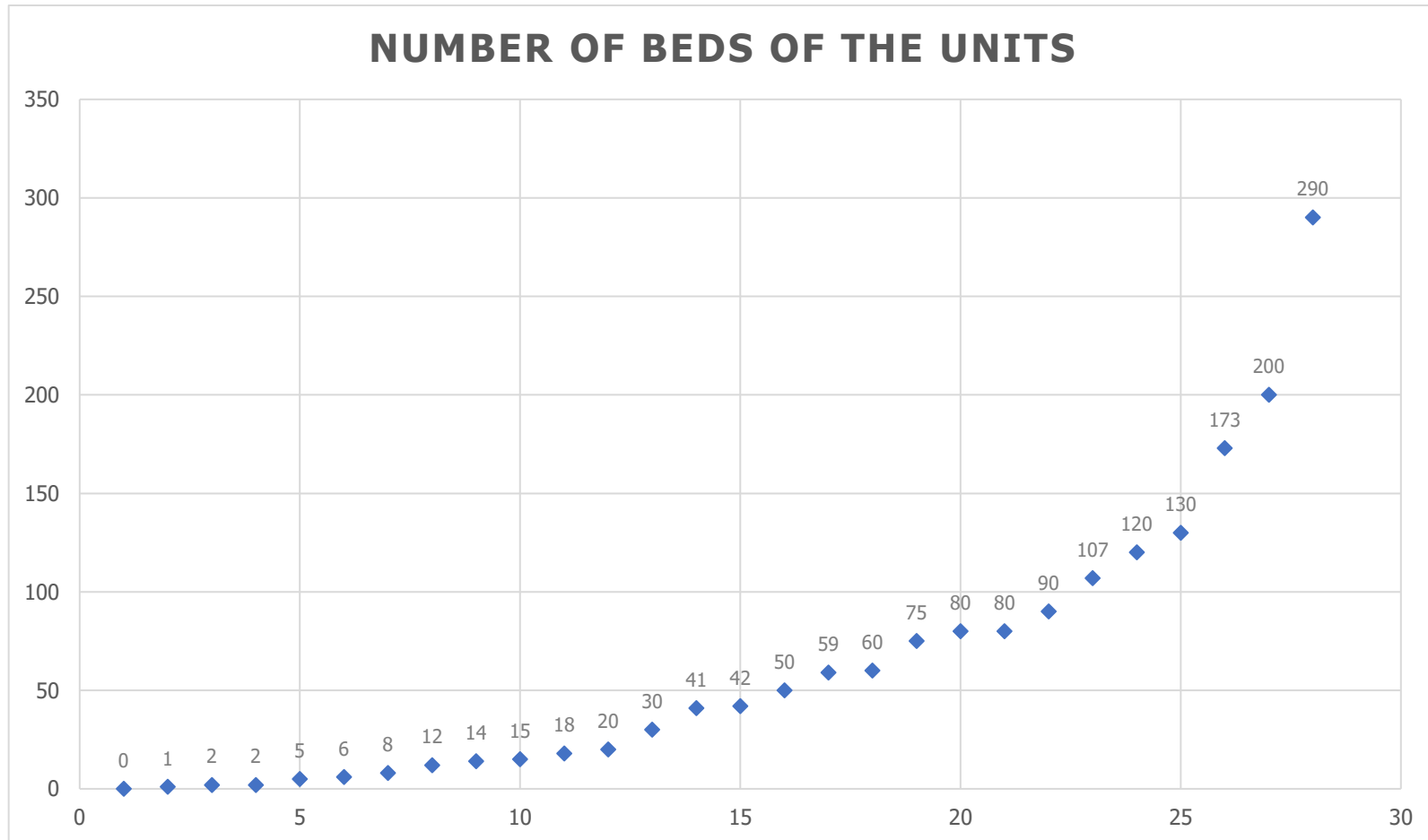


General Overview



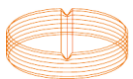
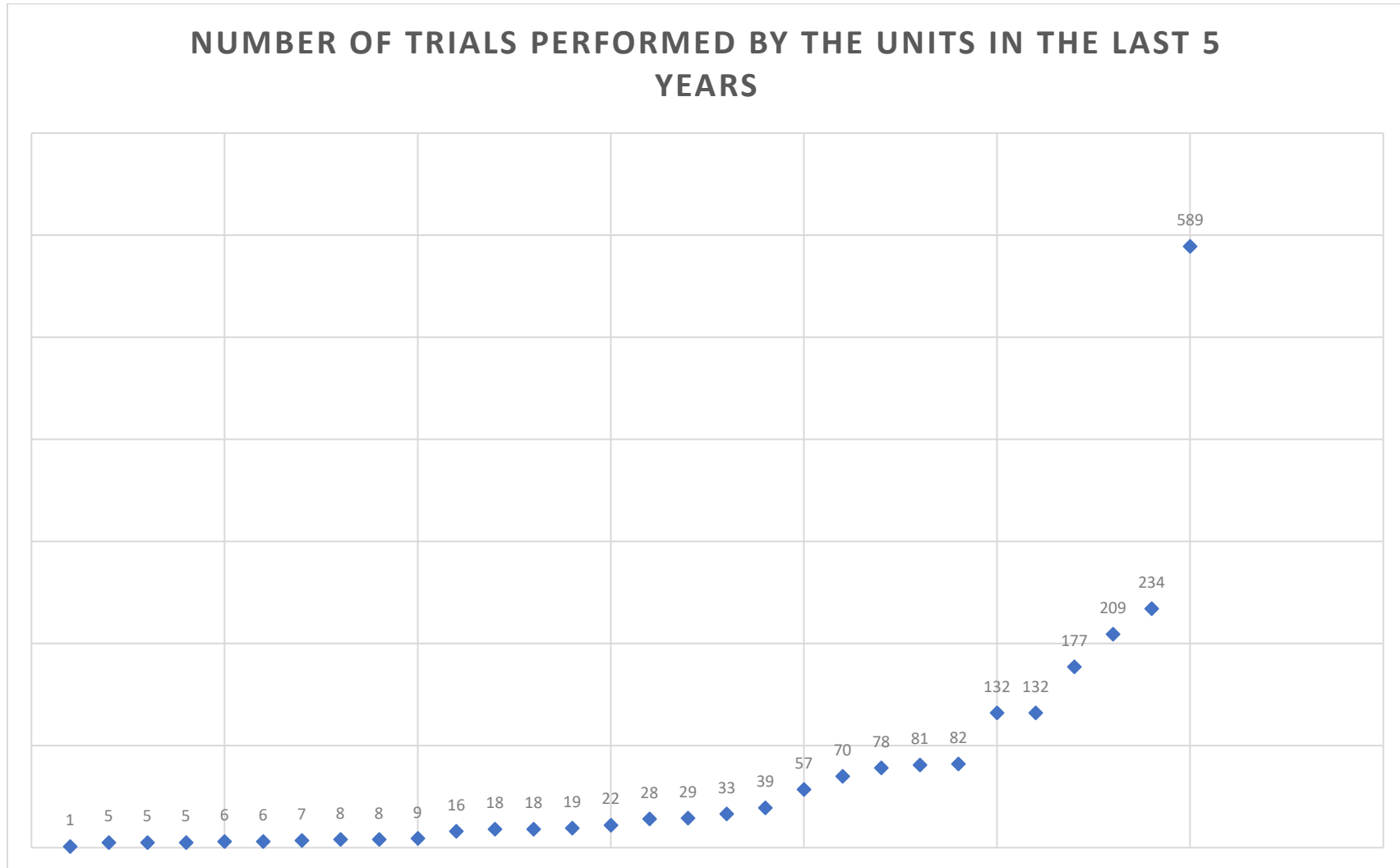


General Overview





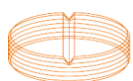
General Overview





Adscription or ownership data

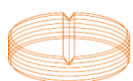
Unit	Ownership	Start year	Unit is linked to the following IEC (Investigation Ethical Committee)
R. SOFÍA	Public	1989	Comité de Ética de la Investigación de Córdoba
HRU MALAGA	Public	1998	Provincial de Málaga
IBSAL	Private	2015	
V. HEBRON	Public	1965	CEIm-HUVH. IRB00002850
H. MAR	Public	2011	CEIC-PSMAR
P. TAULÍ	Public	1982	Corporació Sanitària Parc Taulí
S . J. DEU	Private	2004	CEIm Fundació Sant Joan de Déu
H. S. CIMA	Private	2015	CEIm CIMA
INCLIVA	Public	1985	Comité Ético del Hospital Clínico Universitario de Valencia
HGU ALICANTE	Public	2017	ISABIAL (Instituto de Investigación Sanitaria y Biomédica de Alicante)
HG ELCHE	Public	2001	CEIC Hospital General Universitario de Elche
DR. PESET	Public	2005	CEIC Hospital Universitario Dr. Peset
H. LA FE	Public	1996	CEIm del Hospital Universitario y Politécnico La Fe
H. SANTIAGO	Public	2006	Comité de Ética de la Investigación con medicamentos (CEIm) de Galicia





Adscription or ownership data

Unit	Ownership	Start year	Unit is linked to the following IEC (Investigation Ethical Committee)
G. MARAÑÓN	Public	2002	CEIm área 1. Hospital General Universitario Gregorio Marañón
S. CARLOS	Public	1992	Hospital Universitario Clínico San Carlos
S. OCHOA	Public	1995	CEIC hospital Universitario Severo Ochoa
F. J. DÍAZ	Public with Private Manag.	1980	CEIm-FJD
FI HM HOSP.	Private	2009	CEIm HM Hospitales (Avda. Montepríncipe, 25 – Boadilla del Monte, Madrid)
H. LA PAZ	Public	2009	Hospital Universitario La Paz
H. NIÑO JESÚS	Public	2008	CEIm Hospital Infantil Universitario Niño Jesús
H. ZARZUELA	Private	2007	CEIm Puerta de Hierro
HU TORREJÓN	Public with Private Manag.	2012	Hospital de Getafe
IRYCIS	Public	2004	CEIm Hospital Universitario Ramón y Cajal
HU QUIRONSM	Private	2010	Hospital Universitario La Paz de Madrid y Fundación Jiménez Díaz de Madrid
P. H. MAJAD.	Public	2010	CEIm Hospital Universitario Puerta de Hierro, Madrid
HU 120	Public		CEIC 12 de Octubre
CU NAVARRA	Private	1990	CEIm de Navarra
HU CRUCES	Public	1990	Comité Ético de Investigación con Medicamentos de Euskadi (CEIm Euskadi)
BIODONOSTIA	Public	1998	CEIm de Euskadi





Audits

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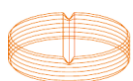
- **Audits by agencies:** Audits where the Unit was under investigation by some of the Regulatory Agencies during the past 3 years.
- **Audits by promoters:** Audits where the Unit was under investigation by some of the promoters in the past 3 year.
- **Own SOPs:** If the Unit uses its own Standard Operating Procedures (SOPs)





Audits

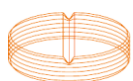
Unit	Audits by agencies	Audits by promoters	Own SOPs
R. SOFÍA	No	No	Yes
HRU MALAGA	Yes	No	No
IBSAL	No	No	No
V. HEBRON	No	No	Yes
H. MAR	Yes	Yes (1)	Yes
P. TAULÍ	No	No	No
S . J. DEU	No	Yes (5)	Yes
H. S. CIMA	No	No	Yes
INCLIVA	No	No	No
HGU ALICANTE	No	No	No
HG ELCHE	No	Yes	Yes
DR. PESET	No	No	No
H. LA FE	No	Yes (5)	No
H. SANTIAGO	No	Yes (2)	Yes





Audits

Unit	Audits by agencies	Audits by promoters	Own SOPs
G. MARAÑÓN	No		No
S. CARLOS	No	No	Yes
S. OCHOA	No	No	Yes
F. J. DÍAZ			
FI HM HOSP.	No	Yes (6)	Yes
H. LA PAZ	Yes	Yes (10)	Yes
H. NIÑO JESÚS	Yes	Yes (3)	Yes
H. ZARZUELA	No	No	Yes
HU TORREJÓN	No	No	Yes
IRYCIS	No	No	Yes
HU QUIRONSM	No	No	Yes
P. H. MAJAD.	No	No	Yes
HU 120	No	No	Yes
CU NAVARRA	No	No	No
HU CRUCES	No	Yes (2)	Yes
BIODONOSTIA	No	No	No





Facilities

The next table shows:

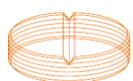
- **Simultaneous trials:** The number of trials that can be performed simultaneously by the Unit.
- **Number of beds:** The number of beds inside the Unit.
- **Code cart:** If the Unit has a code cart to attend emergency situations like cardiac arrest.





Facilities

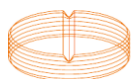
Unit	Simultaneous trials	Number of beds	Code Cart
R. SOFÍA	16	130	Yes
HRU MALAGA	20	173	Yes
IBSAL		80	Yes
V. HEBRON	60	290	Yes
H. MAR	2	14	Yes
P. TAULÍ	6	1	Yes
S . J. DEU	100	0	Yes
H. S. CIMA	4	5	Yes
INCLIVA	3 a 4	90	Yes
HGU ALICANTE	4	75	Yes
HG ELCHE	3	41	Yes
DR. PESET	2	20	Yes
H. LA FE		200	Yes
H. SANTIAGO	40	120	Yes





Facilities

Unit	Simultaneous trials	Number of beds	Code Cart
G. MARAÑÓN			Yes
S. CARLOS	5	42	Yes
S. OCHOA	10	50	Yes
F. J. DÍAZ		18	Yes
FI HM HOSP.	20	30	Yes
H. LA PAZ		8	Yes
H. NIÑO JESÚS	80		Yes
H. ZARZUELA	4	12	Yes
HU TORREJÓN	3	15	Yes
IRYCIS	10	59	Yes
HU QUIRONSM		60	Yes
P. H. MAJAD.	4	2	Yes
HU 120	15	2	Yes
CU NAVARRA	6	6	Yes
HU CRUCES	40	107	Yes
BIODONOSTIA	7	80	Yes





Personnel

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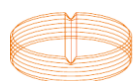
- **Permanent:** personnel who has as his / her main activity the work performed in the Unit
- **Temporary:** personnel who works under a temporary contract or as an intern or a trainee (internships, IMR -Internal Medical Resident, etc)
- **Collaborators:** for instance, doctors or nurses from hospitals cooperating in the Clinical Trials by taking shifts. This would be the equivalent of one person / full day job.





Personnel

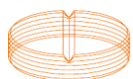
Unit	Permanent	Temporary	Collaborators
R. SOFÍA	40	25	0
HRU MALAGA	35	46	0
IBSAL	12	10	0
V. HEBRON	62	90	150
H. MAR	7	14	0
P. TAULÍ	14		10
S . J. DEU	12	2	65
H. S. CIMA	1	0	9
INCLIVA	6	6	
HGU ALICANTE	12	0	0
HG ELCHE	12	12	2
DR. PESET	12	12	3
H. LA FE	51	20	20
H. SANTIAGO	15	24	0





Personnel

Unit	Permanent	Temporary	Collaborators
G. MARAÑÓN			
S. CARLOS	23	13	3
S. OCHOA	14	16	6
F. J. DÍAZ			11
FI HM HOSP.	12	3	0
H. LA PAZ	6	7	15
H. NIÑO JESÚS	1	4	10
H. ZARZUELA	10	1	0
HU TORREJÓN	17	17	0
IRYCIS	22	7	0
HU QUIRONSM	15		
P. H. MAJAD.	8	2	
HU 120	3	3	1
CU NAVARRA	5	1	0
HU CRUCES	40	22	2
BIODONOSTIA	22	24	4





Services

The next table shows:

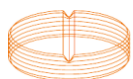
- **Day Care Hospital:** If the Unit has a specific Day Care Hospital for paediatric patients.
- **Pharmacy / Drug Store Service:** If the Unit has a Drug Store Service.
- **Certified Central Lab:** If the Unit is linked to a certified central lab where there can be performed those specific analitics included in the protocol.





Services

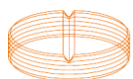
Unit	Day hospital	Drug Store Service	Certified Central Lab
R. SOFÍA	Yes	No	Yes
HRU MALAGA	Yes	Yes	Yes
IBSAL	Yes	Yes	Yes
V. HEBRON	Yes	Yes	Yes
H. MAR	No	Yes	Yes
P. TAULÍ	Yes	Yes	Yes
S . J. DEU	Yes	Yes	Yes
H. S. CIMA	No	Yes	Yes
INCLIVA	Yes	Yes	Yes
HGU ALICANTE	Yes	Yes	Yes
HG ELCHE	Yes	Yes	Yes
DR. PESET	No	Yes	Yes
H. LA FE	Yes	Yes	Yes
H. SANTIAGO	Yes	Yes	Yes





Services

Unit	Day hospital	Drug Store Service	Certified Central Lab
G. MARAÑÓN	No	Yes	Yes
S. CARLOS	Yes	Yes	Yes
S. OCHOA	Yes	Yes	Yes
F. J. DÍAZ	Yes	No	No
FI HM HOSP.	Yes	Yes	Yes
H. LA PAZ	Yes	Yes	Yes
H. NIÑO JESÚS	Yes	Yes	Yes
H. ZARZUELA	No	Yes	Yes
HU TORREJÓN	Yes	Yes	Yes
IRYCIS	Yes	Yes	Yes
HU QUIRONSM	Yes	Yes	Yes
P. H. MAJAD.	No	Yes	Yes
HU SÍZO	Yes	No	Yes
CU NAVARRA	Yes	Yes	Yes
HU CRUCES	Yes	Yes	Yes
BIODONOSTIA	Yes	Yes	Yes





Clinical Trials Subjects

The next table shows the features of the Clinical Trials Subjects where:

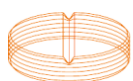
- **Healthy volunteers, Patients, Other population:** Types of population to whom the Unit has Access to.
- **Cooperation with associations:** If the Unit is in contact / cooperates with associations of paediatric patients.
- **Subjects from other centres:** If the centre is linked to a Unit that receives subjects from other centres.





Clinical Trials Subjects

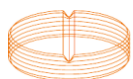
Unit	Healthy Volunteers	Patients	Other populations	Cooperation with patient associations	Subject from other centres
R. SOFÍA	Yes	Yes	No	Yes	Yes
HRU MALAGA	No	Yes	No	Yes	Yes
IBSAL	No	Yes	No	Yes	Yes
V. HEBRON	Yes	Yes	Yes	Yes	Yes
H. MAR	No	Yes	Yes	Yes	No
P. TAULÍ	Yes	Yes	Yes	Yes	Yes
S . J. DEU	No	Yes	No	Yes	Yes
H. S. CIMA	Yes	Yes	No	No	Yes
INCLIVA	No	Yes	No	Yes	Yes
HGU ALICANTE	Yes	Yes	No	Yes	Yes
HG ELCHE	Yes	Yes	No	Yes	Yes
DR. PESET	Yes	Yes	No	Yes	Yes
H. LA FE	Yes	Yes	No	Yes	Yes
H. SANTIAGO	Yes	Yes	No	Yes	No





Clinical Trials Subjects

Unit	Healthy Volunteers	Patients	Other populations	Cooperation with patient associations	Subject from other centres
G. MARAÑÓN	Yes	Yes	No	Yes	Yes
S. CARLOS	Yes	Yes	No	Yes	No
S. OCHOA	No	Yes	No	Yes	No
F. J. DÍAZ	Yes	Yes	No	Yes	Yes
FI HM HOSP.	Yes	Yes	No	Yes	Yes
H. LA PAZ	Yes	Yes	Yes	Yes	Yes
H. NIÑO JESÚS	No	Yes	No	Yes	Yes
H. ZARZUELA	Yes	Yes	No	Yes	Yes
HU TORREJÓN	No	Yes	No	Yes	Yes
IRYCIS	Yes	Yes	No	Yes	Yes
HU QUIRONSM	Yes	Yes	No	Yes	Yes
P. H. MAJAD.	Yes	Yes	No	Yes	Yes
HU SÍZO	Yes	Yes	No	Yes	Yes
CU NAVARRA	Yes	Yes	No	Yes	Yes
HU CRUCES	No	Yes	Yes	Yes	Yes
BIODONOSTIA	No	Yes	No	Yes	Yes





Pharmacodynamic / pharmacokinetic Assesment

The next table shows:

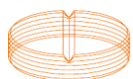
- **PK/PD Analysis:** If the Unit has experience in paediatric clinical trials with PK / PD analysis.
- **Cellular Immunity:** If the Unit has experience with blood sample process for cellular immunity.





Pharmacodynamic / pharmacokinetic Assesment

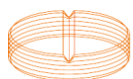
Unit	PK/PD Analysis	Cellular Immunity
R. SOFÍA	No	No
HRU MALAGA	No	Yes
IBSAL	No	No
V. HEBRON	Yes	Yes
H. MAR	Yes	No
P. TAULÍ	Yes	Yes
S . J. DEU	Yes	No
H. S. CIMA	No	No
INCLIVA	No	Yes
HGU ALICANTE	Yes	Yes
HG ELCHE	Yes	Yes
DR. PESET	Yes	Yes
H. LA FE	Yes	No
H. SANTIAGO	Yes	Yes





Pharmacodynamic / pharmacokinetic Assesment

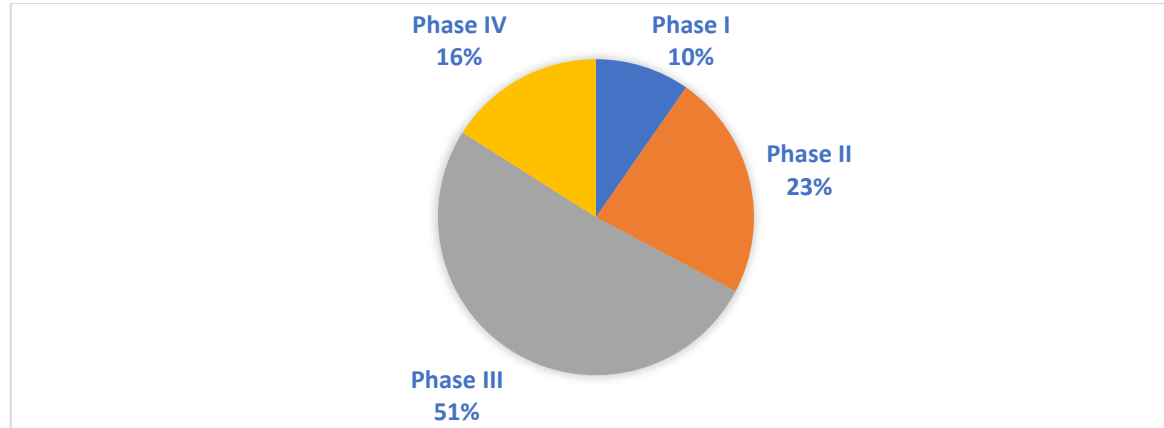
Unit	PK/PD Analysis	Cellular Immunity
G. MARAÑÓN	Yes	Yes
S. CARLOS	Yes	Yes
S. OCHOA	No	No
F. J. DÍAZ	No	No
FI HM HOSP.	Yes	Yes
H. LA PAZ	Yes	Yes
H. NIÑO JESÚS	Yes	Yes
H. ZARZUELA	No	No
HU TORREJÓN	No	No
IRYCIS	Yes	Yes
HU QUIRONSM	Yes	No
P. H. MAJAD.	Yes	Yes
HU SÍZO	Yes	Yes
CU NAVARRA	Yes	Yes
HU CRUCES	Yes	Yes
BIODONOSTIA	Yes	Yes



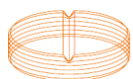
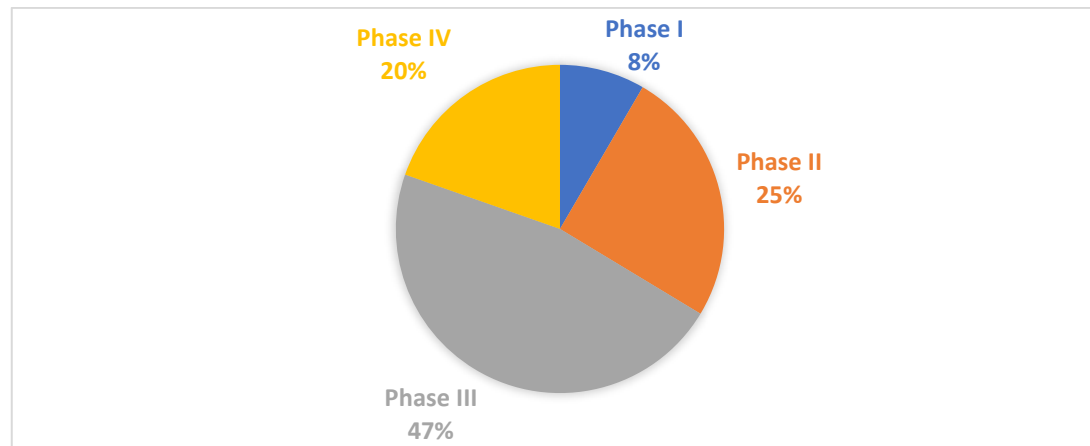


Experience

Graphic of the clinical trials performed by the Units in the last 5 years during different phases (pharmaceutical lab):



Graphic of the clinical trials performed by the Units in the last 5 years during different phases (independent group):





Experience

Clinical trials performed by the Units during the last 5 years (Pharmaceutical Lab):

Unit	Phase I	Phase II	Phase III	Phase IV	Observational	Own Research
R. SOFÍA	1	4	4	1	11	0
HRU MALAGA	2	37	65	12	0	0
IBSAL	0	0	3	0	2	0
V. HEBRON	15	28	46	42	1	0
H. MAR	1	0	0	0	1	0
P. TAULÍ	0	6	14	4	12	0
S . J. DEU	20	30	61	9	39	0
H. S. CIMA	0	0	1	0	0	0
INCLIVA	0	1	1	0	27	0
HGU ALICANTE	0	2	0	0	4	0
HG ELCHE	0	0	1	2	0	0
DR. PESET	0	0	3	1	0	0
H. LA FE	18	14	30	5	24	0
H. SANTIAGO	5	7	27	10	6	0





Experience

Clinical trials performed by the Units during the las 5 years (Pharmaceutical Lab):

Unit	Phase I	Phase II	Phase III	Phase IV	Observational	Own Research
G. MARAÑÓN	2	9	19	6	0	0
S. CARLOS	0	6	10	0	0	0
S. OCHOA	0	0	10	4	0	0
F. J. DÍAZ	0	1	1	0	0	0
FI HM HOSP.	2	8	3	3	2	0
H. LA PAZ	10	47	142	32	141	0
H. NIÑO JESÚS	17	21	40	17	11	0
H. ZARZUELA	0	0	0	3	2	0
HU TORREJÓN	0	0	0	2	0	0
IRYCIS	5	9	23	1	25	0
HU QUIRONSM	0	2	5	0	0	0
P. H. MAJAD.	0	1	2	0	0	0
HU 120	2	3	15	13	30	0
CU NAVARRA	1	0	5	0	0	0
HU CRUCES	1	6	10	2	17	0
BIODONOSTIA	0	2	2	0	X	0





Experience

Clinical trials performed by the Units during the last 5 years (Independent Group):

Unit	Phase I	Phase II	Phase III	Phase IV	Observational	Own Research
R. SOFÍA	0	2	2	1	3	4
HRU MALAGA	1	8	7	0	0	0
IBSAL	0	1(II/III)	0	0	0	2
V. HEBRON	0	0	0	0	0	0
H. MAR	2	1	0	0	0	0
P. TAULÍ	0	0	0	0	42	0
S . J. DEU	2	9	8	1	17	13
H. S. CIMA	0	0	0	0	0	0
INCLIVA	0	0	0	0	0	0
HGU ALICANTE	0	0	0	0	10	0
HG ELCHE	0	0	0	0	2	2
DR. PESET	0	0	0	0	0	5
H. LA FE	1	5	3	0	13	121
H. SANTIAGO	0	0	1	1	25	0

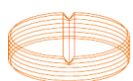




Experience

Clinical trials performed by the Units during the las 5 years (Independent Group):

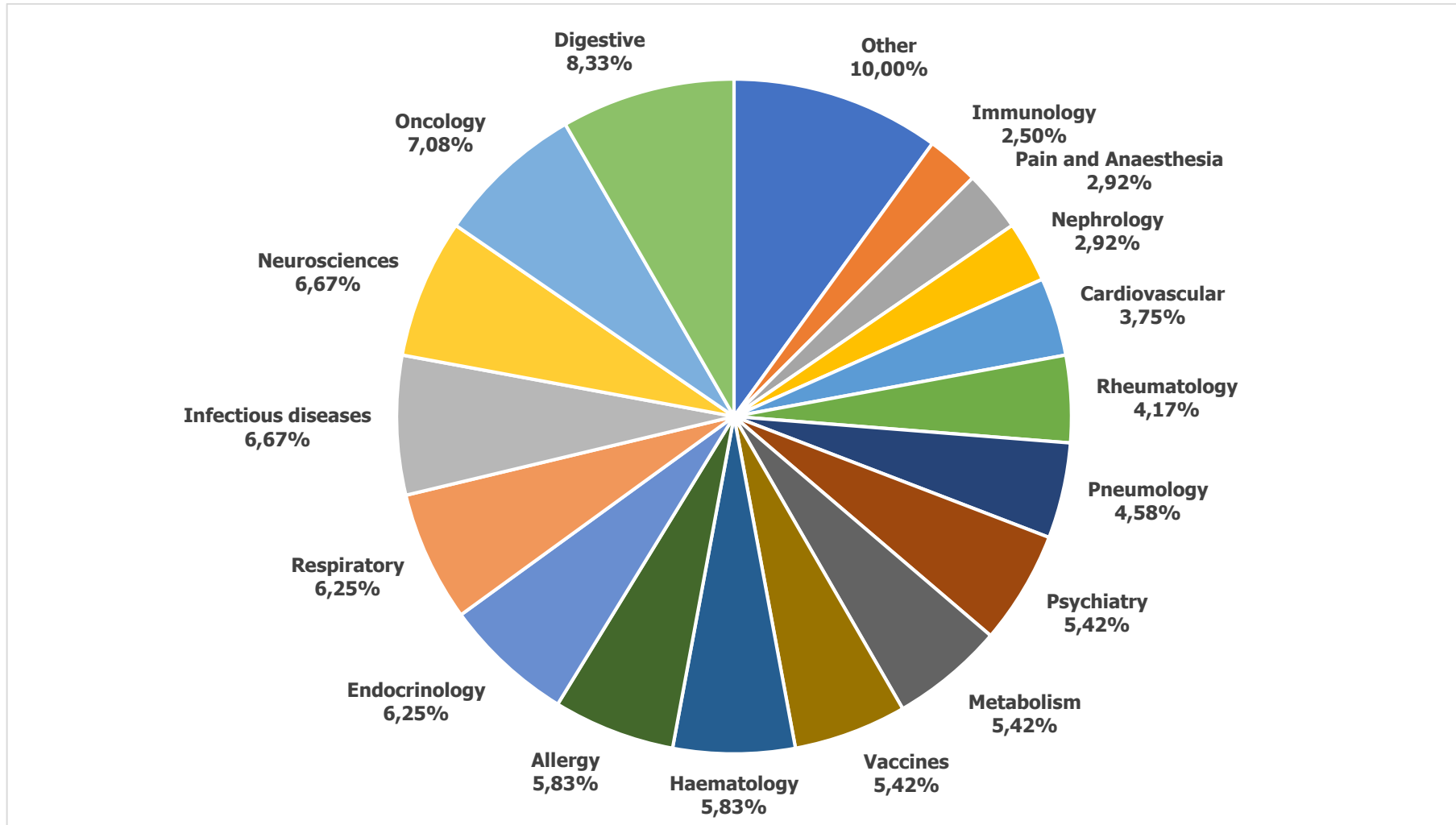
Unit	Phase I	Phase II	Phase III	Phase IV	Observational	Own Research
G. MARAÑÓN	0	2	0	1	0	0
S. CARLOS	0	0	6	0	0	0
S. OCHOA	0	0	0	0	7	7
F. J. DÍAZ	0	0	1	0	0	2
FI HM HOSP.	0	0	0	0	0	0
H. LA PAZ	4	12	22	20	159	0
H. NIÑO JESÚS	6	8	13	6	38	0
H. ZARZUELA	0	0	0	0	0	0
HU TORREJÓN	0	0	0	0	2	2
IRYCIS	0	0	7	0	0	0
HU QUIRONSM	0	1	10	0	0	0
P. H. MAJAD.	0	1	3	2	4	6
HU 120	1	0	7	10	0	0
CU NAVARRA	1	0	0	0	0	1
HU CRUCES	0	4	7	0	5	5
BIODONOSTIA	0	0	2	0	0	X





Experience

Graphic with therapeutical areas in which the Units have performed the clinical trials:

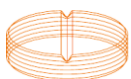




PAEDIATRIC RESEARCH UNITS



- ▶ Andalucía Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC
- ▶ Andalucía Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga
- ▶ Castilla y León Grupo Emergente de Pediatría Clínica - IBSAL
- ▶ Cataluña Hospital Materno-Infantil de la Vall d'Hebron
- ▶ Cataluña Servei Pediatria - Hospital del Mar
- ▶ Cataluña Servicio de Pediatría - Hospital Parc Taulí
- ▶ Cataluña Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu
- ▶ Cataluña Unidad de Investigación Clínica - Hospital Sanitas CIMA
- ▶ C. Valenciana Grupo de Investigación de Nutrición Pediátrica de INCLIVA
- ▶ C. Valenciana Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA)
- ▶ C. Valenciana Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General
- ▶ C. Valenciana Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset
- ▶ C. Valenciana Servicio de Pediatría del Hospital La Fe
- ▶ Galicia Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela





PAEDIATRIC RESEARCH UNITS



- ▶ Madrid Hospital General Universitario Gregorio Marañón
- ▶ Madrid Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos
- ▶ Madrid Servicio de Pediatría - Hospital Universitario Severo Ochoa
- ▶ Madrid Servicio de Pediatría de la Fundación Jiménez Díaz
- ▶ Madrid Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales
- ▶ Madrid Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz
- ▶ Madrid Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ)
- ▶ Madrid Unidad de Investigación Clínica - Hospital La Zarzuela
- ▶ Madrid Unidad de Investigación Clínica - Hospital Universitario de Torrejón
- ▶ Madrid Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria
- ▶ Madrid Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid
- ▶ Madrid Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda
- ▶ Madrid Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre
- ▶ Navarra Unidad de Investigación Pediátrica - Clínica Universidad de Navarra
- ▶ País Vasco BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces
- ▶ País Vasco Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia





Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic assessment
- ▶ Experience





Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC

Affiliation data



Who filled in the inquiry (name)	M ^a Esther Pacheco Rodríguez
Position	Responsable de la Unidad de Investigación Clínica
Email	esther.pacheco@imibic.org
Phone	
Date of completion of inquiry	20/02/2017
Official name of the Paediatric Research Unit, complete address and email	Clinical Research Unit of Paediatrics Hospital Universitario Reina Sofía - IMIBIC Avda. Menéndez Pidal, s/n 14004 CÓRDOBA
Website	http://www.juntadeandalucia.es/servicioandaluzdesalud/hrs3 http://www.imibic.org/





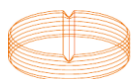
Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC

Membership or ownership data

Unit ownership	Public - University Hospital Reina Sofía / Institute of Biomedical Research of Cordoba (IMIBIC)
When Paediatric Clinical Research was initiated (year)?	1989
Which Ethics Committee is the Unit linked to?	Comité de Ética de la Investigación de Córdoba

Unit manager

Name and family name(s)	Juan Luis Pérez Navero
Education (physician, pharmacist, etc.)	Paediatrics Specialist (Intensive Care)
Department which the Research Unit is linked to	UGC of Paediatrics and Specialties
Manager since (year)	2004
Email address	ucip.hrs.sspa@juntadeandalucia.es juanlperez.sspa@juntadeandalucia.es
Phone number	957 010 497
List of all departments in the institution which perform paediatric research	Traumatology, Mental Health, Otorhinolaryngology, Dermatology, Rheumatology, Hematology, Neurology, Intensive Care, Oncology, Allergy, Pneumology, Cardiology, Gastroenterology, Hepatology, Nutrition, Metabolism, Endocrinology, Nephrology, Infectology.





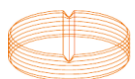
Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

All paediatric specialties:

Paediatric Medicine
Neonatology
Perinatology
Intensive Care
Oncology
Neuropaediatrics
Allergy and Pneumology
Cardiology
Gastroenterology
Hepatology
Nutrition
Metabolism
Endocrinology
Nephrology
Infectology
Social Paediatrics
Urgencies





Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC

Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? **No**

Name of the agency and date of inspection **N/A**

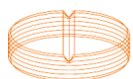
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? **Yes**

Has the Unit been audited by a sponsor in the last 3 years? **No**

Does the Unit use its own Standard Operating Procedures (SOPs)? **Yes**

Do you provide the sponsor with a copy of the SOP if requested? **Yes**

Would the Unit be ready to accept sponsor's SOPs? **Yes**





Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC Facilities



How many paediatric trials can be run in parallel in the Unit?	16
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	130
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





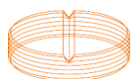
Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

The units of the Unit will be reviewed annually and calibrated by the Electromedicine of the hospital





Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC Personnel

Total number of people working at the Unit

Total permanent personnel 40

Total non-permanent personnel (by contract, Residents, Fellows) 25

Total collaborators (part time)*

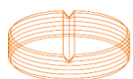
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
UGC Pediatría (Unit of Clinical Management of Paediatrics)	40

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Doctors				35





Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC Services



Does the Unit have a specific day hospital for paediatric population	Yes
Does the Unit have a Pharmacy Service? If yes, availability of Pharmacy Service (Total/Partial) If not, how study medicines are received and stored	No N/A The Hospital Pharmacy is responsible for the receipt and storage of PEIs
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC

Subjects of Clinical Trial



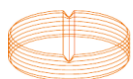
Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Methods used by the Unit for the recruitment of participants

In collaboration with the different hospital services through the principal investigators of each trial and using the electronic medical record





Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

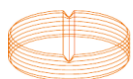
Associations of diverse pathologies: Cystic Fibrosis, Diabetes, Celiac Disease, Rare Diseases, Congenital Heart Diseases, Metabolopathies...

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Andalusia reference centre for surgery of congenital heart disease, cardiac, pulmonary and hepatic transplantation



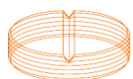


Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses? **No**
If yes, brief description: **N/A**

Does the Unit have experience in processing blood samples for cell immunity? **No**
If yes, brief description: **N/A**





Unidad de Investigación Clínica de Pediatría - Hospital Universitario Reina Sofía - IMIBIC Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	1	4	4	1	11	No
Independent group	0	2	2	1	3	4

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	X
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	X
Gynaecology	
Neurosciences	X
Ophthalmology	
Oncology	X
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

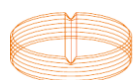
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	X
Allergy	
Anaesthesiology	
Pneumology	X
Odontology	
Biochemistry	
Nephrology	X
Vaccines	X

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga

Affiliation data



Who filled in the inquiry (name)	Antonio Pérez Rielo
Position	Clinical Studies Unit Coordinator
Email	perezrielo@gmail.com
Phone	666 50 40 06
Date of completion of inquiry	24/01/17
Official name of the Paediatric Research Unit, complete address and email	Paediatric Clinical Research Unit, Regional University Hospital of Málaga In December 2016, founding member of the Spanish Network of Clinical Trials in Paediatrics (RECLIP)
Website	---





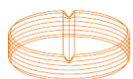
Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga

Membership or ownership data

Unit ownership	Public - Regional University Hospital of Málaga (Andalusian Health Service, SAS)
When Paediatric Clinical Research was initiated (year)?	Before 1998
Which Ethics Committee is the Unit linked to?	Provincial de Málaga

Unit manager

Name and family name(s)	Antonio Urda Cardona
Education (physician, pharmacist, etc.)	Pediatricist
Department which the Research Unit is linked to	Paediatrics
Manager since (year)	2009
Email address	antonio.urda.sspa@juntadeandalucia.es
Phone number	671 59 56 27
List of all departments in the institution which perform paediatric research	Neonatology, Infectious, Cardiology, Intensive Care, Endocrinology, Gastroenterology and Nutrition, Hematology, Neumology, Neurology, Oncology, Rheumatology, Traumatology, Mental Health, and Palliative Care.
	Availability of Clinical Trials Unit in Early Phases (I and II)





Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Neonatology
Infectious
Cardiology
Intensive Care
Endocrinology
Gastroenterology and Nutrition
Hematology
Neumology
Neurology
Oncology
Rheumatology
Traumatology
Mental Health
Palliative Care





Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga

Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? Yes

Name of the agency and date of inspection

ISCIII (Accreditation of the Institute of Biomedical Research of Malaga, IBIMA)

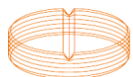
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? Yes

Has the Unit been audited by a sponsor in the last 3 years? No

Does the Unit use its own Standard Operating Procedures (SOPs)? No

Do you provide the sponsor with a copy of the SOP if requested? No

Would the Unit be ready to accept sponsor's SOPs? --





Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga Facilities



How many paediatric trials can be run in parallel in the Unit?	More tan 20
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	173 (90 Paediatrics, 13 Intensive Care, Up to 70 places in Neonatology)
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga Facilities

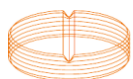
Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

During the warranty period, the trading house takes care of the calibration.

Afterwards, the Hospital Maintenance Service is responsible for each equippe according to their characteristics.





Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga Personnel



Total number of people working at the Unit

Total permanent personnel 35 (Investigators)

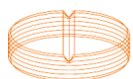
Total non-permanent personnel (by contract, Residents, Fellows) 46 (44 residents)

Total collaborators (part time)*

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
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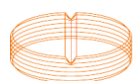




Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
13 doctoral investigators	Partial	Variable	Variable	
14 non doctoral	Partial	Variable	Variable	
5 nurses	Partial	Variable	Variable	
1 Study Coordinator	Complete			
1 Data manager	Complete			





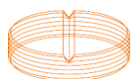
Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga Services



Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) **Partial**
If not, how study medicines are received and stored **N/A**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga

Subjects of Clinical Trial



Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)

Patients

Other populations

X

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

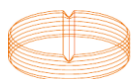
Yes

Methods used by the Unit for the recruitment of participants

Patients attending different hospital areas (hospitalization, outpatients, emergencies, etc.).

Search in medical records.

Contact with Primary Care Paediatrics specialists.





Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

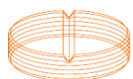
Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Our Unit is the reference unit of some Andalusian provinces that send patients from their centres.

It is also a reference unit for some pathologies at national level. Patients from other Communities are admitted. Their Communities are in charge of the management of transfers and assistance.



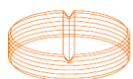


Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses? **No**
If yes, brief description: **N/A**

Does the Unit have experience in processing blood samples for cell immunity? **No**
If yes, brief description: **N/A**





Unidad de Investigación Clínica Pediátrica - Hospital Regional Universitario de Málaga **Experience**



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	2	37	65	12		
Independent group	1	8	7	0		

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	X
Gynaecology	
Neurosciences	X
Ophthalmology	
Oncology	X
Respiratory	X
Urology	
Organ transplantation	
Psychiatry	X

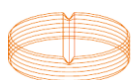
Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	X
Immunology	
Dermatology	X
Metabolism	X
Allergy	X
Anaesthesiology	
Pneumology	X
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Clinical Paediatric Emergent Group - IBSAL



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Grupo Emergente de Pediatría Clínica - IBSAL

Affiliation data

Who filled in the inquiry (name)	Pablo Prieto Matos
Position	LEA Pediatría
Email	pprieto@saludcastillayleon.es
Phone	
Date of completion of inquiry	23/01/2017
Official name of the Paediatric Research Unit, complete address and email	Paediatric Clinical Research Emerging group
Website	---





Grupo Emergente de Pediatría Clínica - IBSAL

Membership or ownership data

Unit ownership	Public - IBSAL
When Paediatric Clinical Research was initiated (year)?	2015
Which Ethics Committee is the Unit linked to?	---
Unit manager	
Name and family name(s)	Pablo Prieto Matos
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Paediatric
Manager since (year)	2015
Email address	pprieto@saludcastillayleon.es
Phone number	
List of all departments in the institution which perform paediatric research	Paediatric





Grupo Emergente de Pediatría Clínica - IBSAL

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

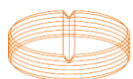
Endocrinology

Nephrology

Cardiology

Neurology

Oncohematology





Grupo Emergente de Pediatría Clínica - IBSAL Audits

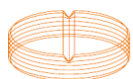
Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? **No**

Name of the agency and date of inspection **N/A**

Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? **Yes**

Has the Unit been audited by a sponsor in the last 3 years? **No**

Does the Unit use its own Standard Operating Procedures (SOPs)? **No**
Do you provide the sponsor with a copy of the SOP if requested? **Yes**
Would the Unit be ready to accept sponsor's SOPs? **Yes**





Grupo Emergente de Pediatría Clínica - IBSAL Facilities

How many paediatric trials can be run in parallel in the Unit?	---
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	Hospitalization beds are 80 aprox.
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





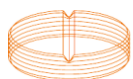
Grupo Emergente de Pediatría Clínica - IBSAL Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Calibration of stadiometer Holtain with its corresponding calibrator





Grupo Emergente de Pediatría Clínica - IBSAL Personnel

Total number of people working at the Unit

Total permanent personnel	12
Total non-permanent personnel (by contract, Residents, Fellows)	10
Total collaborators (part time)*	

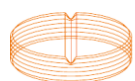
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
---	---

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
---	---	---	---	---



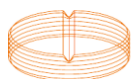


Grupo Emergente de Pediatría Clínica - IBSAL Services

Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) ---
If not, how study medicines are received and stored **Yes**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Grupo Emergente de Pediatría Clínica - IBSAL

Subjects of Clinical Trial

Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)

Patients

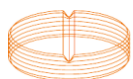
Other populations

X

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Methods used by the Unit for the recruitment of participants

They are included from medical visits of paediatric, surgery and anesthesia subspecializations





Grupo Emergente de Pediatría Clínica - IBSAL

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

If yes, names of associations are:

Yes

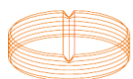
Asociación de diabetes de Salamanca
Asociación de Diabetes de Ciudad Rodrigo
Asociación de Sd Turner Alejandra Grandes
Enfermedades raras

Does the centre receives subjects from other hospitals?

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Yes

Same Autonomous Community (regional state)





Grupo Emergente de Pediatría Clínica - IBSAL
Pharmacodynamic / pharmacokinetic evaluation

Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

No (There is experience from Pharmacy Department of our hospital)

If yes, brief description:

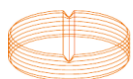
N/A

Does the Unit have experience in processing blood samples for cell immunity?

No

If yes, brief description:

N/A





Grupo Emergente de Pediatría Clínica - IBSAL Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company			1		2	
Independent group		1 (II /III)				2

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	
Digestive	
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	X
Respiratory	
Urology	
Organ transplantation	X
Psychiatry	

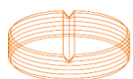
Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

No

If yes, these units are:

N/A





Hospital Materno - Infantil de la Vall d'Hebron



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Hospital Materno - Infantil de la Vall d'Hebron

Affiliation data



Who filled in the inquiry (name)	Xavier Cañas Perea
Position	Director of Promotion of Clinical Research
Email	xavier.canas@vhir.org
Phone	
Date of completion of inquiry	23/01/17
Official name of the Paediatric Research Unit, complete address and email	Mother and Child University Hospital of Vall Hebron
Website	www.vhir.org





Hospital Materno - Infantil de la Vall d'Hebron Membership or ownership data

Unit ownership	Public - University Hospital of Vall Hebron
When Paediatric Clinical Research was initiated (year)?	1965
Which Ethics Committee is the Unit linked to?	CEIm-HUVH. IRB00002850

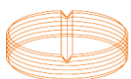
Unit manager

Name and family name(s)	Carlos Rodrigo Gonzalo de Liria
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Paediatric Unit
Manager since (year)	2015
Email address	crodrigo@vhebron.net
Phone number	

List of all departments in the institution which perform paediatric research

Oncology, Hematology, Nephrology, Neonatology, Surgery, Intensive care, Cardiology, Otolaryngology, Ophthalmology, Maxillofacial surgery, Obstetrics and gynecology, Traumatology, Plastic surgery and burns, Neurosurgery, Image diagnosis, Clinical genetic, Microbiology, Rheumatology, Pathological anatomy, Preventive medicine, Dermatology

List of all subspecialties in the organization which perform paediatric research





Hospital Materno - Infantil de la Vall d'Hebron Audits

Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? **No**

Name of the agency and date of inspection **N/A**

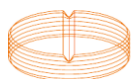
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? **Yes**

Has the Unit been audited by a sponsor in the last 3 years? **No**

Does the Unit use its own Standard Operating Procedures (SOPs)? **Yes**

Do you provide the sponsor with a copy of the SOP if requested? **Yes**

Would the Unit be ready to accept sponsor's SOPs? **Yes**





Hospital Materno - Infantil de la Vall d'Hebron Facilities

How many paediatric trials can be run in parallel in the Unit?	>60
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	290
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	Yes
Does the Unit have experience in home nursing services?	Yes





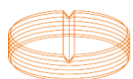
Hospital Materno - Infantil de la Vall d'Hebron Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Calibrations of the devices are subject to the program of calibration of the Unit of warranty of quality of the hospital Vall d'Hebron and VHIR





Hospital Materno - Infantil de la Vall d'Hebron **Personnel**



Total number of people working at the Unit

Total permanent personnel	62
Total non-permanent personnel (by contract, Residents, Fellows)	90
Total collaborators (part time)*	150

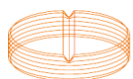
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalent person/full time.

Personnel per service

Service	Personnel
---	---

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
---	---	---	---	---





Hospital Materno - Infantil de la Vall d'Hebron Services

Does the Unit have a specific day hospital for paediatric population	Yes
Does the Unit have a Pharmacy Service? If yes, availability of Pharmacy Service (Total/Partial) If not, how study medicines are received and stored	Yes Total Accredited storage under the Pharmacy Services' regulation
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





Hospital Materno - Infantil de la Vall d'Hebron Subjects of Clinical Trial

Types of population accessed by the Unit

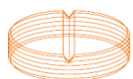
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	X
	Tertiary patients, critical infants

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Yes

Methods used by the Unit for the recruitment of participants

Clinical practice and usual care, and specific search by clinical electronic history





Hospital Materno - Infantil de la Vall d'Hebron

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

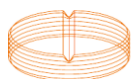
Cancer, minority diseases, diabetics, transplant, immune deficiencies

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

From the same AC, from other ACs and from other countries. By official bypass and as Centre tertiary of reference





Hospital Materno - Infantil de la Vall d'Hebron Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

If yes, brief description:

Yes

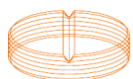
In different trials is required the determination of constants pharmacodynamics and pharmacokinetic

Does the Unit have experience in processing blood samples for cell immunity?

If yes, brief description:

Yes

In the main laboratories of the HUVH





Hospital Materno - Infantil de la Vall d'Hebron Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	15	28	46	42	1	
Independent group						

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	X
Gynaecology	X
Neurosciences	X
Ophthalmology	
Oncology	X
Respiratory	X
Urology	
Organ transplantation	X
Psychiatry	

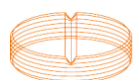
Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	X
Immunology	X
Dermatology	
Metabolism	
Allergy	X
Anaesthesiology	
Pneumology	X
Odontology	
Biochemistry	
Nephrology	X
Vaccines	X

Are there other units interested in paediatric trials?

If yes, these units are:

Yes

Any collaboration of other transversal services of the hospital and of centres of primary attention





Servei Pediatria - Hospital del Mar



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Servei Pediatria - Hospital del Mar

Affiliation data



Who filled in the inquiry (name)	M ^a Ángeles López Vílchez
Position	Head of Paediatric Service
Email	93488@parcdesalutmar.cat
Phone	+34932483144
Date of completion of inquiry	23/01/2017
Official name of the Paediatric Research Unit, complete address and email	SERVEI PEDIATRIA HOSPITAL DEL MAR. P ^o Marítim 25-29 Barcelona 08003, Spain
Website	No





Servei Pediatria - Hospital del Mar

Membership or ownership data

Unit ownership

Public – Parc de Salut Mar

When Paediatric Clinical Research was initiated (year)?

2011

Which Ethics Committee is the Unit linked to?

CEIC-PSMAR

Unit manager

Name and family name(s)

M^a Ángeles López Vílchez

Education (physician, pharmacist, etc.)

Physician

Department which the Research Unit is linked to

Paediatrics

Manager since (year)

2017

Email address

93488@parcdesalutmar.cat

Phone number

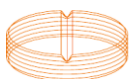
+34932483144

List of all departments in the institution which perform paediatric research

PSMAR Clinical Research Unit, IMIM- Integrated Pharmacology and Neurosciences Systems Research Group

List of all subspecialties in the organization which perform paediatric research

Intellectual disabilities





Servei Pediatria - Hospital del Mar

Audits

Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years?	Yes
Name of the agency and date of inspection	Generalitat de Catalunya (PSMAR Research Unit)
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested?	Yes
Has the Unit been audited by a sponsor in the last 3 years?	Yes, 1 audit (Roche Laboratories)
Does the Unit use its own Standard Operating Procedures (SOPs)?	Yes
Do you provide the sponsor with a copy of the SOP if requested?	Yes
Would the Unit be ready to accept sponsor's SOPs?	Yes





Servei Pediatria - Hospital del Mar Facilities

How many paediatric trials can be run in parallel in the Unit?	2
Does the Unit have beds for hospital admission of paediatric patients?	No
If yes, number of beds in the Unit	--
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	N/A
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	No
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





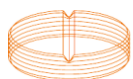
Servei Pediatria - Hospital del Mar Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Following accredited SOP's





Servei Pediatria - Hospital del Mar Personnel



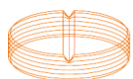
Total number of people working at the Unit

Total permanent personnel	7
Total non-permanent personnel (by contract, Residents, Fellows)	14
Total collaborators (part time)*	

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalent person/full time.

Personnel per service

Service	Personnel
Paediatric Department	1
Clinical Research Unit	3





Servei Pediatria - Hospital del Mar Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Specialist in study contracts	Full time	2	2	2
Nurse	Full time	30	5	4





Servei Pediatria - Hospital del Mar Services



Does the Unit have a specific day hospital for paediatric population	No
Does the Unit have a Pharmacy Service? If yes, availability of Pharmacy Service (Total/Partial) If not, how study medicines are received and stored	Yes Total N/A
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





Servei Pediatria - Hospital del Mar Subjects of Clinical Trial

Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)

Patients

Other populations

X

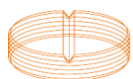
X

Down syndrome, FXS syndrome, FAS (fetal alcohol syndrome)

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Methods used by the Unit for the recruitment of participants

Associations of families





Servei Pediatria - Hospital del Mar

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

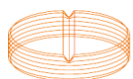
Down España, Fundació Catalana Síndrome de Down, Associació Catalana del X Fràgil

Does the centre receives subjects from other hospitals?

No

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

N/A





Servei Pediatria - Hospital del Mar Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

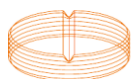
Drug developed by Roche Laboratories for Down syndrome

Does the Unit have experience in processing blood samples for cell immunity?

No

If yes, brief description:

N/A





Servei Pediatria - Hospital del Mar Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	1				1	
Independent group	2	1				

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	
Digestive	
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	
Neurosciences	X
Ophthalmology	
Oncology	
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

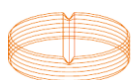
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Servicio de Pediatría - Hospital Parc Taulí



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Servicio de Pediatría - Hospital Parc Taulí

Affiliation data



Who filled in the inquiry (name)	Coloma Moreno Quiroga
Position	Ethical Committee Secretary
Email	cmoreno@tauli.cat
Phone	
Date of completion of inquiry	19/01/2017
Official name of the Paediatric Research Unit, complete address and email	Servicio de Pediatría. Parc Taulí 1, 08208 Sabadell, Barcelona
Website	http://www.tauli.cat/i3pt/





Servicio de Pediatría - Hospital Parc Taulí

Membership or ownership data

Unit ownership

Public - Corporació Sanitària Parc Taulí

When Paediatric Clinical Research was initiated (year)?

1982

Which Ethics Committee is the Unit linked to?

Corporació Sanitària Parc Taulí

Unit manager

Name and family name(s)

Lluís Blanch

Education (physician, pharmacist, etc.)

Médecin

Department which the Research Unit is linked to

Parc Taulí Research and Innovation Institute

Manager since (year)

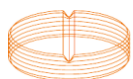
Email address

lblanch@tauli.cat

Phone number

List of all departments in the institution which perform paediatric research

The paediatric research is centralized in the Paediatric Unit for all the subspecialties (see below). The investigation belongs to the Institute.





Servicio de Pediatría - Hospital Parc Taulí

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Neurology

Genetics

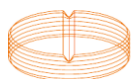
Pneumology

Allergy

Endocrinology

Neonatology

Gastroenterology





Servicio de Pediatría - Hospital Parc Taulí Audits

Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? No

Name of the agency and date of inspection N/A

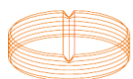
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? ---

Has the Unit been audited by a sponsor in the last 3 years? No

Does the Unit use its own Standard Operating Procedures (SOPs)? No

Do you provide the sponsor with a copy of the SOP if requested? ---

Would the Unit be ready to accept sponsor's SOPs? Yes





Servicio de Pediatría - Hospital Parc Taulí Facilities

How many paediatric trials can be run in parallel in the Unit?	6
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	1
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advance
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	Yes
Does the Unit have experience in home nursing services?	Yes





Servicio de Pediatría - Hospital Parc Taulí Facilities

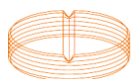
Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

The maintenance service measures regularly all the instruments.

The ultra freezers are located in a special room with an alarm connected to mobiles of people in charge and investigators.





Servicio de Pediatría - Hospital Parc Taulí Personnel



Total number of people working at the Unit

Total permanent personnel	14
Total non-permanent personnel (by contract, Residents, Fellows)	---
Total collaborators (part time)*	10

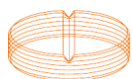
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
---	---

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Nurses	Partial	25	25	+70
Doctors	Partial	25	25	+70





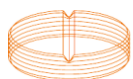
Servicio de Pediatría - Hospital Parc Taulí Services



Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) **Total**
If not, how study medicines are received and stored **N/A**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Servicio de Pediatría - Hospital Parc Taulí Subjects of Clinical Trial

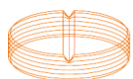
Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	X
	Family

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?
Yes

Methods used by the Unit for the recruitment of participants

Clinical records
Emergency Unit (healthy volunteers)
Paediatric Surgery unit (healthy volunteers)





Servicio de Pediatría - Hospital Parc Taulí

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

If yes, names of associations are:

Yes

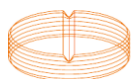
Nacional Society of Quistic Fibrosi
Nacional Society of Prader Willi
Nacional Society of Angelman Sindrom
Nacional Society of X Fragil Sindrom

Does the centre receives subjects from other hospitals?

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Yes

From all Spain and also from the same Autonomous Community, depends on the disease





Servicio de Pediatría - Hospital Parc Taulí Pharmacodynamic / pharmacokinetic evaluation

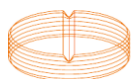


Does the Unit have experience in paediatric clinical trials with PK/PD analyses? **Yes**

If yes, brief description: ---

Does the Unit have experience in processing blood samples for cell immunity? **Yes**

If yes, brief description: ---





Servicio de Pediatría - Hospital Parc Taulí Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company		6	14	4	12	
Independent group					42	
There are 8 projects not Clinical trials with drugs which can't be labeled in the table over. 7 are independent research and 1 from a pharmaceutical company.						

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	X
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	
Respiratory	X
Urology	
Organ transplantation	
Psychiatry	X

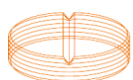
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	X
Anaesthesiology	
Pneumology	X
Odontology	
Biochemistry	
Nephrology	
Vaccines	X

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu

Affiliation data



Who filled in the inquiry (name)	Joana Claverol Torres
Position	CRU Manager
Email	jclaverol@fsjd.org
Phone	+34 936009733
Date of completion of inquiry	18/01/2017
Official name of the Paediatric Research Unit, complete address and email	Unidad de Ensayos Clínicos Sant Joan de Déu / Clinical Research Unit Hospital Sant Joan de Déu Pg. Sant Joan de Déu, 2, planta 0, Consultes Externes 08950 Esplugues de Llobregat
Website	http://www.fsjd.org/es/ensayos-cl%C3%ADnicos_40359 https://www.sjdhospitalbarcelona.org/es/colabora/unidad-ensayos-clinicos





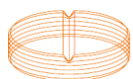
Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu

Membership or ownership data

Unit ownership	Private - Sant Joan de Déu Research Foundation
When Paediatric Clinical Research was initiated (year)?	2004
Which Ethics Committee is the Unit linked to?	CEIm Sant Joan de Déu Research Foundation

Unit manager

Name and family name(s)	Joana Claverol Torres
Education (physician, pharmacist, etc.)	Biology SC
Department which the Research Unit is linked to	Research and innovation
Manager since (year)	2012
Email address	jclaverol@fsjd.org
Phone number	+34936009733
List of all departments in the institution which perform paediatric research	Breakdown by subspecialties





Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Anesthesia

Nephrology

Cardiology

Neonatology

Surgery

Pneumology

Dermatology

Ophthalmology

Endocrinology

Oncology

Gastro

Palliative

Gynecology

Paediatrics

Hematology

Psychiatry

Immunoallergy

Rheumatology

Infectious

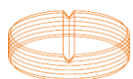
Rehabilitation

Microbiology

Traumatology

Neurology

ICU





Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu

Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years?	No
Name of the agency and date of inspection	N/A
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested?	Yes
Has the Unit been audited by a sponsor in the last 3 years?	Yes, 1 audit in 2016, 4 audits in 2014, 1 audit in 2013
Does the Unit use its own Standard Operating Procedures (SOPs)?	Yes
Do you provide the sponsor with a copy of the SOP if requested?	Yes
Would the Unit be ready to accept sponsor's SOPs?	Yes





Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu Facilities

How many paediatric trials can be run in parallel in the Unit?	>100
Does the Unit have beds for hospital admission of paediatric patients?	No Las camas de hospitalización están disponibles para pacientes de ensayos clínicos
If yes, number of beds in the Unit	0
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	Yes
Does the Unit have experience in home nursing services?	Yes





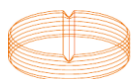
Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers (-20,-80) , fridge	X
Weight Scales	X
Measuring rod	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Electromedicine service of the hospital, with the frequency defined in the SOPs of the Unit





Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu Personnel

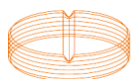
Total number of people working at the Unit

Total permanent personnel	12
Total non-permanent personnel (by contract, Residents, Fellows)	2
Total collaborators (part time)*	See comment

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Number of PI's: 65	The PI's are hospital MD with part of their time devoted to supervision and research in the Research Unit.

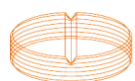




Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
CRU Manager	Complete	18	13	NA
Project manager	Complete	14	14	NA
Economic manager and contract management	Complete	23	10	NA
Administrative	Complete	10	1	NA
Research Nurse/Study Coordinator 1 (CLL)	Complete	10	5	20-30
Research Nurse/Study Coordinator 2 (MM)	Complete	9	2	20-30
Research Nurse/Study Coordinator 3 (CE)	Complete	14	1	20-25
Research Nurse/Study Coordinator 4 (ES)	Complete	6	1	20-25
Research Nurse/Study Coordinator 5 (SM)	Complete	10	7	20-30
Research Nurse/Study Coordinator 6 (LS)	Complete	10	6	20-30
Research Nurse/Study Coordinator 7 (MS)	Complete	10	4	20-30
Pharmacist (AM)	Complete	9	6	ALL





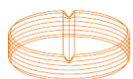
Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu Services



Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) **Total**
If not, how study medicines are received and stored **N/A**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu Subjects of Clinical Trial



Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)

Patients

Other populations

X

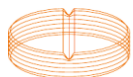
In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Yes (hospital translation service)

Methods used by the Unit for the recruitment of participants

Patients from own database, hospitalized patients and patients referred from other centres in Spain and other countries.

Information related to open trials can be found by patients in our website.





Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

If yes, names of associations are:

Yes

- Association of Lowe's Syndrome of Spain
- Associazione Italiana Lowe's Syndrome
- Association of Lowe Syndrome (France)
- Spanish Association of CDG Syndrome
- Portuguese CDG Association
- ENACH
- AHUCE and AHUCE Foundation
- AMOI (Madrid Association of Imperfect Osteogenesis)
- Retina Spain
- Stargardt Spain
- TWELVE
- Association of Neurodegenerative Diseases by Iron Brain Accumulation (Hallervorden-Spatz) - ENACH
- EURORDIS

+ 100 additional rare diseases patient's associations regularly collaborate with the "Espai d'associacions" of the Hospital

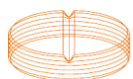
Does the centre receives subjects from other hospitals?

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Yes

From the same AC, national, international.

Through the web of the research unit, through the Paediatric Institute (international medicine)





Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

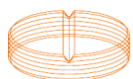
20% of the active CT are phase 1. We have the possibility to admit patients to Day Hospital or to the Hospitalization building to perform PK or other invasive procedures.

Does the Unit have experience in processing blood samples for cell immunity?

No

If yes, brief description:

N/A





Unidad de Ensayos Clínicos Sant Joan de Déu - Hospital Sant Joan de Déu Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	20	30	61	9	39	
Independent group	2	9	8	1	17	13

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	X
Digestive	X
Anaesthesiology and Pain Medicine	X
Endocrinology	X
Gynaecology	X
Neurosciences	X
Ophthalmology	X
Oncology	X
Respiratory	X
Urology	X
Organ transplantation	X
Psychiatry	X

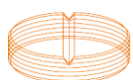
Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	X
Immunology	X
Dermatology	X
Metabolism	X
Allergy	X
Anaesthesiology	X
Pneumology	X
Odontology	
Biochemistry	
Nephrology	X
Vaccines	X

Are there other units interested in paediatric trials?

If yes, these units are:

Yes

As we receive new proposals we evaluate them with the service involved. All Hospital services are open to evaluate and participate in clinical research.





Unidad de Investigación Clínica - Hospital Sanitas CIMA



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad de Investigación Clínica - Hospital Sanitas CIMA

Affiliation data



Who filled in the inquiry (name)	Elena Sánchez-Vizcaíno Mengual
Position	Coordinador de la Unidad de Investigación Clínica
Email	
Phone	+34 935 522 799
Date of completion of inquiry	11/01/2017
Official name of the Paediatric Research Unit, complete address and email	There is not a specific Unit of Paediatrics Research. The Hospital has a Clinical Research Unit that collaborates with all Services involved in Research Projects and Clinical Trials.
Website	http://www.hospitalcima.es/es/nuestro-centro-investigacion-etica.php





Unidad de Investigación Clínica - Hospital Sanitas CIMA

Membership or ownership data

Unit ownership	Private – Sanitas SA de Hospitales
When Paediatric Clinical Research was initiated (year)?	2015
Which Ethics Committee is the Unit linked to?	CEIm CIMA

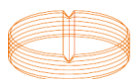
Unit manager

Name and family name(s)	Pelayo De Merlo Martínez
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Medical and Surgical Director
Manager since (year)	2017
Email address	pmerlo@sanitas.es
Phone number	+935522766

List of all departments in the institution which perform paediatric research

List of all subspecialties in the organization which perform paediatric research

There is none





Unidad de Investigación Clínica - Hospital Sanitas CIMA Audits

Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? No

Name of the agency and date of inspection N/A

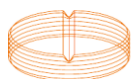
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? Yes

Has the Unit been audited by a sponsor in the last 3 years? No

Does the Unit use its own Standard Operating Procedures (SOPs)? Yes

Do you provide the sponsor with a copy of the SOP if requested? Yes

Would the Unit be ready to accept sponsor's SOPs? Yes





Unidad de Investigación Clínica - Hospital Sanitas CIMA Facilities

How many paediatric trials can be run in parallel in the Unit?	4
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	5 (depending on the needs)
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	No
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	No
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





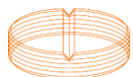
Unidad de Investigación Clínica - Hospital Sanitas CIMA Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers -85°C	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

The calibrations are performed by the Electromedical Service





Unidad de Investigación Clínica - Hospital Sanitas CIMA Personnel



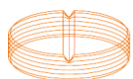
Total number of people working at the Unit

Total permanent personnel	1
Total non-permanent personnel (by contract, Residents, Fellows)	0
Total collaborators (part time)*	9

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Paediatrics	3 (part time)
Nurses	2 (part time)
Laboratory Technician	2 (part time)
Radiology Technician	2 (part time)
Study Coordinator	1 (complete)

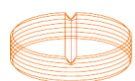




Unidad de Investigación Clínica - Hospital Sanitas CIMA Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
3 Paediatrics	part time	3 to 11	6 to 11	4
2 Nurses	part time	6 to 7	2	1
2 Laboratory Technicians	part time	10 to 13	2	1
2 Radiology Technicians	part time	3	0	0
1 Study Coordinator	complete	3	2	1





Unidad de Investigación Clínica - Hospital Sanitas CIMA Services



Does the Unit have a specific day hospital for paediatric population	No
Does the Unit have a Pharmacy Service? If yes, availability of Pharmacy Service (Total/Partial) If not, how study medicines are received and stored	Yes Monday to Friday (8 a.m. to 8 p.m.), Saturday from 8 a.m. to 1 p.m. N/A
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





Unidad de Investigación Clínica - Hospital Sanitas CIMA

Subjects of Clinical Trial

Types of population accessed by the Unit

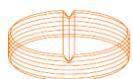
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

There are people who speak English and if patient/parents speak another idiom we can request a translator

Methods used by the Unit for the recruitment of participants

Activity of the Department of Paediatrics and the hospital database





Unidad de Investigación Clínica - Hospital Sanitas CIMA

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations? **No**
If yes, names of associations are: **N/A**

Does the centre receives subjects from other hospitals? **Yes**
If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral: **---**

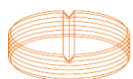




Unidad de Investigación Clínica - Hospital Sanitas CIMA Pharmacodynamic / pharmacokinetic evaluation

Does the Unit have experience in paediatric clinical trials with PK/PD analyses? **No**
If yes, brief description: **N/A**

Does the Unit have experience in processing blood samples for cell immunity? **No**
If yes, brief description: **N/A**





Unidad de Investigación Clínica - Hospital Sanitas CIMA Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	0	0	1	0	0	0
Independent group	0	0	0	0	0	0

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	
Digestive	
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

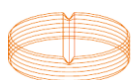
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	1
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Grupo de Investigación de Nutrición Pediátrica de INCLIVA



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Grupo de Investigación de Nutrición Pediátrica de INCLIVA

Affiliation data



Who filled in the inquiry (name)	Cecilia Martínez Costa
Position	Coordinator
Email	cecilia.martinez@uv.es
Phone	961 973 912
Date of completion of inquiry	03/07/2017
Oficial name of the Paediatric Research Unit, complete address and email	Grupo de Investigación de Nutrición Pediátrica de INCLIVA Avenida de Menéndez y Pelayo, 4, 46010 Valencia cecilia.martinez@uv.es
Website	http://www.incliva.es/investigacion/areas/cardiovascular/grupo-de-investigacion-de-nutricion-paediatria





Grupo de Investigación de Nutrición Pediátrica de INCLIVA

Membership or ownership data

Unit ownership	Public - Instituto de Investigación Sanitaria INCLIVA. Servicio de Pediatría, Hospital Clínico Universitario de Valencia. Universidad de Valencia
When Paediatric Clinical Research was initiated (year)?	1985
Which Ethics Committee is the Unit linked to?	Ethics Committee of Valencia Clinical Hospital
Unit manager	
Name and family name(s)	Cecilia Martínez Costa
Education (physician, pharmacist, etc.)	Physician, Paediatrician specialist
Department which the Research Unit is linked to	Department of Paediatrics, Hospital Clínico Universitario de Valencia
Manager since (year)	2005
Email address	cecilia.martinez@uv.es
Phone number	961 973 912
List of all departments in the institution which perform paediatric research	Department of Paediatrics, Hospital Clínico Universitario de Valencia





Grupo de Investigación de Nutrición Pediátrica de INCLIVA **Membership or ownership data**

List of all subspecialties in the organization which perform paediatric research

Paediatric Gastroenterology and Nutrition Section

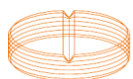
Paediatric Cardiology Section

Paediatric Endocrinology Section

Paediatric Oncohematology

Neonatology

Paediatric Neumology





Grupo de Investigación de Nutrición Pediátrica de INCLIVA Audits

Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? **No**

Name of the agency and date of inspection **N/A**

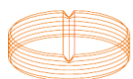
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? **Yes**

Has the Unit been audited by a sponsor in the last 3 years? **No**

Does the Unit use its own Standard Operating Procedures (SOPs)? **No**

Do you provide the sponsor with a copy of the SOP if requested? **---**

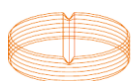
Would the Unit be ready to accept sponsor's SOPs? **Yes**





Grupo de Investigación de Nutrición Pediátrica de INCLIVA Facilities

How many paediatric trials can be run in parallel in the Unit?	3-4
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	90
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	Yes
Does the Unit have experience in home nursing services?	Yes





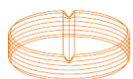
Grupo de Investigación de Nutrición Pediátrica de INCLIVA Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

The equipment is calibrated according to the manufacturer's instructions





Grupo de Investigación de Nutrición Pediátrica de INCLIVA
Personnel

Total number of people working at the Unit

Total permanent personnel 6

Total non-permanent personnel (by contract, Residents, Fellows) 6

Total collaborators (part time)*

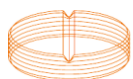
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
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Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
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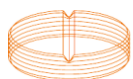
Grupo de Investigación de Nutrición Pediátrica de INCLIVA Services



Does the Unit have a specific day hospital for paediatric population Yes

Does the Unit have a Pharmacy Service? Yes
If yes, availability of Pharmacy Service (Total/Partial) ---
If not, how study medicines are received and stored N/A

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? Yes





Grupo de Investigación de Nutrición Pediátrica de INCLIVA Subjects of Clinical Trial

Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)

Patients

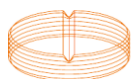
X

Other populations

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Methods used by the Unit for the recruitment of participants

Patients are recruited from the hospital and from primary healthcare centres





Grupo de Investigación de Nutrición Pediátrica de INCLIVA

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

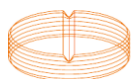
AsinDown

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Patients from other hospitals of the same region are admitted following the standard procedure.





Grupo de Investigación de Nutrición Pediátrica de INCLIVA Pharmacodynamic / pharmacokinetic evaluation

Does the Unit have experience in paediatric clinical trials with PK/PD analyses?	No
If yes, brief description:	N/A
Does the Unit have experience in processing blood samples for cell immunity?	Yes
If yes, brief description:	---





Grupo de Investigación de Nutrición Pediátrica de INCLIVA Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company		1	1		27	
Independent group						

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	X
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	X
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	X
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

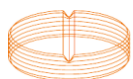
Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA)



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience



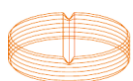


Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA)

Affiliation data



Who filled in the inquiry (name)	Javier González de Dios
Position	Head of the department of paediatrics
Email	javier.gonzalezdedios@gmail.com
Phone	
Date of completion of inquiry	23/01/2017
Official name of the Paediatric Research Unit, complete address and email	Research Group in Paediatrics- General University Hospital of Alicante (GIPHGUA) Address: Paediatric Department.i- General University Hospital of Alicante Avda. Pintor Baeza 12 03010 Alicante E-mail: wordpress@serviciopediatria.com
Website	http://www.serviciopediatria.com/





Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA)

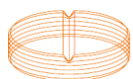
Membership or ownership data



Unit ownership	Public - Hospital General Universitario de Alicante
When Paediatric Clinical Research was initiated (year)?	2017
Which Ethics Committee is the Unit linked to?	ISABIAL (Institute of Sanitary and Biomedical Research of Alicante)

Unit manager

Name and family name(s)	Luis Moral Gil
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Paediatric
Manager since (year)	2017
Email address	lmoralg@gmail.com
Phone number	639602220
List of all departments in the institution which perform paediatric research	Neonatology Section Paediatric Section and its Specific Areas Paediatric Oncology Section Paediatric Emergency Section





Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA)

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Nenonatology

Paediatric Oncology

Paediatric Neumology and Allergy

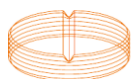
Endocrinology Paediatric and Diabetes

Paediatric Neurology

Paediatric Gastroenterology

General Paediatric (School-Nursing)

Paediatric Emergency and UHD-Palliative Care





Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA) **Audits**



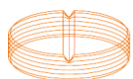
Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? **No**

Name of the agency and date of inspection **N/A**

Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? **Yes**

Has the Unit been audited by a sponsor in the last 3 years? **No**

Does the Unit use its own Standard Operating Procedures (SOPs)? **No**
Do you provide the sponsor with a copy of the SOP if requested? **No**
Would the Unit be ready to accept sponsor's SOPs? **Yes**

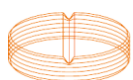




Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA) Facilities



How many paediatric trials can be run in parallel in the Unit?	4
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	75
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	No
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	Yes
Does the Unit have experience in home nursing services?	Yes





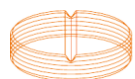
Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA) **Facilities**

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Performed by clinical staff under usual conditions and by the technicians in special conditions





Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA)
Personnel



Total number of people working at the Unit

Total permanent personnel

12

Total non-permanent personnel (by contract, Residents, Fellows)

Total collaborators (part time)*

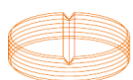
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
---	---

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
12	Partial	20	20	6





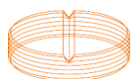
Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA) Services



Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) **Total**
If not, how study medicines are received and stored **N/A**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA) **Subjects of Clinical Trial**



Types of population accessed by the Unit

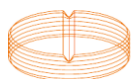
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Seldom

Methods used by the Unit for the recruitment of participants

As specified in each clinical trial





Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA)

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

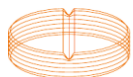
ASPANION

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Of the same AC, generally of the different hospitals (public and private) of the province of Alicante, which are at least 10 hospital centres





Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA)
Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

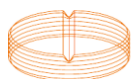
Clinical Pharmacology collaboration

Does the Unit have experience in processing blood samples for cell immunity?

Yes

If yes, brief description:

Clinical Immunology collaboration





Grupo de Investigación en Pediatría - Hospital General Universitario de Alicante (GIP-HGUA) Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company		2			4	
Independent group					10	

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	
Digestive	
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	X
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

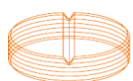
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	X
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

Yes

Primary care centres

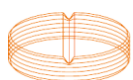




Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General

Affiliation data



Who filled in the inquiry (name)	José Pastor Rosado
Position	Head of Paediatric Unit
Email	pastor_jos@gva.es
Phone	+34 966 616 336
Date of completion of inquiry	17/01/2017
Official name of the Paediatric Research Unit, complete address and email	Research Group in Paediatrics of Elche Health Department General University Hospital of Elche Address: c/ Almàspera 11 03202 Elche pastor_jos@gva.es
Website	https://pediatriaselche.wordpress.com/





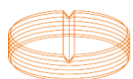
Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General

Membership or ownership data

Unit ownership	Public - General University Hospital from Elche, FISABIO
When Paediatric Clinical Research was initiated (year)?	2001
Which Ethics Committee is the Unit linked to?	Ethics Committee from the University Hospital of Elche

Unit manager

Name and family name(s)	José Pastor Rosado
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Paediatric Unit
Manager since (year)	2006
Email address	pastor_jos@gva.es
Phone number	+34 966 616 336
List of all departments in the institution which perform paediatric research	Pharmacy, Clinical analysis, microbiology





Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General **Membership or ownership data**

List of all subspecialties in the organization which perform paediatric research

Endocrinology (obesity, dyslipemias, vitamin D)

Rare Diseases

Cardiology

Nephrology

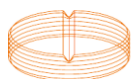
Neurology

Neonatology

Digestive

Nutrition

Allergology





Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General

Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years?	No
Name of the agency and date of inspection	N/A
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested?	Yes
Has the Unit been audited by a sponsor in the last 3 years?	Yes, Protocol: A2581173 (2011-2013)
Does the Unit use its own Standard Operating Procedures (SOPs)?	Yes
Do you provide the sponsor with a copy of the SOP if requested?	Yes
Would the Unit be ready to accept sponsor's SOPs?	Yes





Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General Facilities



How many paediatric trials can be run in parallel in the Unit?	3
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	41
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	No
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	Yes
Does the Unit have experience in home nursing services?	Yes





Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General

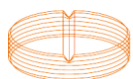
Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

There is an electromedicine service and responsible maintenance of the calibration and maintenance of the equipment, issuing the appropriate certificates.





Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General Personnel



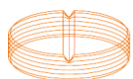
Total number of people working at the Unit

Total permanent personnel	12
Total non-permanent personnel (by contract, Residents, Fellows)	12
Total collaborators (part time)*	2

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Paediatric	---
Pharmacy, Clinical analysis	---





Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Nurse	Complete	20	5	3
Pharmacist	Complete	20	5	>10
Analyst	Complete	20	5	3





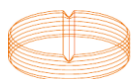
Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General Services



Does the Unit have a specific day hospital for paediatric population Yes

Does the Unit have a Pharmacy Service? Yes
If yes, availability of Pharmacy Service (Total/Partial) Total
If not, how study medicines are received and stored N/A

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? Yes





Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General

Subjects of Clinical Trial



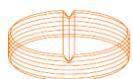
Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Methods used by the Unit for the recruitment of participants

Aleatory, groups, cases and controls





Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

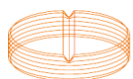
Family hypercholesterolemia

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Same Autonomous Community





Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

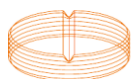
PK/PD study: "Multicentre, randomized, placebo-controlled study of SBC-102 in patients with lysosomal acid lipase deficiency".
Protocol: LAL-CL02. The enzyme sebelipase alpha was administered IV, in collaboration with the laboratory COVANCE

Does the Unit have experience in processing blood samples for cell immunity?

Yes

If yes, brief description:

Our hospital's Hematology Lab has experience in cellular immunity blood sample processing (lymphocyte population ...)





Grupo de Investigación en Pediatría del Departament de Salut Elx - Hospital General Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company			1	2		
Independent group					2	2

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	X
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

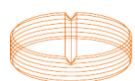
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	X
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience



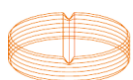


Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset

Affiliation data



Who filled in the inquiry (name)	Miguel Tortajada Girbés
Position	Head of the Paediatric Neuroallergic Unit. Paediatric Department at the University Hospital Dr. Peset. Associate Professor of Paediatrics. School of Medicine. University of Valencia. Principal Investigator in Clinical Trials in Paediatrics
Email	tortajadamig@gmail.com
Phone	
Date of completion of inquiry	17/01/2017
Oficial name of the Paediatric Research Unit, complete address and email	Translational research in paediatrics. Avda Gaspar Aguilar, 90, 46017 Valencia (Spain)
Website	---





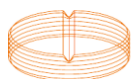
Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset

Membership or ownership data

Unit ownership	Public - University Hospital Dr. Peset
When Paediatric Clinical Research was initiated (year)?	2005
Which Ethics Committee is the Unit linked to?	Ethics Committee from the University Hospital Dr. Peset

Unit manager

Name and family name(s)	Pilar Codoñer Franch
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Paediatrics
Manager since (year)	1991
Email address	pilar.codone@uv.es
Phone number	
List of all departments in the institution which perform paediatric research	Paediatrics





Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset

Membership or ownership data

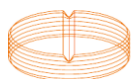
List of all subspecialties in the organization which perform paediatric research

Neuroallergic paediatric

Paediatric Neurology

Paediatric Endocrinology

Paediatric Gastroenterology and Nutrition





Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset

Audits



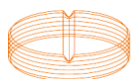
Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? **No**

Name of the agency and date of inspection **N/A**

Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? **Yes**

Has the Unit been audited by a sponsor in the last 3 years? **No**

Does the Unit use its own Standard Operating Procedures (SOPs)? **No**
Do you provide the sponsor with a copy of the SOP if requested? **Yes**
Would the Unit be ready to accept sponsor's SOPs? **Yes**





Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset Facilities



How many paediatric trials can be run in parallel in the Unit?	2
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	20
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	N/A
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





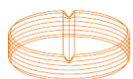
Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

The maintenance service from the hospital is in charge





Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset Personnel

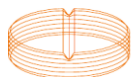
Total number of people working at the Unit

Total permanent personnel	12
Total non-permanent personnel (by contract, Residents, Fellows)	12
Total collaborators (part time)*	3

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
---	---



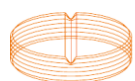


Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset

Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Nurse		5	5	3
Data manager		5	5	3
Paediatrician		5	5	7





Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset Services



Does the Unit have a specific day hospital for paediatric population	No
Does the Unit have a Pharmacy Service?	Yes
If yes, availability of Pharmacy Service (Total/Partial)	---
If not, how study medicines are received and stored	N/A
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset

Subjects of Clinical Trial



Types of population accessed by the Unit

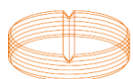
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Yes

Methods used by the Unit for the recruitment of participants

Personal interview





Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

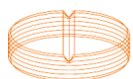
Allergic. Association of Affections of PRADER-WILLI Syndrome, Celiac Association

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Same Autonomous Community



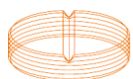


Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses? Yes
If yes, brief description: ---

Does the Unit have experience in processing blood samples for cell immunity? Yes
If yes, brief description: Laboratory technicians





Investigación Translacional en Pediatría - Hospital Universitario Dr. Peset Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company			3	1		
Independent group						5

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	
Digestive	
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

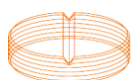
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	X
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	X

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Servicio de Pediatría del Hospital La Fe

- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Servicio de Pediatría del Hospital La Fe

Affiliation data



Who filled in the inquiry (name)	Emilio Monteagudo Montesinos
Position	Head of Paediatric Service and its Specific Areas Head of Clinical Research Area IIS La Fe
Email	emonteagudo@aehh.org investigacion_clinica@iislafe.es
Phone	
Date of completion of inquiry	17/01/2017
Official name of the Paediatric Research Unit, complete address and email	<p>The data exposed below are related to the activity and resources of the different paediatric research groups existing in the Paediatric Service of the Hospital La Fe, located in different sections or clinical units with links and support at the La Fe Research Institute.</p> <p>Centres that do not have a specific paediatric Unit instead they do have a Central Unit EECC that renders support to the service.</p>
Website	http://www.hospital-lafe.com/ http://www.iislafe.es/





Servicio de Pediatría del Hospital La Fe Membership or ownership data

Unit ownership

Public - University and Polytechnic La Fe Hospital

When Paediatric Clinical Research was initiated (year)?

1996

Which Ethics Committee is the Unit linked to?

The Ethics Committee of the University and Polytechnic La Fe Hospital

Unit manager

Name and family name(s)

Emilio Monteagudo Montesinos

Education (physician, pharmacist, etc.)

Doctor, Paediatrics Specialist

Department which the Research Unit is linked to

Paediatrics and its Specific Areas

Manager since (year)

2011

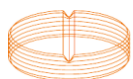
Email address

emonteagudo@aehh.org

Phone number

List of all departments in the institution which perform paediatric research

Paediatric Surgery
Paediatric Anesthesiology





Servicio de Pediatría del Hospital La Fe **Membership or ownership data**

List of all subspecialties in the organization which perform paediatric research

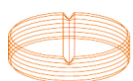
Paediatric Oncology
Paediatric Pneumology and Allergy
Paediatric Rheumatology
Gastroenterology and Paediatric Nutrition
Neonatology
Paediatric Infectious
Paediatric General
Paediatric Hematology
Paediatric Endocrinology
Metabolopathies
Neuropaediatrics
Paediatric General Surgery
Paediatric Cardiology
Paediatric Intensive Care
Paediatric Nephrology





Servicio de Pediatría del Hospital La Fe Audits

Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years?	No
Name of the agency and date of inspection	N/A
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested?	Yes
Has the Unit been audited by a sponsor in the last 3 years?	Yes, 5 audits
Does the Unit use its own Standard Operating Procedures (SOPs)?	No
Do you provide the sponsor with a copy of the SOP if requested?	N/A
Would the Unit be ready to accept sponsor's SOPs?	Yes





Servicio de Pediatría del Hospital La Fe Facilities

How many paediatric trials can be run in parallel in the Unit?	Multiple, minimum one for each research group
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	200
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	Yes
Does the Unit have experience in home nursing services?	Yes





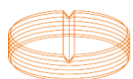
Servicio de Pediatría del Hospital La Fe Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

The Hospital's Electromedicine Service has outsourced a specialized company that performs preventive maintenance, calibration and repair of the centre's equipment





Servicio de Pediatría del Hospital La Fe Personnel

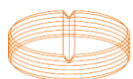
Total number of people working at the Unit

Total permanent personnel	51
Total non-permanent personnel (by contract, Residents, Fellows)	20
Total collaborators (part time)*	20

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Oncology	12
Neumology and Allergy	9
Rheumatology	4
Gastroenterology, Hepatology and Nutrition	8
Neonatology	15
Infectious and General Paediatric	8
Haematology	3
Endocrinology	3
Metabopathies	2
Neuropaediatrics	5
Nephrology	1
Cardiology	1



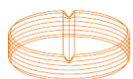


Servicio de Pediatría del Hospital La Fe Services

Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) **The Hospital has an own Pharmacy Service for clinical trials**
If not, how study medicines are received and stored **N/A**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Servicio de Pediatría del Hospital La Fe Subjects of Clinical Trial

Types of population accessed by the Unit

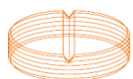
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

No, the centre contacts the consulates and requests an interpreter if it is necessary

Methods used by the Unit for the recruitment of participants

Offering inpatients or outpatients who are potential candidates, immediate relatives and patient associations





Servicio de Pediatría del Hospital La Fe **Subjects of Clinical Trial**

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

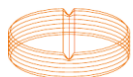
ASPANION, ASPANIJER

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

YES, either the same region or from other regions. Communication by mail or telephone; Occasionally by teleconference or videoconference.





Servicio de Pediatría del Hospital La Fe Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

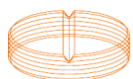
The different Paediatric services have participated in numerous Phase I, II and III trials with PK / PD analysis, extractions, processing and shipping done by specialized personnel trained in clinical research.

Does the Unit have experience in processing blood samples for cell immunity?

No

If yes, brief description:

N/A





Servicio de Pediatría del Hospital La Fe Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	18	14	30	5	24	
Independent group	1	5	3	0	13	121

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	7
Cardiovascular	
Digestive	9
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	
Neurosciences	4
Ophthalmology	
Oncology	18
Respiratory/Pneumology	5
Urology	
Organ transplantation	
Psychiatry	

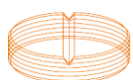
Therapeutic areas	Clinical trials
Haematology	4
Rheumatology	11
Immunology	
Dermatology	
Metabolism	1
Allergy	
Anaesthesiology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	
Paediatric General	3
Neonatology	5

Are there other units interested in paediatric trials?

If yes, these units are:

Yes

Paediatric Intensive Care and Paediatric Nephrology





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela

Affiliation data



Who filled in the inquiry (name)	Carmen Rodríguez-Tenreiro Sánchez
Position	Research manager
Email	carmentenreiro@hotmail.es
Phone	655 299 502
Date of completion of inquiry	30/01/2017
Official name of the Paediatric Research Unit, complete address and email	Paediatrics Clinical Trials Unit. Hospital Clínico Universitario de Santiago de Compostela. A Choupana, 15706 Santiago de Compostela, Spain
Website	Under construction. Temporarily http://www.genvip.eu





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela

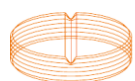
Membership or ownership data



Unit ownership	Public - Hospital Clínico Universitario de Santiago de Compostela; Health Research Institute of Santiago de Compostela (IDIS)
When Paediatric Clinical Research was initiated (year)?	2006
Which Ethics Committee is the Unit linked to?	Comité de Ética de la Investigación con medicamentos (CEIm) de Galicia. Ethics Committees for research purposes of Galicia

Unit manager

Name and family name(s)	Federico Martín-Torres
Education (physician, pharmacist, etc.)	Médico, PhD
Department which the Research Unit is linked to	Servicio de Pediatría
Manager since (year)	2006
Email address	federico.martinon.torres@sergas.es
Phone number	981 955373 / 950142
List of all departments in the institution which perform paediatric research	Paediatrics Department of Hospital Clínico Universitario de Santiago de Compostela





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Infectious diseases and vaccines

Neonatology and rare diseases

Onco-hematology

Endocrinology

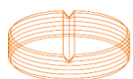
Intensive care

Nephrology

Gastroenterology and nutrition

Paediatric surgery

Pneumology





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela

Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years?	No
Name of the agency and date of inspection	N/A
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested?	N/A
Has the Unit been audited by a sponsor in the last 3 years?	Yes, 2 audits
Does the Unit use its own Standard Operating Procedures (SOPs)?	Yes
Do you provide the sponsor with a copy of the SOP if requested?	Yes
Would the Unit be ready to accept sponsor's SOPs?	Yes





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela Facilities



How many paediatric trials can be run in parallel in the Unit?	40
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	120
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	Yes
Does the Unit have experience in home nursing services?	Yes





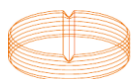
Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

The equipment of the unit is calibrated annually through the Hospital Maintenance Service





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela
Personnel



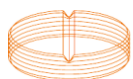
Total number of people working at the Unit

Total permanent personnel	15
Total non-permanent personnel (by contract, Residents, Fellows)	24
Total collaborators (part time)*	0

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Infectious diseases and vaccines	17
Onco-hematology	3
Neonatology and rare diseases	5
Intensive care	3
Pneumology	3
Gastroenterology and nutrition	4
Endocrinology	3
Nephrology	1





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Researchers	Full-time: 4 Part-time: 24			
Research nurses	Full-time: 5 Part-time: 2			
Data manager	Full-time: 2			
Management Staff	Full-time: 2			





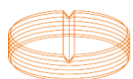
Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela Services



Does the Unit have a specific day hospital for paediatric population Yes

Does the Unit have a Pharmacy Service? Yes
If yes, availability of Pharmacy Service (Total/Partial) Total
If not, how study medicines are received and stored N/A

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? Yes





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela

Subjects of Clinical Trial



Types of population accessed by the Unit

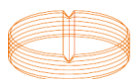
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Just English and Galician language

Methods used by the Unit for the recruitment of participants

Patients in the Unit are recruited through direct information to the parents / tutors when they go to the Hospital as part of their usual Health assistance, whether ambulatory or because the patient is hospitalized and is a candidate to participate in a particular study. Clinical trial.





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

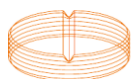
Fundación Andrea, Fundacion ASANOG, AGAPREM, Fundación Down Compostela

Does the centre receives subjects from other hospitals?

No

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

N/A





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

If yes, brief description:

Yes

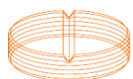
The unit has participated in 12 clinical trials (phase I / II) with pharmacokinetic evaluation of the investigational products

Does the Unit have experience in processing blood samples for cell immunity?

If yes, brief description:

Yes

The unit has recently been certified by GSK for the processing of samples for cellular immunity





Unidad de Ensayos Clínicos Pediátricos - Hospital Clínico Universitario de Santiago de Compostela Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	5	7	27	10	6	N/A
Independent group	0	0	1	1	25	N/A

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	5
Cardiovascular	
Digestive	2
Anaesthesiology and Pain Medicine	1
Endocrinology	3
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	4
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

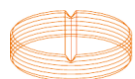
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	4
Pneumology	1
Odontology	
Biochemistry	
Nephrology	1
Vaccines	27
Neonatology	3

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Hospital General Universitario Gregorio Marañón



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Hospital General Universitario Gregorio Marañón

Affiliation data



Who filled in the inquiry (name)	M C. de la Cruz
Position	Head of UCAICEC
Email	ucaicec@fibhgm.org
Phone	
Date of completion of inquiry	23/01/2017
Official name of the Paediatric Research Unit, complete address and email	Pediatric Clinical Research at HGUGM is not organized in a Unit. Each Paediatric Service has its own unit. Thus, there are units for paediatric ICU, Neonatal Services, Paediatric Cardiology, Infectious, Allergology, Anesthesiology, Endocrinology, etc.
Website	No





Hospital General Universitario Gregorio Marañón

Membership or ownership data

Unit ownership	Public - Hospital General Universitario Gregorio Marañón
When Paediatric Clinical Research was initiated (year)?	> 15 years
Which Ethics Committee is the Unit linked to?	CEIm area 1. Hospital General Universitario Gregorio Marañón

Unit manager

Name and family name(s)

Education (physician, pharmacist, etc.)

Department which the Research Unit is linked to

Manager since (year)

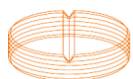
Email address

Phone number

List of all departments in the institution which perform paediatric research

Paediatric IUC, Paediatric cardiology, Neonatology, Infectious diseases and vaccines, Allergology, Rheumatology, Anesthesiology and Resuscitation, Psychiatry, Pneumology, Neurology, Nephrology, Gastroenterology and Nutrition, Dermatology, General Paediatrics, Oncology and Hematology, Clinical Genetics

List of all subspecialties in the organization which perform paediatric research





Hospital General Universitario Gregorio Marañón Audits

Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years?	No
Name of the agency and date of inspection	N/A
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested?	N/A
Has the Unit been audited by a sponsor in the last 3 years?	---
Does the Unit use its own Standard Operating Procedures (SOPs)?	No
Do you provide the sponsor with a copy of the SOP if requested?	---
Would the Unit be ready to accept sponsor's SOPs?	The units usually take upon the procedures from the promotor





Hospital General Universitario Gregorio Marañón Facilities

How many paediatric trials can be run in parallel in the Unit?

Does the Unit have beds for hospital admission of paediatric patients?

It depends on each unit, but mostly yes. Some of them actually are mainly of hospitalization. The Maternal Child Hospital belongs to Gregorio Marañón Hospital. This hospital is a main reference in the Madrid Community for a population of 700.000 inhabitants, out of which 90.000 are underage of 16 years old. Every year there are **6000 Paediatric hospitalizations and their medical and surgical specialties.**

If yes, number of beds in the Unit

Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?

N/A

Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?

Yes

Does this cart have emergency medicines with safe but immediate access?

Yes

Type of life support the personnel of the Unit is trained and qualified to perform

Basic and Advanced

Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?

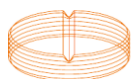
Yes

Is the Hospital equipped with rooms for continued education of children while hospitalized?

Yes

Does the Hospital have home nursing service?

Does the Unit have experience in home nursing services?





Hospital General Universitario Gregorio Marañón

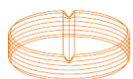
Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

The calibration is driven by the Hospital except in those cases of exceptional calibration requests by the promoter





Hospital General Universitario Gregorio Marañón **Personnel**



Total number of people working at the Unit

Total permanent personnel	---
Total non-permanent personnel (by contract, Residents, Fellows)	---
Total collaborators (part time)*	---

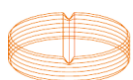
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Total of physicians	95
Doctors	51
Not doctors	35
Nurses	248
Coordinators	6
Monitors	1
Data manager	4
Others (technicians, statisticians, etc.)	15
Total	455

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
---	---	---	---	---





Hospital General Universitario Gregorio Marañón Services

Does the Unit have a specific day hospital for paediatric population	No
Does the Unit have a Pharmacy Service? If yes, availability of Pharmacy Service (Total/Partial) If not, how study medicines are received and stored	Yes Total: the service of pharmacy has specific facilities and personnel inside the building of the child hospital. N/A
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





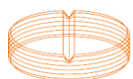
Hospital General Universitario Gregorio Marañón Subjects of Clinical Trial

Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Methods used by the Unit for the recruitment of participants





Hospital General Universitario Gregorio Marañón

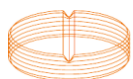
Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations? **Yes**

If yes, names of associations are: ---

Does the centre receives subjects from other hospitals? **Yes**

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral: **The Hospital is a national reference centre in different areas**





Hospital General Universitario Gregorio Marañón **Pharmacodynamic / pharmacokinetic evaluation**



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

If yes, brief description:

Yes

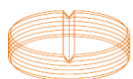
There isn't any Phase I trial unit as such, instead there are different units that have participated at the trials with pharmacokinetic assessment.

Does the Unit have experience in processing blood samples for cell immunity?

If yes, brief description:

Yes

The centre has experience in this, above all in the subspecialties related to research in Infectious diseases, vaccines etc.





Hospital General Universitario Gregorio Marañón Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	2	9	19	6		
Independent group		2		1		
Total	2	11	19	7	158	29

Therapeutic areas in which the clinical trials were developed

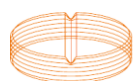
Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	X
Digestive	X
Anaesthesiology and Pain Medicine	X
Endocrinology	
Gynaecology	
Neurosciences	X
Ophthalmology	
Oncology	X
Respiratory	X
Urology	
Organ transplantation	
Psychiatry	X

Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	X
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No





Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos

Affiliation data



Who filled in the inquiry (name)	José Tomás Ramos
Position	Head of Paediatric Unit
Email	josetora@ucm.es
Phone	
Date of completion of inquiry	03/02/2017
Official name of the Paediatric Research Unit, complete address and email	Research on INA Infectious Disease Paediatric Unit - Hospital Universitario Clínico San Carlos C/ Profesor Martín Lagos s/n 28040 Madrid Telephone: 91 3303555 josetora@ucm.es
Website	http://www.idissc.org/en/investigacion-inflamacion-infeccion-inmunidad-y-alergia.php





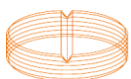
Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos

Membership or ownership data

Unit ownership	Public - Hospital Universitario Clinico San Carlos, Instituto de Investigación Sanitaria San Carlos (IdISSC)
When Paediatric Clinical Research was initiated (year)?	1992
Which Ethics Committee is the Unit linked to?	Hospital Universitario Clínico San Carlos

Unit manager

Name and family name(s)	José Tomás Ramos Amador
Education (physician, pharmacist, etc.)	Médico, MD, PhD
Department which the Research Unit is linked to	Servicio de Pediatría
Manager since (year)	2014
Email address	Josetomas.ramos@salud.madrid.org
Phone number	+34 91 330 35 55
List of all departments in the institution which perform paediatric research	<ul style="list-style-type: none">• Paediatrics Unit: Cardiology, Neurology, Pneumology, Digestive, Hematology, Endocrinology, Nephrology, Immunology, Infectious Diseases, Paediatric Intensive Care and Emergency.• Neonatal Unit• Paediatric Surgery Unit





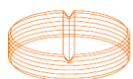
Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

In IdISSC there are two research groups that perform clinical paediatric clinical trials. These groups are made up of the following services and sections:

- Paediatrics Unit: Cardiology, Neurology, Pneumology, Digestive, Hematology, Endocrinology, Nephrology, Immunology, Infectious Diseases, Paediatric Intensive Care and Emergency.
- Neonatal Unit
- Paediatric Surgery Unit





Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos

Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? **No**

Name of the agency and date of inspection **N/A**

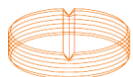
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? **Yes**

Has the Unit been audited by a sponsor in the last 3 years? **No**

Does the Unit use its own Standard Operating Procedures (SOPs)? **Yes, in some of the services / sections**

Do you provide the sponsor with a copy of the SOP if requested? **Yes**

Would the Unit be ready to accept sponsor's SOPs? **Yes**





Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos Facilities



How many paediatric trials can be run in parallel in the Unit?	5
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	42 (20 Paediatric Unit + 22 Neonatal Unit)
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	Yes, only Neonatology
Does the Unit have experience in home nursing services?	Yes, only Neonatology





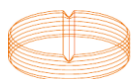
Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Periodic calibration by central services of Hospital Clínico San Carlos





Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos Personnel



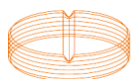
Total number of people working at the Unit

Total permanent personnel	23
Total non-permanent personnel (by contract, Residents, Fellows)	13
Total collaborators (part time)*	3

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Paediatric Unit	12 permanent personnel + 1 Fellows + 1 contract part time
Neonatal Unit	8 permanent personnel + 2 contracts part time
Paediatric Surgery Unit	3.5 permanent personnel



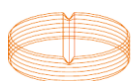


Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos

Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Doctor	Permanent personnel	25	25	40
Doctor	Permanent personnel	20	8	5
Doctor	Permanent personnel	10	8	5
Doctor	Permanent personnel	5	3	3
Doctor	Permanent personnel	5	3	3





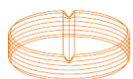
Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos Services



Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) **Total**
If not, how study medicines are received and stored **N/A**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos

Subjects of Clinical Trial



Types of population accessed by the Unit

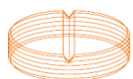
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Yes

Methods used by the Unit for the recruitment of participants

Intra-hospital recruitment methods. Sometimes through Primary Care.





Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

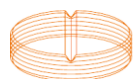
Association of Diabetics, Positive Support for HIV, etc.

Does the centre receives subjects from other hospitals?

No

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

N/A





Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos

Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

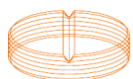
Serialized samples of the hospitalized patient

Does the Unit have experience in processing blood samples for cell immunity?

Yes

If yes, brief description:

There is a central Immunology laboratory





Instituto del Niño y del Adolescente - Hospital Universitario Clínico San Carlos Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company		6	10			
Independent group		0	6			

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	
Digestive	X
Anaesthesiology and Pain Medicine	X
Endocrinology	
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

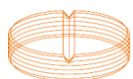
Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	X

Are there other units interested in paediatric trials?

If yes, these units are:

Yes

Neonatology

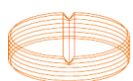




Servicio de Pediatría - Hospital Universitario Severo Ochoa



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Servicio de Pediatría - Hospital Universitario Severo Ochoa

Affiliation data



Who filled in the inquiry (name)	María Luz García García
Position	Service Head Manager
Email	marialuz.hso@gmail.com
Phone	616868544
Date of completion of inquiry	02/02/2017
Official name of the Paediatric Research Unit, complete address and email	SERVICIO DE PEDIATRÍA. HOSPITAL UNIVERSITARIO SEVERO OCHOA. Avda. Orellana s/n. Leganés. Madrid. 28911.
Website	---





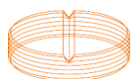
Servicio de Pediatría - Hospital Universitario Severo Ochoa

Membership or ownership data

Unit ownership	Public - Servicio Madrileño de Salud. Consejería de Sanidad de la Comunidad de Madrid
When Paediatric Clinical Research was initiated (year)?	1995
Which Ethics Committee is the Unit linked to?	CEIC Hospital Universitario Severo Ochoa

Unit manager

Name and family name(s)	María Luz García García
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Paediatrics
Manager since (year)	2006
Email address	Marialuz.hso@gmail.com
Phone number	+34914818460
List of all departments in the institution which perform paediatric research	Pulmonology, Allergy, Endocrinology, Rheumatology, Neonatology, Neurology, Gastroenterology





Servicio de Pediatría - Hospital Universitario Severo Ochoa

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Pulmonology

Allergy

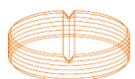
Endocrinology

Rheumatology

Gastroenterology

Neonatology

Neurology





Servicio de Pediatría - Hospital Universitario Severo Ochoa Audits

Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? No

Name of the agency and date of inspection N/A

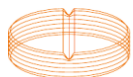
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? ---

Has the Unit been audited by a sponsor in the last 3 years? No

Does the Unit use its own Standard Operating Procedures (SOPs)? Yes

Do you provide the sponsor with a copy of the SOP if requested? Yes

Would the Unit be ready to accept sponsor's SOPs? Yes

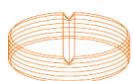




Servicio de Pediatría - Hospital Universitario Severo Ochoa Facilities



How many paediatric trials can be run in parallel in the Unit?	10
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	50
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





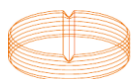
Servicio de Pediatría - Hospital Universitario Severo Ochoa Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Our Department is certified according to ISO-9001 as well as the Electromedicine Department in our hospital. All the equipment follows a preventive maintenance and is calibrated as specified for each manufacturer.





Servicio de Pediatría - Hospital Universitario Severo Ochoa Personnel

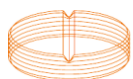
Total number of people working at the Unit

Total permanent personnel	10
Total non-permanent personnel (by contract, Residents, Fellows)	16
Total collaborators (part time)*	6

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Paediatrics	Paediatrician 32
Paediatrics	Nurses 4

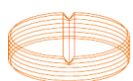




Servicio de Pediatría - Hospital Universitario Severo Ochoa Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Nurse (4)	Part time	25	20	30
Paediatrician (4)	Part time	25	20	30





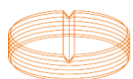
Servicio de Pediatría - Hospital Universitario Severo Ochoa Services



Does the Unit have a specific day hospital for paediatric population Yes

Does the Unit have a Pharmacy Service? Yes
If yes, availability of Pharmacy Service (Total/Partial) Total
If not, how study medicines are received and stored N/A

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? Yes





Servicio de Pediatría - Hospital Universitario Severo Ochoa Subjects of Clinical Trial

Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)

Patients

Other populations

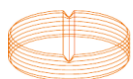
X

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Yes

Methods used by the Unit for the recruitment of participants

We recruit the patients who are under our hospital care





Servicio de Pediatría - Hospital Universitario Severo Ochoa

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

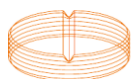
Diabetes and celiac associations

Does the centre receives subjects from other hospitals?

No

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

N/A



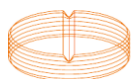


Servicio de Pediatría - Hospital Universitario Severo Ochoa Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses? **No**
If yes, brief description: **N/A**

Does the Unit have experience in processing blood samples for cell immunity? **No**
If yes, brief description: **N/A**





Servicio de Pediatría - Hospital Universitario Severo Ochoa Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company			10	4		
Independent group					7	7

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	X
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	
Respiratory	X
Urology	
Organ transplantation	
Psychiatry	

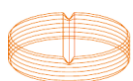
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	X
Immunology	X
Dermatology	
Metabolism	
Allergy	X
Anaesthesiology	
Pneumology	X
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Servicio de Pediatría de la Fundación Jiménez Díaz



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Servicio de Pediatría de la Fundación Jiménez Díaz

Affiliation data



Who filled in the inquiry (name)	Leandro Soriano Guillén / Lucía Llanos Jiménez
Position	Paediatrics Service Associated Head Manager / Methodological Counselor Clinical Trial Research Unit
Email	lsoriano@fjd.es lucia.llanos@fjd.es
Phone	
Date of completion of inquiry	24/01/2017
Official name of the Paediatric Research Unit, complete address and email	Presently we do not have a Paediatric Research / Clinical Trial Unit at our Paediatric Service at Fundación Jiménez Díaz. However in the last years there were some clinical trials on paediatric patients that we will do our best to show upon in this Poll. We didn't fill in the fields regarding a specific structure for a Clinical Trials Unit. The information filled in is related to our own Paediatric Service features as far as the performance of the Clinical Trials are concerned.
Website	N/A





Servicio de Pediatría de la Fundación Jiménez Díaz

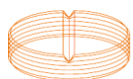
Membership or ownership data

Unit ownership	Private (Public with Private Management. Fundación Jiménez Díaz - Grupo Quirón Salud)
When Paediatric Clinical Research was initiated (year)?	1980
Which Ethics Committee is the Unit linked to?	CEIm-FJD

Unit manager

Name and family name(s)	Leandro Soriano Guillén
Education (physician, pharmacist, etc.)	Pediatricist
Department which the Research Unit is linked to	Paediatrics
Manager since (year)	2012
Email address	lsoriano@fjd.es
Phone number	
List of all departments in the institution which perform paediatric research	N/A

List of all subspecialties in the organization which perform paediatric research





Servicio de Pediatría de la Fundación Jiménez Díaz Audits

Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years?	N/A
Name of the agency and date of inspection	N/A
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested?	Yes
Has the Unit been audited by a sponsor in the last 3 years?	N/A
Does the Unit use its own Standard Operating Procedures (SOPs)?	Yes. Our Centre does not have a Paediatric Research Unit. However there is a Clinical Trial Unit pertaining SCREN (Spanish Clinical Trials Platform), and it has its own SOPs with whom they are working.
Do you provide the sponsor with a copy of the SOP if requested?	Yes
Would the Unit be ready to accept sponsor's SOPs?	Yes

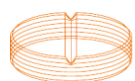




Servicio de Pediatría de la Fundación Jiménez Díaz Facilities

(Information given refers to the Paediatric Department)

How many paediatric trials can be run in parallel in the Unit?	---
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	18
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	No
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	No
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





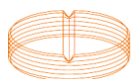
Servicio de Pediatría de la Fundación Jiménez Díaz Facilities

(Information given refers to the Paediatric Department)

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:





Servicio de Pediatría de la Fundación Jiménez Díaz **Personnel**

Total number of people working at the Unit

Total permanent personnel

Total non-permanent personnel (by contract, Residents, Fellows)

Total collaborators (part time)*

8 paediatricians and 3 nurses (refers to staff personnel that usually collaborates in clinical trials procedures)

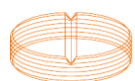
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
---	---

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
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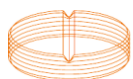


Servicio de Pediatría de la Fundación Jiménez Díaz Services

Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **No**
If yes, availability of Pharmacy Service (Total/Partial) **N/A**
If not, how study medicines are received and stored **---**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **No**





Servicio de Pediatría de la Fundación Jiménez Díaz

Subjects of Clinical Trial

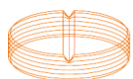
Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?
It is available if needed

Methods used by the Unit for the recruitment of participants

N/A





Servicio de Pediatría de la Fundación Jiménez Díaz

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

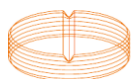
Several associations as Epilepsy, diabetic, or celiac patients

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Both from our AC and others

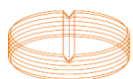




Servicio de Pediatría de la Fundación Jiménez Díaz Pharmacodynamic / pharmacokinetic evaluation

Does the Unit have experience in paediatric clinical trials with PK/PD analyses? **No**
If yes, brief description: **N/A**

Does the Unit have experience in processing blood samples for cell immunity? **No**
If yes, brief description: **N/A**





Servicio de Pediatría de la Fundación Jiménez Díaz Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	1	1				1
Independent group		1				

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	
Digestive	
Anaesthesiology and Pain Medicine	
Endocrinology	X
Gynaecology	
Neurosciences	X
Ophthalmology	
Oncology	
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

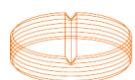
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales

Affiliation data



Who filled in the inquiry (name)	Rocío Díaz Sánchez
Position	Operational Director
Email	rdiaz@fundacionhm.com
Phone	
Date of completion of inquiry	31/01/ 2017
Official name of the Paediatric Research Unit, complete address and email	Unidad Central de Ensayos Clínicos (UCEC) of Fundación de investigación HM Hospitales
Website	www.fundacionhm.com





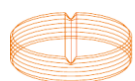
Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales

Membership or ownership data

Unit ownership	Private - Fundación de investigación HM Hospitales
When Paediatric Clinical Research was initiated (year)?	2009
Which Ethics Committee is the Unit linked to?	CEIm of HM Hospitales (Avda. Montepríncipe, 25 – Boadilla del Monte, Madrid)

Unit manager

Name and family name(s)	Rocío Díaz Sánchez
Education (physician, pharmacist, etc.)	Chemistry
Department which the Research Unit is linked to	Unidad Central de Ensayos Clínicos (UCEC)
Manager since (year)	2015
Email address	rdiaz@fundacinhm.com
Phone number	917567984
List of all departments in the institution which perform paediatric research	HM Hospitals (HM Sanchinarro, HM Puerta del Sur, HM Montepríncipe, HM Modelo y Maternidad HM Belén) develop research activity in paediatrics and clinical trials experience





Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales **Membership or ownership data**

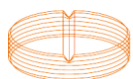
List of all subspecialties in the organization which perform paediatric research

Vaccines

Paediatric endocrinology

Paediatric oncology and hematology

Neonatology





Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? No

Name of the agency and date of inspection N/A

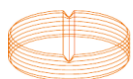
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? Yes

Has the Unit been audited by a sponsor in the last 3 years? Yes, 6 audits without findings

Does the Unit use its own Standard Operating Procedures (SOPs)? Yes

Do you provide the sponsor with a copy of the SOP if requested? Yes

Would the Unit be ready to accept sponsor's SOPs? Yes





Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales Facilities



How many paediatric trials can be run in parallel in the Unit?	20
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	30
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	Yes
Does the Unit have experience in home nursing services?	Yes





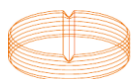
Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

We have certificates and calibrations of all our equipment. They are available for the sponsors.





Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales Personnel

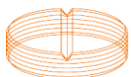
Total number of people working at the Unit

Total permanent personnel	12
Total non-permanent personnel (by contract, Residents, Fellows)	3
Total collaborators (part time)*	0

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
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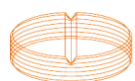




Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Study coordinator	4	4	3	6
Data manager	3	4	3	6
Research nurse	2	2	2	6
Pharmacist	1	2	2	6
Start-up management	3	3	3	6





Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales Services



Does the Unit have a specific day hospital for paediatric population	Yes
Does the Unit have a Pharmacy Service? If yes, availability of Pharmacy Service (Total/Partial) If not, how study medicines are received and stored	Yes Exclusive availability for clinical trials N/A
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales Subjects of Clinical Trial



Types of population accessed by the Unit

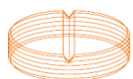
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Yes, mainly in English

Methods used by the Unit for the recruitment of participants

Recruitment is based on patients of HM Hospitales. We also develop dissemination activities through our website and a monthly newsletter. Depending on the clinical trial, we also use business intelligence software for searching patients or healthy volunteers in our electronic clinical records and data base.





Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

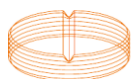
Mainly SEHOP

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

We receive patients from all ACs. Some HM Hospitales are located in Galicia and the rest in Madrid. We also receive international patients, although in paediatric service it is not so common.





Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

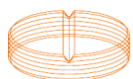
If yes, brief description:

We have experience in Phase I clinical trials

Does the Unit have experience in processing blood samples for cell immunity?

Yes

If yes, brief description:





Unidad Central de Ensayos Clínicos (UCEC) de la Fundación de Investigación HM Hospitales Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	2	8	3	3	2	
Independent group						

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	
Digestive	
Anaesthesiology and Pain Medicine	
Endocrinology	X
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	X
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

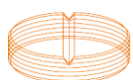
Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	X

Are there other units interested in paediatric trials?

No

If yes, these units are:

N/A





Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience



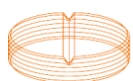


Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz

Affiliation data



Who filled in the inquiry (name)	Alberto M. Borobia
Position	Manager of the Clinical Trials Unit
Email	alberto.borobia@idipaz.es
Phone	+34 912 071 466
Date of completion of inquiry	23/01/17
Official name of the Paediatric Research Unit, complete address and email	La Paz Central Research and Clinical Trials Unit 2ª Planta. Hospital Maternal Hospital Universitario La Paz Pº de la Castellana, 261 28046 Madrid
Website	http://www.idipaz.es/PaginaDinamica.aspx?IdPag=187&Lang=EN





Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz

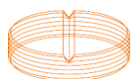
Membership or ownership data



Unit ownership	Public - Hospital Universitario La Paz. Comunidad Autónoma de Madrid
When Paediatric Clinical Research was initiated (year)?	2009
Which Ethics Committee is the Unit linked to?	La Paz University Hospital

Unit manager

Name and family name(s)	Alberto M. Borobia
Education (physician, pharmacist, etc.)	Pyhysician. Clinical Pharmacologist.
Department which the Research Unit is linked to	Instituto de Investigación Biomédica del Hospital Universitario La Paz - IdiPAZ
Manager since (year)	2014
Email address	alberto.borobia@idipaz.es
Phone number	
List of all departments in the institution which perform paediatric research	---



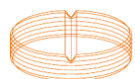


Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Allergy	Pharmacy	Child nutrition
Anesthesia and Resuscitation	Clinical Pharmacology	Obstetrics / Gynecology
Clinical Pharmacology	Gynecology	Ophthalmology
Biochemistry	Paediatric Hemato-oncology	Oncology
Cardiology	Hematology	General Paediatrics
Children's Cardiology	Hepatology	Psychiatry
Cardiac surgery for children	Paediatric Infectious-Tropical Diseases and Vaccines	Radiology
General Surgery	Immunology	Rehabilitation
Maxillofacial Surgery	Medical and Molecular Genetic Institute	Rheumatology
Orthopedic Surgery and Traumatology	Internal Medicine	Traumatology
Paediatric surgery	Microbiology	Childhood Pain Unit
Paediatric Intensive Care	Nephrology	Electrophysiology Sleep Unit
Dermatology	Neonatology	HIV Unit
Digestive / Gastroenterology	Pneumology	Tuberculosis Unit
Endocrinology	Neurology	Paediatric Emergencies
Nursing		





Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz

Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? Yes

Name of the agency and date of inspection

Accredited in 2011 by the Autonomous Community of Madrid (compliance with good clinical practice). Last reaccreditation in 2016.

Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? Yes

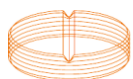
Has the Unit been audited by a sponsor in the last 3 years?

Yes, 10 audits

Does the Unit use its own Standard Operating Procedures (SOPs)? Yes

Do you provide the sponsor with a copy of the SOP if requested? Yes

Would the Unit be ready to accept sponsor's SOPs? Yes





Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz Facilities



How many paediatric trials can be run in parallel in the Unit?	It depends on the phase: 2 Phase I with simultaneous admits
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	8
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





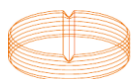
Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz Facilities

Other Unit equipment:

Centrifuge	2
ECG equipment	1
Ultra-freezers	3
Scales	2
Height-meters	2
Tensiometer	4
Equipment for serum handling and draw	1

Brief description of the equipment calibration process:

Annual calibrations of the whole equipment according to our SOPs and specifications of each equipment. Calibration certificates available to promoters.





Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz

Personnel

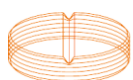
Total number of people working at the Unit

Total permanent personnel	6
Total non-permanent personnel (by contract, Residents, Fellows)	7
Total collaborators (part time)*	15

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Allergy Anesthesia, Children's Surgery Cardiology Gastroenterology Hepatology Immunology Pneumology Nephrology Neonatology Neurology Onco-hematology Pediat-IIDD-vaccines Rheumatology UCI Psychiatry	20 Physicians in the dayshift 10 of them also make guards (24-hour shift) 15 Nurses of paediatric hospitalization plants accustomed to the management of children, distributed among all shifts and all specialties. At least 1 nurse per specialty and shift. In morning shifts, 6 nurses participating in CT are also added from the external consultations of the paediatric specialties

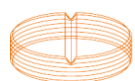




Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
6 hospitalization nurses	Partial, distributed in three shifts	20	> 10 years	It depends on the department: between 3 and 10
6 consultation nurses	Morning shifts of 7 hours			





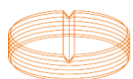
Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz Services



Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) **Total**
If not, how study medicines are received and stored **N/A**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz Subjects of Clinical Trial



Types of population accessed by the Unit

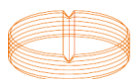
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	X
	Adopters, immigrants and refugees

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

We received a high percentage of foreign population. People in the services speak English, French and Portuguese. For other Languages Translator is requested to the Ministry.

Methods used by the Unit for the recruitment of participants

Through different paediatric services all over the hospital





Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

HIV, Hemato-oncologic, renal, hepatic, cystic fibrosis páncreas and celiac patients abd transplanted children

Does the centre receives subjects from other hospitals?

Yes

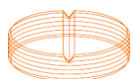
If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

From all national territory:

Critical burn patients
Congenital anomalies of the eye development (globe and eye lids defects) Extraocular tumours in childhood (rhabdomyosarcoma)
Intraocular tumours in childhood (retinoblastoma)
Advanced retinopathy of prematurity
Kidney transplantation in children.
Liver transplantat in children
Heart transplantation in children
Intestinal transplantation in children and adults

Penetrating keratoplasty in children
Replantations, including traumatic hand injury
Allogenic hematopoietic progenitor cell transplantationin
Comprehensive care for the newborn with congenital heart disease and for the child with congenital heart disease
Comprehensive care for the adult with congenital heart disease (chd)
Brachial plexus surgery
Refractory epilepsy
Hereditary ataxia and paraplegia
Multiple sclerosis Archivo pdf. Se abrirá en una ventana nueva.
Crossover kidney transplantation

Complex paediatric neurosurgery
Imported tropical diseases
Complex disorders of the autonomic nervous system
Complex pulmonary hypertension
Imported Diseases
International adoption
Refugees and immigrants
Teenagers
Complex chronic pathology





Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

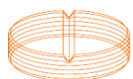
Participation in 14 CT in Phase 1 with evaluation PK/PD

Does the Unit have experience in processing blood samples for cell immunity?

Yes

If yes, brief description:

Participation in 7 CT Phase I-II in which blood samples are processed for cell immunity





Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital La Paz Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	10	47	142	32	141	
Independent group	4	12	22	20	159	

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	X
Digestive	X
Anaesthesiology and Pain Medicine	X
Endocrinology	X
Gynaecology	X
Neurosciences	X
Ophthalmology	X
Oncology	X
Respiratory	X
Urology	X
Organ transplantation	X
Psychiatry	X

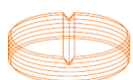
Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	X
Immunology	X
Dermatology	X
Metabolism	X
Allergy	X
Anaesthesiology	X
Pneumology	X
Odontology	
Biochemistry	X
Nephrology	X
Vaccines	X

Are there other units interested in paediatric trials?

If yes, these units are:

Yes

Potentialt any Unit/Service of the HULP would participate in CTs





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ)



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ)
Affiliation data



Who filled in the inquiry (name)	Lucas Moreno
Position	Head, Clinical Trials Unit
Email	Lucas.moreno@salud.madrid.org
Phone	
Date of completion of inquiry	06/02/2017
Official name of the Paediatric Research Unit, complete address and email	Unidad de Ensayos Clínicos FIB-HNJ, Fundación de Investigación Biomédica Hospital Niño Jesús & Hospital Infantil Universitario Niño Jesús Av. Menéndez Pelayo 65, Madrid 28009 Lucas.moreno@salud.madrid.org
Website	---





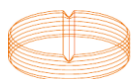
Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ) Membership or ownership data



Unit ownership	Public - Fundación de Investigación Biomédica Hospital Niño Jesús & Hospital Infantil Universitario Niño Jesús
When Paediatric Clinical Research was initiated (year)?	2008
Which Ethics Committee is the Unit linked to?	CEIm Hospital Infantil Universitario Niño Jesús

Unit manager

Name and family name(s)	Lucas Moreno Martín-Retortillo
Education (physician, pharmacist, etc.)	Doctor
Department which the Research Unit is linked to	Fundación de Investigación Biomédica del Hospital Niño Jesús
Manager since (year)	2016
Email address	Lucas.moreno@salud.madrid.org
Phone number	
List of all departments in the institution which perform paediatric research	---





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ)

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Onco-Hematology

Endocrinology

Paediatric Intensive Care Unit (PICU)

Allergy

Pneumology

Rheumatology

Psychiatry

Movement Analysis Laboratory

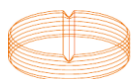
Cardiology

Dermatology

Gastroenterology

Neurology

General Paediatrics





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ)

Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? **Yes**

Name of the agency and date of inspection

The clinical trials pharmacy has been inspected by the relevant section of the Ministry of Health of SERMAS (regional health system)

Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? **No**

Has the Unit been audited by a sponsor in the last 3 years?

Yes, 3 audits

Does the Unit use its own Standard Operating Procedures (SOPs)?

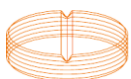
Yes

Do you provide the sponsor with a copy of the SOP if requested?

Yes

Would the Unit be ready to accept sponsor's SOPs?

Yes





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ) Facilities



How many paediatric trials can be run in parallel in the Unit?	80
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	They are assigned according to the needs of each speciality
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





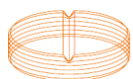
Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ) Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Equipment calibration is carried out annually or bi-annually by an external company. Calibration certificates are available for sponsors.





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ) Personnel



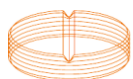
Total number of people working at the Unit

Total permanent personnel	1
Total non-permanent personnel (by contract, Residents, Fellows)	4
Total collaborators (part time)*	10

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Nursing Staff	For Onco-Hematology there are two nurses: one full-time and one part-time nurse. For the remaining trials there is a pool of nurses trained in GCP.
Medical-research staff	For Onco-Hematology there are two full-time medical researchers. For other Onco-Hematology trials and other specialties, the principal investigator and sub-I are burdened with patient's care and only dedicate to clinical trials partial time.





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ) Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Contracts	Complete	7	7	80
Study coordinator 1	Complete	2.5	2	35
Study coordinator 2	Complete	2.5	1	35
Research nurse 1	Complete	12	1.5	35
Research nurse 2	Partial	20	4	35
Head of the Clinical Trials Unit	Complete	13	9	60
Medical Researcher	Complete	12	6	55





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ) Services



Does the Unit have a specific day hospital for paediatric population	Yes
Does the Unit have a Pharmacy Service? If yes, availability of Pharmacy Service (Total/Partial) If not, how study medicines are received and stored	Yes Total Espacio de farmacia de ensayos clínicos pediátricos completamente separado del resto de la farmacia, espacio a temperatura ambiente, nevera y congeladores calibrados
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ)

Subjects of Clinical Trial



Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)	
Patients	X
Other populations	

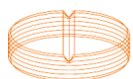
In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Yes

Methods used by the Unit for the recruitment of participants

The Unit offers treatment to the patient's treated in Hospital Niño Jesús which is a regional and national reference centre for multiple pathologies.

Patients are recruited from the site's database. Site receives patients from the whole region and referred from the entire national geography, especially for serious diseases such as paediatric cancer, metabolopathies or hemopathies.





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ) Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

If yes, names of associations are:

Yes

Each year or two years there is a day of patient's associations for updating in research. We work with rare disease associations (Tay Sachs), cancer (Federación de Padres de Niños con Cáncer, ASPANION, Asociación Pablo Ugarte, Fundación Neuroblastoma, etc), hemopathies (Fanconi Parent Fathers Association, Blackfan-Diamond, etc.).

The KIDS Madrid group has just been created so that the hospital interacts with children and young people in society, both healthy patients and children.

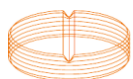
Does the centre receives subjects from other hospitals?

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Yes

Patients are received from the Community of Madrid without any limitation given the unique area. Patients from other communities are routinely received in case of rare diseases, access to treatments within clinical trials of new drugs, reference units (CSUR), hematopoietic transplantation, etc. These cases must be approved by the respective autonomous communities but it is usual to be accepted.

International patients are rare. Patients can be received from the European Union after the approval of the health system of the referring country, but private patients can not be accepted for treatment.





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ) Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

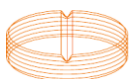
The Unit has performed more than 10 first-in-child trials, as well as more than 20 Phase I-II trials in onco-hematology paediatric, all of high complexity, so staff is accustomed to PK / PD assay procedures, Shipments, handling after hours, etc.

Does the Unit have experience in processing blood samples for cell immunity?

Yes

If yes, brief description:

The unit participates in several clinical trials with immunotherapy (oncolytic virus, monoclonal antibodies, etc.) and there is a White Room (GMP Facility) for preparation of cell therapy, virotherapy and gene therapy accredited by the AEMPS





Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ) Experience



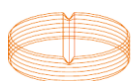
Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	17	21	40	17	11	
Independent group	6	8	13	6	38	

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	
Digestive	X
Anaesthesiology and Pain Medicine	X
Endocrinology	X
Gynaecology	
Neurosciences	X
Ophthalmology	X
Oncology	X
Respiratory	X
Urology	
Organ transplantation	
Psychiatry	X

Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	X
Immunology	
Dermatology	X
Metabolism	X
Allergy	X
Anaesthesiology	X
Pneumology	X
Odontology	
Biochemistry	
Nephrology	
Vaccines	





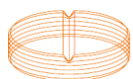
Unidad de Ensayos Clínicos - Fundación de Investigación Biomédica Hospital Niño Jesús (FIB-HNJ) Experience

Are there other units interested in paediatric trials?

If yes, these units are:

No

Our Clinical Trial Unit was born in 2013 with exclusive dedication to Onco-Hematology. Since 2016, we are initiating the activity in trials of all the paediatric specialties and giving service to other trials for start-up and recruitment, on demand of the other involved services. Our Unit serves as a single point of contact to identify possible participation in trials of all the specialties of our hospital by having access to the pool of investigators, specialties, expertise and capabilities available





Unidad de Investigación Clínica - Hospital La Zarzuela



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad de Investigación Clínica - Hospital La Zarzuela

Affiliation data

Who filled in the inquiry (name)	Isabel Carretero Manzano
Position	Clinical Research Unit Coordinator
Email	icarretero@sanitas.es
Phone	+34915858053
Date of completion of inquiry	16/01/2017
Oficial name of the Paediatric Research Unit, complete address and email	We are not a Paediatric Research Unit, we are a broad Clinical Research Unit working with every specialties of the hospital, including Paediatrics. Hospital La Zarzuela C/ Pléyades, 25 28023 Aravaca (Madrid) uichlz@sanitas.es
Website	No





Unidad de Investigación Clínica - Hospital La Zarzuela

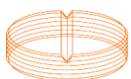
Membership or ownership data

Unit ownership	Private - Sanitas SA de Hospitales
When Paediatric Clinical Research was initiated (year)?	2007
Which Ethics Committee is the Unit linked to?	CEIm Puerta de Hierro

Unit manager

Name and family name(s)	Juan Carlos Fuertes Treviño
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Medical Director
Manager since (year)	2008
Email address	jcfuertes@sanitas.es
Phone number	915858661
List of all departments in the institution which perform paediatric research	Paediatric and Neonatology

List of all subspecialties in the organization which perform paediatric research





Unidad de Investigación Clínica - Hospital La Zarzuela Audits

Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? No

Name of the agency and date of inspection N/A

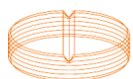
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? Yes

Has the Unit been audited by a sponsor in the last 3 years? No

Does the Unit use its own Standard Operating Procedures (SOPs)? Yes

Do you provide the sponsor with a copy of the SOP if requested? No

Would the Unit be ready to accept sponsor's SOPs? No





Unidad de Investigación Clínica - Hospital La Zarzuela Facilities

How many paediatric trials can be run in parallel in the Unit?	4
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	12
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	No
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	No
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





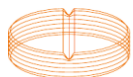
Unidad de Investigación Clínica - Hospital La Zarzuela Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

The Electromedical department make the annual calibration procedure





Unidad de Investigación Clínica - Hospital La Zarzuela Personnel

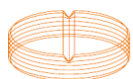
Total number of people working at the Unit

Total permanent personnel	10
Total non-permanent personnel (by contract, Residents, Fellows)	1
Total collaborators (part time)*	0

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Paediatrics	6 (complete time)
Nurses	2 (complete time)
Study Coordinator	1 (complete time)

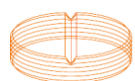




Unidad de Investigación Clínica - Hospital La Zarzuela Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
6 Paediatrics	Complete	From 8 to 15	From 1 to 8	4
2 Nurses	Complete	From 6 to 10	2	3
1 StudyCoordinator	Complete	1	1	3





Unidad de Investigación Clínica - Hospital La Zarzuela Services



Does the Unit have a specific day hospital for paediatric population	Yes
Does the Unit have a Pharmacy Service? If yes, availability of Pharmacy Service (Total/Partial) If not, how study medicines are received and stored	Yes Monday to Friday (8 to 20h), Saturday 8 to 15h N/A
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





Unidad de Investigación Clínica - Hospital La Zarzuela Subjects of Clinical Trial

Types of population accessed by the Unit

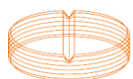
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

No

Methods used by the Unit for the recruitment of participants

Appointments, electronic clinical records, contact with associations





Unidad de Investigación Clínica - Hospital La Zarzuela

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

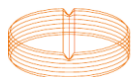
If yes, names of associations are:

Padres Prematuros (APREM)

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral: ---

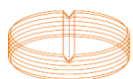




Unidad de Investigación Clínica - Hospital La Zarzuela Pharmacodynamic / pharmacokinetic evaluation

Does the Unit have experience in paediatric clinical trials with PK/PD analyses? **No**
If yes, brief description: **N/A**

Does the Unit have experience in processing blood samples for cell immunity? **No**
If yes, brief description: **N/A**





Unidad de Investigación Clínica - Hospital La Zarzuela Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	0	0	0	3	2	0
Independent group	0	0	0	0	0	0

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

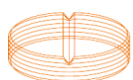
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	X
Neonatology	X

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Unidad de Investigación Clínica - Hospital Universitario de Torrejón



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience



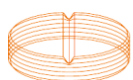


Unidad de Investigación Clínica - Hospital Universitario de Torrejón

Affiliation data



Who filled in the inquiry (name)	Emiliano Agüero
Position	Head of Clinical Research Unit
Email	eaguero@torrejonsalud.com
Phone	91 626 26 00 / Ext. 7132
Date of completion of inquiry	11/01/2017
Official name of the Paediatric Research Unit, complete address and email	We are not a Paediatric Research Unit, we are a broad Clinical Research Unit working with every specialties of the hospital, including Paediatrics. Hospital Universitario de Torrejón Unidad Investigación Clínica Calle Mateo Inurria s/n 28850 Torrejón de Ardoz (Madrid)
Website	No





Unidad de Investigación Clínica - Hospital Universitario de Torrejón

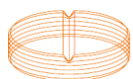
Membership or ownership data



Unit ownership	Private (Public, but private management): TorrejonSalud (Sanitas)
When Paediatric Clinical Research was initiated (year)?	2012
Which Ethics Committee is the Unit linked to?	Hospital Universitario de Getafe

Unit manager

Name and family name(s)	Miguel Mariné Blanco
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Medical Director
Manager since (year)	2014
Email address	mmarine@torrejonsalud.com
Phone number	
List of all departments in the institution which perform paediatric research	Paediatric





Unidad de Investigación Clínica - Hospital Universitario de Torrejón

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Paediatric Department disposes of the following sub-specialties:

Cardiology

Hematology

Pneumology

Nephrology

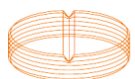
Neurology

Endocrinology

Gastroenterology

Infectious diseases

Neonatology





Unidad de Investigación Clínica - Hospital Universitario de Torrejón

Audits



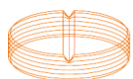
Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? **No**

Name of the agency and date of inspection **N/A**

Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? **Yes**

Has the Unit been audited by a sponsor in the last 3 years? **No**

Does the Unit use its own Standard Operating Procedures (SOPs)? **Yes**
Do you provide the sponsor with a copy of the SOP if requested? **No**
Would the Unit be ready to accept sponsor's SOPs? **No**





Unidad de Investigación Clínica - Hospital Universitario de Torrejón Facilities

How many paediatric trials can be run in parallel in the Unit?	3
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	15
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	No
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	No
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





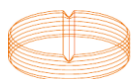
Unidad de Investigación Clínica - Hospital Universitario de Torrejón Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Anually, by electromedicine department





Unidad de Investigación Clínica - Hospital Universitario de Torrejón Personnel



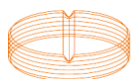
Total number of people working at the Unit

Total permanent personnel	17
Total non-permanent personnel (by contract, Residents, Fellows)	17
Total collaborators (part time)*	0

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
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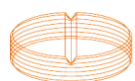




Unidad de Investigación Clínica - Hospital Universitario de Torrejón Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Paediatrics	17	5-20	0-5	4
Nursing	8	1-15	0-2	1
Study Coordinator	1	4	3	2
Specialist in study contracts	1	4	4	2





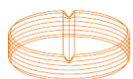
Unidad de Investigación Clínica - Hospital Universitario de Torrejón Services



Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) **Partial**
If not, how study medicines are received and stored **N/A**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Unidad de Investigación Clínica - Hospital Universitario de Torrejón

Subjects of Clinical Trial



Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)

Patients

Other populations

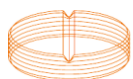
X

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

No

Methods used by the Unit for the recruitment of participants

Appointments, electronic clinical records, contact with associations





Unidad de Investigación Clínica - Hospital Universitario de Torrejón

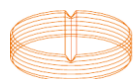
Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations? **Yes**

If yes, names of associations are: ---

Does the centre receives subjects from other hospitals? **Yes**

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral: **Same Autonomous Community (AC)**



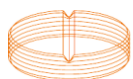


Unidad de Investigación Clínica - Hospital Universitario de Torrejón Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses? **No**
If yes, brief description: **N/A**

Does the Unit have experience in processing blood samples for cell immunity? **No**
If yes, brief description: **N/A**





Unidad de Investigación Clínica - Hospital Universitario de Torrejón Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	0	0	2	0	0	0
Independent group	0	0	0	2	2	0

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

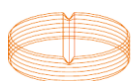
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria

Affiliation data



Who filled in the inquiry (name)	Ana Moreno Bofarull
Position	Manager of the RTD Office of IRYCIS
Email	ambofarull@salud.madrid.org
Phone	+34 913369016
Date of completion of inquiry	06/02/2017
Official name of the Paediatric Research Unit, complete address and email	Paediatric Clinical Research Unit of the Ramón y Cajal Health Research Institute (IRYCIS) Ctra. Colmenar Viejo Km 9,100. 28034-Madrid. España fund_inv.hrc@salud.madrid.org
Website	IRYCIS Clinical Trial Unit (Spanish): http://www.irykis.org/uca_ensayos.htm http://www.madrid.org/cs/Satellite?cid=1354602737512&language=es&pagina me=HospitalRamonCajal%2FPage%2FHRYC_ServiciosPrincipal





Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria

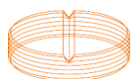
Membership or ownership data



Unit ownership	Public - Ramón y Cajal Health Research Institute (IRYCIS)
When Paediatric Clinical Research was initiated (year)?	2004
Which Ethics Committee is the Unit linked to?	University Hospital Ramón y Cajal Ethics Committee

Unit manager

Name and family name(s)	Beatriz García Cuartero
Education (physician, pharmacist, etc.)	Physician-Paediatrician
Department which the Research Unit is linked to	Paediatrics
Manager since (year)	2014
Email address	bgcuartero@salud.madrid.org
Phone number	660037333





Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria

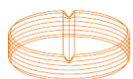
Membership or ownership data

List of all departments in the institution which perform paediatric research

Paediatrics	Infectious diseases
Allergy	Traumatology
Genetics	Nephrology
Rheumatology	Urology
Paediatric Intensive Care	Neurology
Paediatric Cardiology	Oncology
Maxillofacial Surgery	Ophthalmology
Dermatology	Otorhinolaryngology
Endocrinology / Gynecology	Unit of Child and Youth Psychiatry
Gastroenterology	Pneumology
Hematology	Emergency Medicine
Immunology	

List of all subspecialties in the organization which perform paediatric research

Paediatric Gastroenterology	Oncology, Hematology and Paediatric Bone Marrow Transplants
Unit of Endocrinology and Paediatric Diabetes	Paediatric Infectious Diseases
Unit of Congenital Metabolic Diseases	Paediatric Nephrology
Paediatric Pneumology Unit	Paediatric Cardiology
Cystic Fibrosis Unit	Paediatric Intensive Care
Paediatric Neurology	





Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? No

Name of the agency and date of inspection N/A

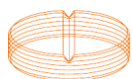
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? Yes

Has the Unit been audited by a sponsor in the last 3 years? No

Does the Unit use its own Standard Operating Procedures (SOPs)? Yes

Do you provide the sponsor with a copy of the SOP if requested? Yes

Would the Unit be ready to accept sponsor's SOPs? ---





Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria Facilities



How many paediatric trials can be run in parallel in the Unit?	> 10
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	49 hospitalization beds and 6 beds of the paediatric day hospital and 4 beds of the Clinical Trials Unit
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	No
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No



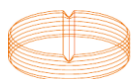


Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:





Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria

Personnel



Total number of people working at the Unit

Total permanent personnel	22
Total non-permanent personnel (by contract, Residents, Fellows)	7
Total collaborators (part time)*	

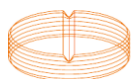
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Paediatrics Dpt.	8 physicians; 7 nurses; 1 data manager
Clinical Trials Unit	3 pharmacologists; 1 nurse; 1 laboratory technician, 2 monitors

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
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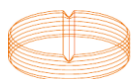
Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria Services



Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) **Total**
If not, how study medicines are received and stored **N/A**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria Subjects of Clinical Trial



Types of population accessed by the Unit

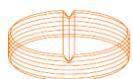
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

The Hospital has a simultaneous telephone translator

Methods used by the Unit for the recruitment of participants

Population-based sampling, consecutive recruitment according to hospital admission and/or consultation, etc.





Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

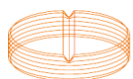
Spanish Federation of Cystic Fibrosis, Spanish Federation of Rare Diseases, Spanish Federation of Diabetes, etc.

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

We receive patients from Madrid and the rest of the national territory through the national contact system for sending patients (CISCO). Occasionally we also receive some foreign patients.



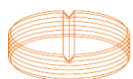


Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses? **Yes**
If yes, brief description: ---

Does the Unit have experience in processing blood samples for cell immunity? **Yes**
If yes, brief description: ---





Unidad de Investigación Clínica Pediátrica - Instituto Ramón y Cajal de Investigación Sanitaria Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	5	9	23	1	25	
Independent group			7			

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	X
Digestive	
Anaesthesiology and Pain Medicine	X
Endocrinology	X
Gynaecology	
Neurosciences	X
Ophthalmology	
Oncology	X
Respiratory	
Urology	
Organ transplantation	
Psychiatry	X

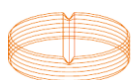
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	X
Immunology	
Dermatology	
Metabolism	X
Allergy	X
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid

Affiliation data



Who filled in the inquiry (name)	Fernando Cabañas González
Position	Chief of Paediatrics and Neonatology Department. Hospital Universitario Quirónsalud Madrid
Email	fernando.cabanas@quironsalud.es
Phone	
Date of completion of inquiry	13/07/2017
Official name of the Paediatric Research Unit, complete address and email	Paediatric Research Unit. Hospital Universitario Quirónsalud Madrid
Website	---





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid

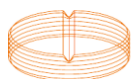
Membership or ownership data



Unit ownership	Private - Research Foundation Quirónsalud. European University of Madrid
When Paediatric Clinical Research was initiated (year)?	2010
Which Ethics Committee is the Unit linked to?	Ethic Committee of La Paz University Hospital and Ethic Committee of "Fundación Jimenez Díaz-FJD"

Unit manager

Name and family name(s)	Fernando Cabañas González
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Paediatrics and Neonatology Department
Manager since (year)	2010
Email address	fernando.cabanas@quironsalud.es
Phone number	
List of all departments in the institution which perform paediatric research	Services of Paediatrics, Neonatology, Oncology, Neumology, Endocrinology, Gastroenterology, Neurology, Neurosurgery and Paediatric Surgery.





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Services of Paediatrics

Neonatology

Oncology

Neumology

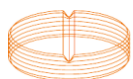
Endocrinology

Gastroenterology

Neurology

Neurosurgery

Paediatric Surgery





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid

Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? No

Name of the agency and date of inspection N/A

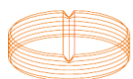
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? Yes

Has the Unit been audited by a sponsor in the last 3 years? No

Does the Unit use its own Standard Operating Procedures (SOPs)? Yes

Do you provide the sponsor with a copy of the SOP if requested? Yes

Would the Unit be ready to accept sponsor's SOPs? Yes





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid Facilities



How many paediatric trials can be run in parallel in the Unit?	It is depending on population to recruit. We tried not to reclute competitive trials.
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	60
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	No
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





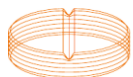
Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

There is a specific department in charge of the equipment calibration which periodically calibrates the different equipments.





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid

Personnel



Total number of people working at the Unit

Total permanent personnel 15

Total non-permanent personnel (by contract, Residents, Fellows)

Total collaborators (part time)*

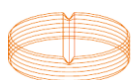
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
---	---

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Nurse	Complete	7	7	
Contracts and another documents coordinator	Complete	7	7	200





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid Services



Does the Unit have a specific day hospital for paediatric population	Yes
Does the Unit have a Pharmacy Service?	Yes
If yes, availability of Pharmacy Service (Total/Partial)	Total
If not, how study medicines are received and stored	N/A
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid

Subjects of Clinical Trial



Types of population accessed by the Unit

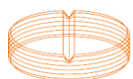
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

There is foreign population Department who receives and manages patients (mainly Russians, Arab and Latin Americans). There is a Translation Service

Methods used by the Unit for the recruitment of participants

During clinical sessions on a daily basis, Hospital web page, patients derived from other Group Hospitals





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

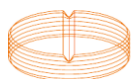
Associations of Premature and Down Syndrome patients (mainly)

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

From the same Autonomous Community and even from others of those hospitals belonging Quirónsalud Group





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid

Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

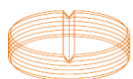
We have experience in several paediatric clinical trials with PK/PD analyses: Only the example of the last one: Double Blind Clinical Trial in perinatal asphyxia and hipotermia patients with Topiramato and Iboprofen for Ductus closure.

Does the Unit have experience in processing blood samples for cell immunity?

No

If yes, brief description:

The centre has experience in this, above all in the subspecialties related to research in Infectious diseases, vaccines etc.





Unidad de Investigación de Pediatría - Hospital Universitario Quirónsalud Madrid Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	0	2	5			
Independent group	0	1	10			

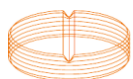
Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	X
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	
Neurosciences	X
Ophthalmology	
Oncology	
Respiratory	X
Urology	
Organ transplantation	
Psychiatry	

Therapeutic areas	Clinical trials
Haematology - Oncology	X
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	X

Are there other units interested in paediatric trials?

If yes, these units are:





Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda

Affiliation data



Who filled in the inquiry (name)	Dra. Belén Ruiz Antorán
Position	FEA
Email	mariabelen.ruiz@salud.madrid.org
Phone	91 191 74 79
Date of completion of inquiry	09/05/2017
Official name of the Paediatric Research Unit, complete address and email	Unidad de Investigación Farmacológica (CTU). Hospital Universitario Puerta de Hierro Majadahonda C/ Manuel de Falla, 1.- 28222 Majadahonda (Madrid) Farmacología_clinica@idiphim.org
Website	No





Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda

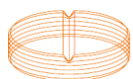
Membership or ownership data



Unit ownership	Public - Instituto de Investigación sanitaria del Hospital Universitario Puerta de Hierro Majadahonda
When Paediatric Clinical Research was initiated (year)?	2010
Which Ethics Committee is the Unit linked to?	CEIm Hospital Universitario Puerta de Hierro, Madrid

Unit manager

Name and family name(s)	Dra. Belén Ruiz Antorán
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Farmacología Clínica
Manager since (year)	2006
Email address	mariabelen.ruiz@salud.madrid.org
Phone number	+34 91 1916479
List of all departments in the institution which perform paediatric research	---





Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Neuropaediatric Area

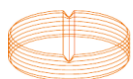
Paediatric Endocrinology Area

Paediatric Neumology Area

Infectious and vaccine Area

Neonatology Area

Child Psychiatry Area





Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? No

Name of the agency and date of inspection N/A

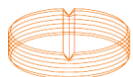
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? Yes

Has the Unit been audited by a sponsor in the last 3 years? No

Does the Unit use its own Standard Operating Procedures (SOPs)? Yes

Do you provide the sponsor with a copy of the SOP if requested? Yes

Would the Unit be ready to accept sponsor's SOPs? Yes





Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda Facilities



How many paediatric trials can be run in parallel in the Unit?	4
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	2
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	No
Does the Hospital have home nursing service?	Yes
Does the Unit have experience in home nursing services?	Yes





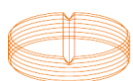
Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Calibration performed by the company IBERMANSA





Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda Personnel



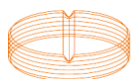
Total number of people working at the Unit

Total permanent personnel	8
Total non-permanent personnel (by contract, Residents, Fellows)	2
Total collaborators (part time)*	It varies

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Clinical Pharmacology	Main Researcher, Cooperating Researcher, Nurse, Data Manager

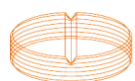




Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Main Researcher				
Cooperating Researcher				
Nurses (2)	Full time / Part time	10 / 5		
Data Manager	Full time	7	7	>50





Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda Services



Does the Unit have a specific day hospital for paediatric population	Yes
Does the Unit have a Pharmacy Service? If yes, availability of Pharmacy Service (Total/Partial) If not, how study medicines are received and stored	Yes Total 2 pharmacists
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda

Subjects of Clinical Trial



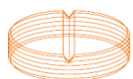
Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Methods used by the Unit for the recruitment of participants

They are performed in cooperation with different hospital services through the main researchers of each trial, according to the SOPs of the Unit.





Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

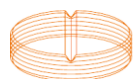
Asociación Síndrome de Angelman
FEDER

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Mostly in the same autonomous community, but there are cases where they can be sent to other autonomous community.



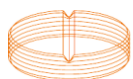


Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses? **Yes**
If yes, brief description: ---

Does the Unit have experience in processing blood samples for cell immunity? **Yes**
If yes, brief description: ---





Unidad de Investigación Farmacológica (CTU) - Hospital Univ. Puerta de Hierro Majadahonda **Experience**



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company		1	2			
Independent group		1	3	2	4	6

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	
Digestive	3
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	1
Neurosciences	1
Ophthalmology	
Oncology	
Respiratory	2
Urology	
Organ transplantation	
Psychiatry	6

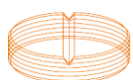
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	1
Allergy	1
Anaesthesiology	
Pneumology	1
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A





Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre

Affiliation data



Who filled in the inquiry (name)	Daniel Blázquez Gamero
Position	Manager of Paediatric Unit
Email	danielblazquezgamero@gmail.com
Phone	
Date of completion of inquiry	03/02/2017
Official name of the Paediatric Research Unit, complete address and email	Unidad Pediátrica de Ensayos Clínicos (UPEC). Hospital Universitario 12 de Octubre. Instituto de Investigación 12 de Octubre. Avenida de Córdoba s/n, 28041 Madrid
Website	http://www.imas12.es http://www.madrid.org/cs/Satellite?c=Page&cid=1354297586043&pagename=Hospital12Octubre%2FPage%2FH12O_ServiciosPrincipal





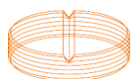
Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre

Membership or ownership data

Unit ownership	Public - Hospital Universitario 12 de Octubre. Universidad Complutense. Instituto de Investigación 12 de Octubre. Imas12
When Paediatric Clinical Research was initiated (year)?	---
Which Ethics Committee is the Unit linked to?	CEIC 12 de Octubre

Unit manager

Name and family name(s)	Daniel Blázquez gamero
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Paediatrician
Manager since (year)	2016
Email address	danielblazquezgamero@gmail.com
Phone number	
List of all departments in the institution which perform paediatric research	---





Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Cardiology
Metabolism
Endocrinology
Neonatology
Infectious and Immunodeficiencies
Rheumatology
Oncology and Hematology
Nephrology
Respiratory
Digestive
Emergency medicine
Paediatric Intensive Care Unit
Paediatric Surgery
Fetal Medicine





Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? No

Name of the agency and date of inspection N/A

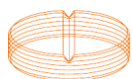
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? Yes

Has the Unit been audited by a sponsor in the last 3 years? No

Does the Unit use its own Standard Operating Procedures (SOPs)? Yes

Do you provide the sponsor with a copy of the SOP if requested? Yes

Would the Unit be ready to accept sponsor's SOPs? Yes





Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre Facilities



How many paediatric trials can be run in parallel in the Unit?	15
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	2
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	No
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





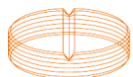
Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Annual calibration driven by sponsor and the unit





Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre

Personnel

Total number of people working at the Unit

Total permanent personnel	3
Total non-permanent personnel (by contract, Residents, Fellows)	3
Total collaborators (part time)*	1

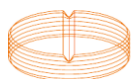
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
---	---

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Study Coordinator	partial	30	20	40
Nurse	partial	15	2	10





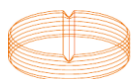
Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre Services



Does the Unit have a specific day hospital for paediatric population Yes

Does the Unit have a Pharmacy Service? No
If yes, availability of Pharmacy Service (Total/Partial) N/A
If not, how study medicines are received and stored ---

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? Yes





Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre

Subjects of Clinical Trial



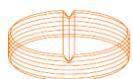
Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Methods used by the Unit for the recruitment of participants

Recruitment within the appointments and through the website





Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

If yes, names of associations are:

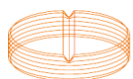
Stop CMV, FQ, metabólicos, Apoyo positivo

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Usual canalization



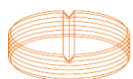


Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses? **Yes**
If yes, brief description: ---

Does the Unit have experience in processing blood samples for cell immunity? **Yes**
If yes, brief description: ---





Unidad Pediátrica de Ensayos Clínicos (UPEC) - Hospital Universitario 12 de Octubre Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	2	3	15	13	30	
Independent group	1		7	10		

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	X
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	X
Gynaecology	
Neurosciences	X
Ophthalmology	
Oncology	X
Respiratory	X
Urology	
Organ transplantation	X
Psychiatry	X

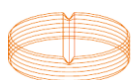
Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	X
Immunology	X
Dermatology	X
Metabolism	X
Allergy	
Anaesthesiology	
Pneumology	X
Odontology	
Biochemistry	X
Nephrology	X
Vaccines	X

Are there other units interested in paediatric trials?

If yes, these units are:

Yes

HIV, congenital infections, immunodeficiencies





Unidad de Investigación Pediátrica - Clínica Universidad de Navarra



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Unidad de Investigación Pediátrica - Clínica Universidad de Navarra

Affiliation data



Who filled in the inquiry (name)	Cristina Azcona San Julián
Position	Consultant in Paediatrics
Email	cazcona@unav.es
Phone	+34 948 296 236
Date of completion of inquiry	07/02/2017
Official name of the Paediatric Research Unit, complete address and email	Paediatric Research Unit-CUN
Website	www.cun.es





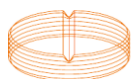
Unidad de Investigación Pediátrica - Clínica Universidad de Navarra

Membership or ownership data

Unit ownership	Private - Clínica Universidad de Navarra
When Paediatric Clinical Research was initiated (year)?	1990
Which Ethics Committee is the Unit linked to?	CEIm of Navarra

Unit manager

Name and family name(s)	Ana Patiño García
Education (physician, pharmacist, etc.)	Biologist
Department which the Research Unit is linked to	Paediatrics
Manager since (year)	January 1995
Email address	apatigar@unav.es
Phone number	948296236
List of all departments in the institution which perform paediatric research	Paediatrics and Paediatrics subspecialties





Unidad de Investigación Pediátrica - Clínica Universidad de Navarra

Membership or ownership data

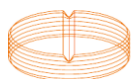
List of all subspecialties in the organization which perform paediatric research

Endocrinology

Nutrition

Oncology

Neurology





Unidad de Investigación Pediátrica - Clínica Universidad de Navarra Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? **Yes, not in the Paediatric Unit**

Name of the agency and date of inspection ---

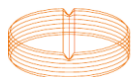
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? **No**

Has the Unit been audited by a sponsor in the last 3 years? **Yes, not in the Paediatric Unit**

Does the Unit use its own Standard Operating Procedures (SOPs)? **No**

Do you provide the sponsor with a copy of the SOP if requested? **No**

Would the Unit be ready to accept sponsor's SOPs? **Yes**





Unidad de Investigación Pediátrica - Clínica Universidad de Navarra Facilities

How many paediatric trials can be run in parallel in the Unit?	6
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	6
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	Yes





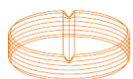
Unidad de Investigación Pediátrica - Clínica Universidad de Navarra Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

It is performed annually by an external company





Unidad de Investigación Pediátrica - Clínica Universidad de Navarra Personnel



Total number of people working at the Unit

Total permanent personnel 5

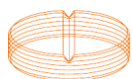
Total non-permanent personnel (by contract, Residents, Fellows) 1

Total collaborators (part time)*

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Cellular Therapy Unit	Researches in the advanced therapies GMP laboratory
Neurophysiology	Physicians and nurses





Unidad de Investigación Pediátrica - Clínica Universidad de Navarra Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Researcher	Partial	20	5	2
Physician	Partial	20	4	4





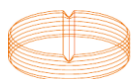
Unidad de Investigación Pediátrica - Clínica Universidad de Navarra Services



Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) **Total**
If not, how study medicines are received and stored **N/A**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Unidad de Investigación Pediátrica - Clínica Universidad de Navarra Subjects of Clinical Trial



Types of population accessed by the Unit

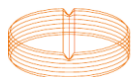
Healthy volunteers (e.g. vaccines)	X
Patients	X
Other populations	

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Yes

Methods used by the Unit for the recruitment of participants

Advertisements at the clinical trials website





Unidad de Investigación Pediátrica - Clínica Universidad de Navarra

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

Yes

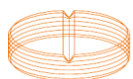
If yes, names of associations are:

Children against Cancer Foundation, Dravet Foundation

Does the centre receives subjects from other hospitals?

Yes

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral: ---





Unidad de Investigación Pediátrica - Clínica Universidad de Navarra Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

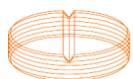
The clinical trials central unit

Does the Unit have experience in processing blood samples for cell immunity?

Yes

If yes, brief description:

It is performed by the cell therapy area





Unidad de Investigación Pediátrica - Clínica Universidad de Navarra Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	1		5			
Independent group	1				CUN promotion	1

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	
Cardiovascular	
Digestive	
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	
Neurosciences	X
Ophthalmology	
Oncology	X
Respiratory	
Urology	
Organ transplantation	
Psychiatry	

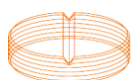
Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	
Metabolism	
Allergy	
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

Yes

Endocrinology, Gastroenterology, Pneumology





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces

Affiliation data



Who filled in the inquiry (name)	Itziar Astigarraga Aguirre / Teresa Gonzalez-Granda
Position	Manager of the Paediatric Unit in the CUH (Cruces University Hospital); Research Coordinator of the Maternal Child Healthcare and Assisted Reproduction Area; Research Coordinator of the Paediatric Oncology Research Group / Clinical Trials Responsible, BioCruces
Email	Itziar astigarraga Mariaiciar ASTIGARRAGAAGUIRRE@osakidetza.eus / Teresa González Granda TERESA.GONZALEZGRANDA@osakidetza.eus
Phone	Itziar astigarraga Mariaiciar 94 600 6000 Ext. 6582 / Teresa González Granda 94 600 6473 Ext. 7248
Date of completion of inquiry	24/01/2017
Website	---





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces

Affiliation data

Official name of the Paediatric Research Unit, complete address and email

BioCruces: Research Area in Maternal Child Healthcare and Assisted Reproduction (Coordinator: Itziar Astigarraga Aguirre, data above), with the following research groups:

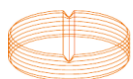
- Neonatology
- Research into the causes, prevention and treatment of genetic disorders
- Maternal and foetal health
- Paediatric Oncology
- Paediatric Intensive Care Unit

And other research áreas involved, with the following research groups:

- Pneumology
- Renal rare and hereditary diseases
- Congenital metabolism disorders
- Endocrinology, diabetes and paediatric obesity
- Coeliac disease, nutrition and alimentary tract disorders

Website

<http://www.biocruces.com/web/biocruces/inicio>





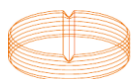
BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces

Membership or ownership data

Unit ownership	Public - Cruces University Hospital (OSI Ezkerraldea Enkarterri Cruces)
When Paediatric Clinical Research was initiated (year)?	1990
Which Ethics Committee is the Unit linked to?	Ethics Committee for the Clinical Investigation with Medicines in Euskadi (CEIm Euskadi)

Unit manager

Name and family name(s)	Itziar Astigarraga Aguirre / Luis Antonio Castaño González
Education (physician, pharmacist, etc.)	Doctor / Doctor
Department which the Research Unit is linked to	Paediatrics / Paediatric Endocrinology Endocrinology BioCruces Scientific Director
Manager since (year)	2004 / 2013
Email address	MARIAICIAR.ASTIGARRAGAAGUIRRE@osakidetza.eus / LUISANTONIO.CASTANOGONZALEZ@osakidetza.eus
Phone number	94 600 6000 Ext. 6582 / 94 600 6073
List of all departments in the institution which perform paediatric research	Paediatrics Unit





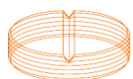
BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Paediatrics and Paediatric Emergency Department:

- Paediatric Cardiology
- Paediatric Allergology
- Neonatology
- Paediatric Intensive Care Unit
- Paediatric Endocrinology
- Perinatology
- Paediatric Neumology
- Paediatric Oncology and Haematology
- Paediatric Nephrology
- Paediatric Metabolism
- Neuropaediatrics
- Paediatric Gastroenterology
- Paediatric Reumatology
- Hospital Paediatrics
- Paediatric Emergency





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces Audits



Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years?	No
Name of the agency and date of inspection	N/A
Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested?	Yes
Has the Unit been audited by a sponsor in the last 3 years?	Yes, 2 audits
Does the Unit use its own Standard Operating Procedures (SOPs)?	Yes
Do you provide the sponsor with a copy of the SOP if requested?	Yes
Would the Unit be ready to accept sponsor's SOPs?	Yes





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces Facilities



How many paediatric trials can be run in parallel in the Unit?	40
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	107
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	Yes
Does the Hospital have home nursing service?	Yes
Does the Unit have experience in home nursing services?	Yes





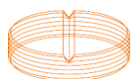
BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces Facilities

Other Unit equipment:

Centrifuge	X	
ECG equipment	X	
Ultra-freezers	X	
Scales	X	
Height-meters	X	
Tensiometer	X	
Equipment for serum handling and draw	Equipment for handling and draw of samples	X
Monitoring equipment	X	

Brief description of the equipment calibration process:

All equipment in the CUH facilities are inventoried, controlled and under a routinely calibration program. This program is managed by the Maintenance Unit in the CUH.





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces Personnel

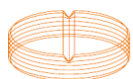
Total number of people working at the Unit

Total permanent personnel	40
Total non-permanent personnel (by contract, Residents, Fellows)	22
Total collaborators (part time)*	2

* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
Paediatrics	408





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces Personnel

Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
Specialist in study contracts (1)	Complete	7	3	380
Data manager (2)	Complete/partial	7/2	6/2	15/2
Nurse (4)	partial	12/26/30/35	12/26/30/35	5/15/15/20
CRA/CTA (2)	Complete	15	11	60





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces Services



Does the Unit have a specific day hospital for paediatric population	Yes
Does the Unit have a Pharmacy Service? If yes, availability of Pharmacy Service (Total/Partial) If not, how study medicines are received and stored	Yes From 8:30 to 22h Separate area for the storage of PEIs; a freezer and a fridge exclusively for CT medication.
Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed?	Yes





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces **Subjects of Clinical Trial**



Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)

Patients

X

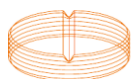
Other populations

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Phone interpreters

Methods used by the Unit for the recruitment of participants

Invitation to participate in CT related to patient's pathology





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations? **Yes**

If yes, names of associations are:

AECOM: Asociación Española para el Estudio de los Errores Congénitos del Metabolismo

AEP: Asociación Española de Pediatría

CRE: Asociación de Científicos Retornados a España.

ASPANOVAS: Asociación de padres de niños con cáncer de Bizkaia

La Cuadri del Hospi

Federación Española de Enfermedades Raras (FEDER)

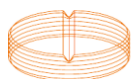
Asociación Española contra la Histiocitosis (ACHE)

ONPED: Asociación para la investigación y formación en oncología pediátrica

Does the centre receives subjects from other hospitals? **Yes**

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral: **Patients from the same AC, different ACs and other countries are admitted:**

- From other ACs: through the Health Local Governmental Dept., managed through assistance orders.
- From other countries: through NGOs.





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces **Pharmacodynamic / pharmacokinetic evaluation**



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

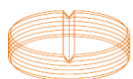
9 Phase II Clinical Trials during the last 5 years. Mainly in the fields of Paediatric Oncology and Metabolism disorders.

Does the Unit have experience in processing blood samples for cell immunity?

Yes

If yes, brief description:

Only for isolation of monoclonal Abs by density gradient





BioCruces (Instituto de Investigación Sanitaria) - Hospital Universitario de Cruces Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company	1	6	10	2	17	N/A
Independent group	0	4	7	0	5	5

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	X
Digestive	X
Anaesthesiology and Pain Medicine	
Endocrinology	X
Gynaecology	
Neurosciences	X
Ophthalmology	
Oncology	X
Respiratory	X
Urology	
Organ transplantation	
Psychiatry	

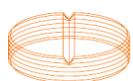
Therapeutic areas	Clinical trials
Haematology	X
Rheumatology	X
Immunology	X
Dermatology	
Metabolism	X
Allergy	X
Anaesthesiology	
Pneumology	
Odontology	
Biochemistry	
Nephrology	X
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

Yes

Obstetrics and gynecology, Medical Oncology, Endocrinology, Internal Medicine





Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia



- ▶ Affiliation data
- ▶ Membership or ownership data
- ▶ Audits
- ▶ Facilities
- ▶ Personnel
- ▶ Services
- ▶ Subjects of Clinical Trial
- ▶ Pharmacodynamic / pharmacokinetic evaluation
- ▶ Experience





Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia

Affiliation data



Who filled in the inquiry (name)	Eduardo González Pérez-Yarza
Position	Titular Professor and Head of Paediatrics Service
Email	eduardo.gonzalez@ehu.eus
Phone	
Date of completion of inquiry	19/01/2017
Official name of the Paediatric Research Unit, complete address and email	Servicio de Pediatría, Hospital Universitario Donostia – Instituto de Investigación Sanitaria BioDonostia. Avda. Dr. Begiristain, 118. 20014 - San Sebastián.
Website	http://www.ehu.eus/es/web/pediatrica





Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia

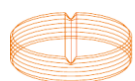
Membership or ownership data



Unit ownership	Public - Donostia University Hospital – Biodonostia Health Research Institute, San Sebastián
When Paediatric Clinical Research was initiated (year)?	1998
Which Ethics Committee is the Unit linked to?	CEIm de Euskadi

Unit manager

Name and family name(s)	Eduardo González Pérez-Yarza
Education (physician, pharmacist, etc.)	Physician
Department which the Research Unit is linked to	Paediatrics Service, Donostia Hospital – Biodonostia Health Research Institute, Basque Country (UPV/EHU)
Manager since (year)	2002
Email address	eduardo.gonzalez@ehu.eus
Phone number	+34 609 069 758
List of all departments in the institution which perform paediatric research	Microbiology Service Neurology Service Genetic Service





Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia

Membership or ownership data

List of all subspecialties in the organization which perform paediatric research

Child Pneumology Section

Paediatric Onco-Hematology Section

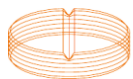
Child Neurology Section

Gastroenterology, Hepatology and Child Nutrition Section

Child Allergology Section

Paediatric Emergency Section

Neonatology Section





Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia Audits



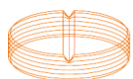
Has the Unit been submitted to paediatric clinical trials inspection by a Regulatory agency in the last 3 years? No

Name of the agency and date of inspection N/A

Is the Unit willing to share the results of the inspection performed by a Regulatory agency with the sponsor if requested? Yes

Has the Unit been audited by a sponsor in the last 3 years? No

Does the Unit use its own Standard Operating Procedures (SOPs)? No
Do you provide the sponsor with a copy of the SOP if requested? ---
Would the Unit be ready to accept sponsor's SOPs? Yes

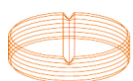




Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia Facilities



How many paediatric trials can be run in parallel in the Unit?	7
Does the Unit have beds for hospital admission of paediatric patients?	Yes
If yes, number of beds in the Unit	80
Do you have any agreement with organizations/associations which allow for families to stay with hospitalized children?	Yes
Does the Unit have a cart for attention of emergency situations such as cardiorespiratory arrest?	Yes
Does this cart have emergency medicines with safe but immediate access?	Yes
Type of life support the personnel of the Unit is trained and qualified to perform	Basic and Advanced
Do the Unit health personnel have previous specialized experience in blood draws in babies and little children?	Yes
Is the Hospital equipped with rooms for continued education of children while hospitalized?	No
Does the Hospital have home nursing service?	No
Does the Unit have experience in home nursing services?	No





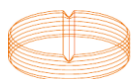
Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia Facilities

Other Unit equipment:

Centrifuge	X
ECG equipment	X
Ultra-freezers	X
Scales	X
Height-meters	X
Tensiometer	X
Equipment for serum handling and draw	X

Brief description of the equipment calibration process:

Calibration performed by hospital electromedicine staff to request of the paediatric service or the clinical research platform of the IIS Biodonostia





Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia Personnel



Total number of people working at the Unit

Total permanent personnel	22
Total non-permanent personnel (by contract, Residents, Fellows)	24
Total collaborators (part time)*	4

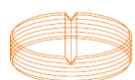
* E.g.: Hospital physicians or nurses who collaborate in Clinical Trials doing duty shifts. Indicate equivalente person/full time.

Personnel per service

Service	Personnel
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Personnel experience in paediatric clinical trials

Personnel	Complete/partial	Years of experience	Years of experience in paediatric trials	Number of studies
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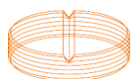
Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia Services



Does the Unit have a specific day hospital for paediatric population **Yes**

Does the Unit have a Pharmacy Service? **Yes**
If yes, availability of Pharmacy Service (Total/Partial) **Total**
If not, how study medicines are received and stored **N/A**

Is the Unit linked to a certified central laboratory where analytic tests specified in the protocol can be performed? **Yes**





Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia

Subjects of Clinical Trial



Types of population accessed by the Unit

Healthy volunteers (e.g. vaccines)

Patients

Other populations

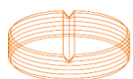
X

In case foreign populations are received, has the Unit an interpreter to communicate with child's family?

Yes

Methods used by the Unit for the recruitment of participants

Through (1) the Primary Care centres of the Donostia Integrated Services Organization,
(2) external consultations of the Paediatric Service of the Donostia University Hospital





Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia

Subjects of Clinical Trial

Does the Unit have contact / collaborate with paediatric patient associations?

If yes, names of associations are:

Yes

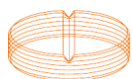
- ASPANOI, Association of parents and families of children with cancer
- Association of parents of premature children
- Association of Parents and families of children with Celiac disease
- Association of parents and families of children with Cystic Fibrosis

Does the centre receives subjects from other hospitals?

If yes, from the same Autonomous Community (AC), from another AC, or from other country? and a brief summary of the communication process for subject referral:

Yes

Autonomous Community of the Basque Country, same community
Autonomous Community of Navarre, per concert
Autonomous Community of La Rioja, per concert





Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia
Pharmacodynamic / pharmacokinetic evaluation



Does the Unit have experience in paediatric clinical trials with PK/PD analyses?

Yes

If yes, brief description:

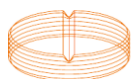
Three clinical trials with PK/PD

Does the Unit have experience in processing blood samples for cell immunity?

Yes

If yes, brief description:

There is collaboration with the Immunology Service of the Donostia University Hospital





Servicio de Pediatría - H.U. Donostia - Instituto de Investigación Sanitaria Biodonostia Experience



Number of paediatric clinical trials in the last 5 years and type of studies performed at the Unit

Number of studies	Phase I	Phase II	Phase III	Phase IV	Observational	Individual research
Pharmaceutical company		2	2		X	
Independent group			2			X

Therapeutic areas in which the clinical trials were developed

Therapeutic areas	Clinical trials
Infectious diseases	X
Cardiovascular	
Digestive	
Anaesthesiology and Pain Medicine	
Endocrinology	
Gynaecology	
Neurosciences	
Ophthalmology	
Oncology	
Respiratory	X
Urology	
Organ transplantation	
Psychiatry	

Therapeutic areas	Clinical trials
Haematology	
Rheumatology	
Immunology	
Dermatology	X
Metabolism	
Allergy	X
Anaesthesiology	
Pneumology	X
Odontology	
Biochemistry	
Nephrology	
Vaccines	

Are there other units interested in paediatric trials?

If yes, these units are:

No

N/A

