

Jornada sobre INVESTIGACIÓN CLÍNICA EN PEDIATRÍA

Cristina Calvo
Hospital Universitario La Paz

What is IdiPAZ?

Presentation

FAQs

Organization chart

Documentation

Location

Contact

Buyer profile

IdiPAZ is a place for
biomedical research
as a result of the union between:

- Hospital Universitario La Paz
- Universidad Autónoma de Madrid
- Fundación para la Investigación Biomédica del Hospital Universitario La Paz



Hospital Universitario La Paz
Fundación para la Investigación Biomédica

Comunidad de Madrid



Hospital Universitario La Paz
Hospital Carlos III
Hospital Cantoblanco

IdiPAZ
Instituto de Investigación
Hospital Universitario La Paz

INDEX

1. Research structure
 1. Clinical Trials Unit
 2. Pediatric Research Groups
2. Research Networks

RESEARCH STRUCTURE



CLINICAL TRIALS UNIT (UCICEC)



Comunidad de Madrid
CONSEJERIA DE SANIDAD
DIRECCIÓN GENERAL DE INSPECCIÓN Y ORDENACIÓN

Unidad Central de Investigación Clínica y Ensayos Clínicos del Hospital Universitario La Paz, located at the Hospital Universitario La Paz, established in Paseo de la Castellana, 261 in Madrid, has been inspected by the General Subdirectorate of Pharmaceutical Inspection and Regulation to verify compliance with the principles of Good Clinical Practice (GCP) in force in the European Union¹ and Spain² and the "Technical requirements for the Units which conduct early stage clinical trials with medicines in the Community"³.

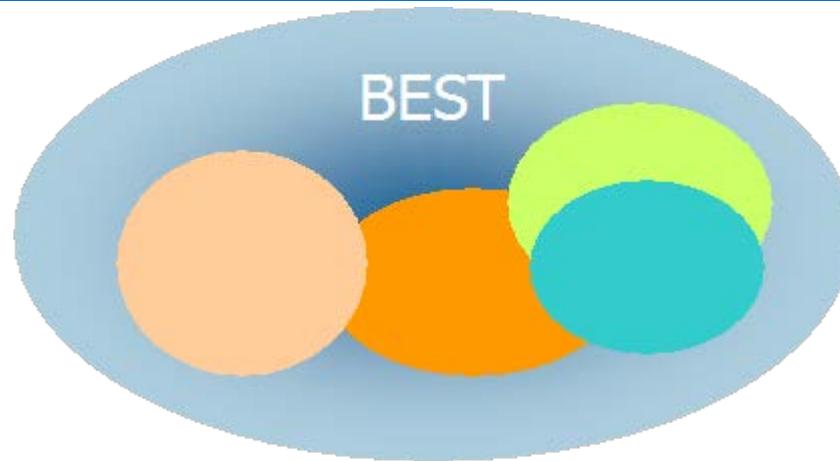


Spanish
Clinical
Research
Network

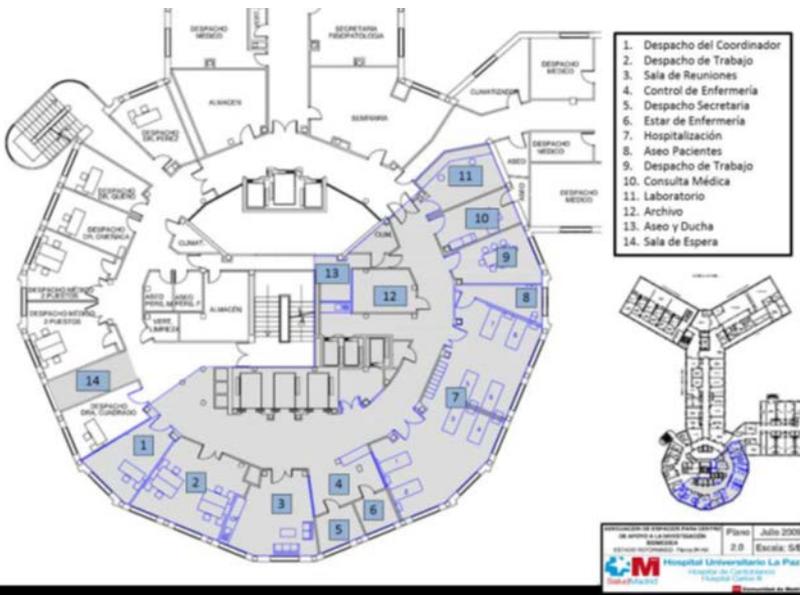


LA PAZ: PEDIATRIC CLINICAL TRIAL UNIT (UCICEC)

DIRECTORY ON PEDIATRIC RESEARCH UNITS



2º FLOOR Mother & child hospital.



LA PAZ: PEDIATRIC CLINICAL TRIAL UNIT (UCICEC)



Areas of Pediatric Clinical Trials

- Allergy
- Anesthesia and Resuscitation
- Clinical Pharmacology
- Biochemistry
- Cardiology
- Children's Cardiology
- Cardiac surgery for children
- General Surgery
- Maxillofacial Surgery
- Orthopedic Surgery and Traumatology
- Pediatric surgery
- Pediatric Intensive Care
- Dermatology
- Digestive / Gastroenterology
- Endocrinology
- Nursing
- Pharmacy
- Clinical Pharmacology
- Gynecology
- Pediatric Hemato-oncology
- Hematology
- Hepatology
- Pediatric Infectious-Tropical Diseases and Vaccines
- Immunology

Alberto Borobia
Clinical Pharmacologist

- Immunology
- Medical and Molecular Genetic Institute
- Internal Medicine
- Microbiology
- Nephrology
- Neonatology
- Pneumology
- Neurology
- Child nutrition
- Obstetrics / Gynecology
- Ophthalmology
- Oncology
- General Pediatrics
- Psychiatry
- Radiology
- Rehabilitation
- Rheumatology
- Traumatology
- Childhood Pain Unit
- Electrophysiology Sleep Unit
- HIV Unit
- Pediatric Emergencies



FACILITIES



8 beds
2 simultaneous
admissions phase I.

Personnel trained in
Advance Life Support



PERSONNEL

UCICEC

Permanent: 6
Non-permanent: 7
Partial time: 15

PEDIATRIC UNITS

20 Physicians in the dayshift, 10 of them also make guards (24-hour shift)

15 Nurses of pediatric 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 pediatric specialties



SUBJECTS & PATIENTS

POPULATION

- ✓ Healthy volunteers
- ✓ Patients
- ✓ Adopters, immigrants and refugees
- ✓ Tertiary reference center of all especialities.

PHARMACODYNAMIC / PHARMACOKINETIC

14 CT in Phase 1 with evaluation PK/PD

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





EXPERIENCE (5 LAST YEARS)

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

AREAS & RESEARCH GROUPS



PEDIATRIC RESEARCH GROUPS

INFECIOUS DISEASES & IMMUNITY AREA



**PATOLOGÍA INFECCIOSA RESPIRATORIA,
SISTÉMICA Y NEUROLÓGICA EN LA
INFANCIA, Y RESPUESTA INMUNOLÓGICA
DEL HUÉSPED**

Cristina Calvo Rey

**INFECCIONES SISTÉMICAS EN PEDIATRÍA;
VIH, TUBERCULOSIS, PATOLOGÍA
IMPORTADA Y ENFERMEDADES
EMERGENTES**

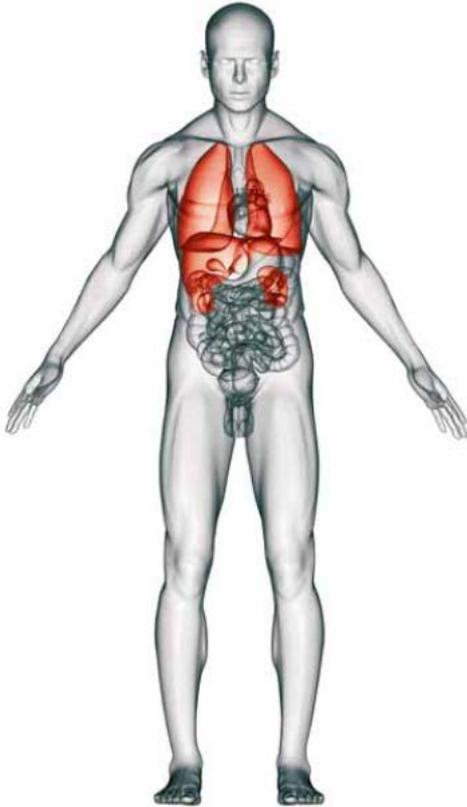
María José Mellado Peña

**INVESTIGACIÓN TRASLACIONAL EN CÁNCER
INFANTIL, TRASPLANTE HEMATOPOYÉTICO Y
TERAPIA CELULAR**

Antonio Pérez Martínez

PEDIATRIC RESEARCH GROUPS

PATHOLOGY OF LARGE SYSTEMS



NEONATOLOGÍA

Adelina Pellicer

HEPATOLOGÍA MOLECULAR

Paloma Jara Vega

CIRUGÍA DE MALFORMACIONES CONGÉNITAS

Leopoldo Martínez Martínez

TRASPLANTES

Francisco Hernandez Oliveros



SURGERY, TRANSPLANTATION AND HEALTH TECHNOLOGY

Networks





European
Reference
Network

for rare or low prevalence
complex diseases

European Reference Network in Pediatric Transplantation



Hospital Universitario La Paz

Hospital de Cantoblanco
Hospital Carlos III



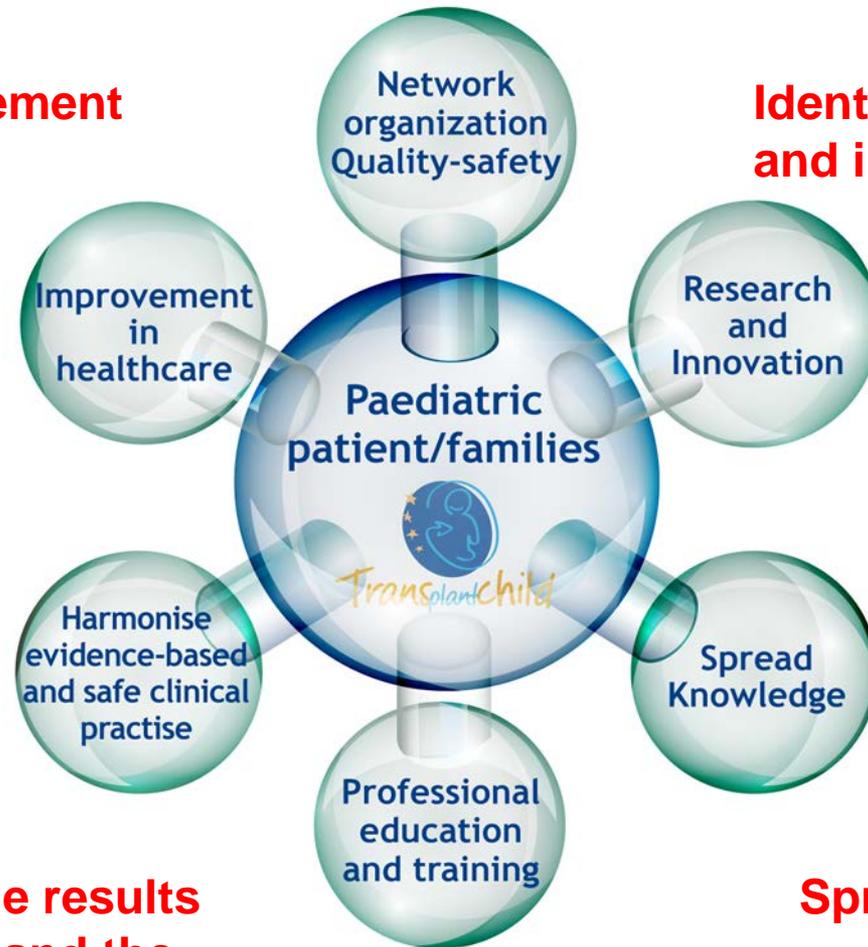
Transplantchild

Transplantation (SOT & HSCT) in Children

Health Care Improvement

Facilitating patient empowerment

Improvement of the results of the procedures and the quality of life (clinical guidelines).



Identify areas of research and innovation

Spread Knowledge

IDIPAZ FOUNDATION



EXECUTIVE COMMITTEE

GENERAL COORDINATOR
Federico Martín



CLINICAL LEADERS OF CONSOLIDATED/THEMATIC CENTRES

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE
Daniel Blázquez



HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE
Eduardo Montesinos



HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESÚS
Lucas Moreno



HOSPITAL UNIVERSITARIO VALL D'HEBRON
Carlos Rodrigo



MANAGEMENT LEADERS

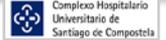
HOSPITAL UNIVERSITARIO LA PAZ
José Luis Narro



HOSPITAL SANT JOAN DE DÉU
Joana Claverol



HOSPITAL CLÍNICO UNIVERSITARIO DE SANTIAGO DE COMPOSTELA
María Gómez Reino



THEMATIC NETWORKS



RED DE INVESTIGACIÓN TRALACIONAL EN INFECTOLOGÍA PEDIÁTRICA (RITIP)
Cristina Calvo

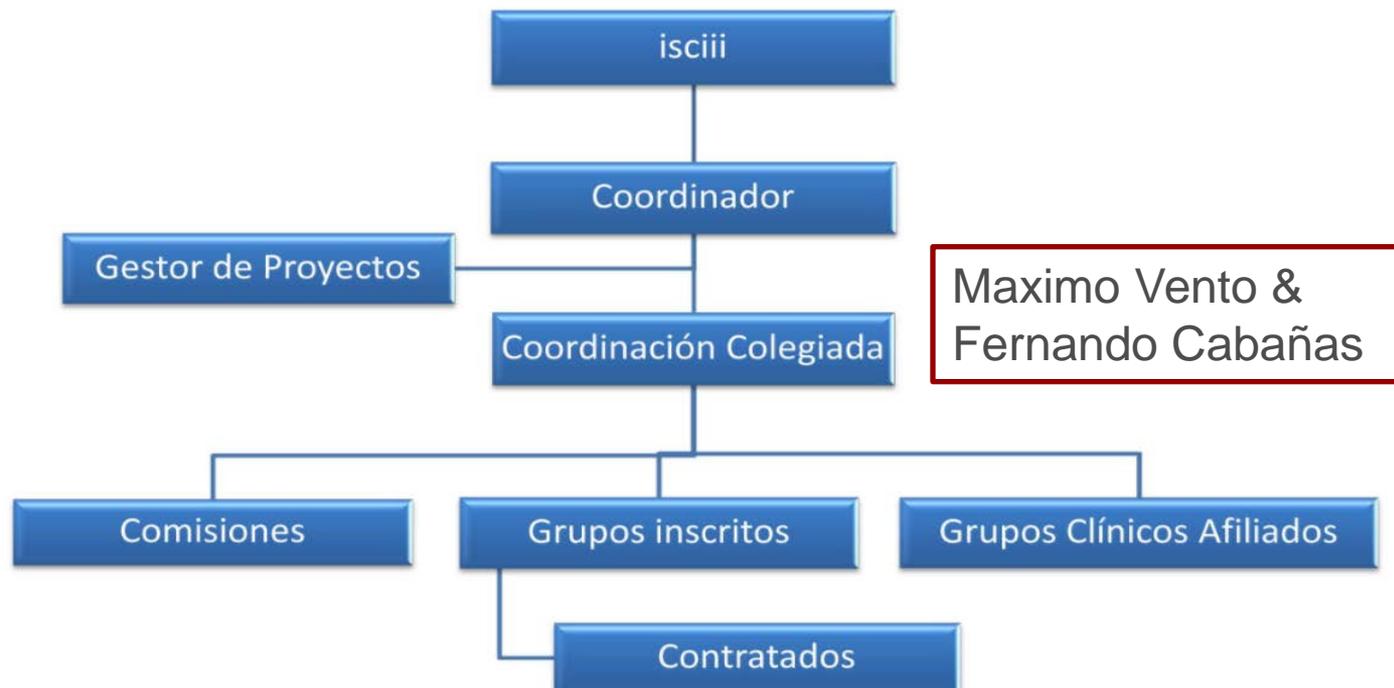
RED DE SALUD MATERNO INFANTIL Y DESARROLLO (SAMID)
Fernando Cabañas



SAMID NETWORK



RETICS financiada por el PN I+D+I 2013-2016, ISCIII - Subdirección General de Evaluación y Fomento de la Investigación y el Fondo Europeo de Desarrollo Regional (FEDER), ref. RD16/0022.



SAMID NETWORK

Maternal and Child Health and Development Research Network

| HOME | WHO ARE WE ▾ | COMMISSIONS ▾ | RESEARCH GROUPS ▾ | PROD |
|---|--------------|---------------|-------------------|--|
|  | | | | IIS BIOCRUCES |
| | | | | IIS ARAGON |
| | | | | HOSPITAL SANT JOAN DE DEU |
| | | | | HOSPITAL Universitario VALL d'HEBRON |
| | | | | HOSPITAL DEL MAR |
| | | | | HOSPITAL G. Universitario GREGORIO MARAÑON |
| | | | | HOSPITAL Universitario MARQUES DE VALDECILLA |
| | | | | HOSPITAL Universitario LA PAZ (NEONATAL) |
| | | | | HOSPITAL Universitario LA PAZ (SURGERY) |
| | | | | HOSPITAL Universitario 12 DE OCTUBRE |



Fernando Cabañas



Leopoldo Martínez

RITIP NETWORK

Traslational Research Network in Pediatric Infectious Diseases



Translational Research
Network in Pediatric
Infectious Diseases

HOME

STRUCTURE

INVESTIGATION
GROUPS



Cristina Calvo &
Federico Martínón



RITIP NETWORK



Translational Research
Network in Pediatric
Infectious Diseases

 HOME

 STRUCTURE

 INVESTIGATION
GROUPS

INVESTIGATION GROUPS

➤ Grupo 1: GENVIP (Genética, Vacunas, Infecciones y Pediatría)

➤ Grupo 2: Malalties infeccioses i resposta inflamatòria sistèmica en pediatria

➤ Grupo 3: Grupo de infección en el paciente pediátrico inmunodeprimido (Infecciones, Inmunodeficiencias y Pediatría)

➤ Grupo 4: Grupo de Infecciones Pediátricas Respiratorias y Sistémicas-Neurológicas



Cristina Calvo

➤ Grupo 5: GIPP – Grupo de Investigación de Infecciones en Población Pediátrica (Instituto de Investigación Sanitaria Gregorio Marañón)

➤ Grupo 6: Grupo de Enfermedades Infecciosas y Tropicales Pediátricas



M^a José
Mellado

➤ Grupo 7: Enfermedades Infecciosas Pediátricas.

➤ Grupo 8: Grupo de Investigación VIH Madrid

➤ Grupo 9: Enfermedades infecciosas e inmunopatología en Pediatría

TEDDY network

Task-force in Europe for Drug Development for the Young



Network Project and Studies SOPs Ethics EPTRI YPAG – KIDS BARI Patients and Families Media

Members

+ Geniko Nosokomeio Paidon Athinon I Agia Sophia-Paidon Pentelis - Greece

+ Gothia Forum Sahlgrenska University Hospital - Sweden

+ Gruppo Italiano per gli Studi di Farmacoeconomia – Italy

+ Hospital Clínico Universitario de Santiago de Compostela - Spain

+ Hospital Universitario 12 de Octubre - Spain

+ Hospital Universitario La Paz – Spain



M^a José Mellado

+ Inserm SC10 - France

+ Institute of Physiology of ASCR, v.v.i. – Czech Republic

+ Instytut Pomnik – Centrum Zdrowia Dziecka – Poland

+ Istituto Superiore di Sanità – Italy

TEDDY network

Task-force in Europe for Drug Development for the Young



- Network
- Project and Studies
- SOPs
- Ethics
- EPTRI
- YPAG – KIDS BARI
- Patients and Families
- Media

EPTRI

EPTRI – European Paediatric Tra

Designing of a pan-European Infrastructure to promote technology

European Strategy Forum
on Research Infrastructures



PROJECT COMPLEMENTARY

EPCTRI, European Paediatric Clinical T

IdiPAZ

**STRATEGY REPORT
ON RESEARCH
INFRASTRUCTURES**

THANK YOU

Working in Group
Working in Network
Working in Europe

