Spanish Paediatric Clinical Trials Network (RECLIP)

RECLIP Presentation Report at TEDDY 2016 (Rome)

Prof. Dr. Federico Martinón-Torres
Coordinator of RECLIP (www.reclip.org)
Head of Pediatrics, Hospital Clínico Universitario de Santiago

Improvements in child health depend on the access to new treatments. Paediatric clinical trials allow to validate the safety and the efficacy of new medicines and their appropriate dosage in paediatric patients.

Child health as a priority

Only a small percentage of drugs and devices approved by the European Medicines Agency (EMA) or the Food and Drug Administration (FDA) are labelled for paediatric use. Moreover, only 30% of marketed drugs in Europe include a paediatric authorisation and less than 50% of authorised medicines commonly used in children have been properly tested in paediatric populations.

Children should be protected from inadequate dosage and inappropriate use of medical treatments. This protection could be achieved by the participation in **well designed clinical trials**. A change in culture is necessary as well as the promotion of initiatives that lead to **strong paediatric clinical research** aiming at the approval of new drugs and labeled for paediatric use and including information about efficacy, dosing and safety.

General Overview

The implementation of an European Paediatric Regulation in 2007 has lead to continuous increase in the number of clinical studies for new drug approvals in children and in the number of children involved in such studies in Europe.

CURRENT SITUATION

Approximately 754 ongoing paediatric investigation plans (PIPs) in 2015

Approximately 763 paediatric trials requiring 210.000 enrolled children to complete the trials in 2015

Source: European Medicines Agency, Paediatric Medicines Office. http://ec.europa.eu/health/files/paediatrics/2015_annual_report.pdf

The paediatric clinical trial infrastructure across the EU lacks organization and appropriate support from industry-sponsored and academic non-industry sponsored clinical trials.

WHAT DO WE NEED?

A better organized infrastructure and strong support from sponsors aiming at new paediatric drug approval, a complete labelling of existing drugs, valid comparisons among already marketed paediatric therapies and the development of observational studies analyzing paediatric diseases indications.

Overview for Spain

In Spain the synergy of researchers and infrastructures in specialized institutions is promoted through the creation of clusters, health research institutes, consortia and networks with the aim of achieving a greater specialization and adaptation to current challenges in clinical research.

CONSORTIA AND THEMATIC RESEARCH NETWORKS

RETICs (Networks for Cooperative Research in Health) promote research projects joining different research groups of the National Health System working on related areas together. The main objectives of RETICs are:

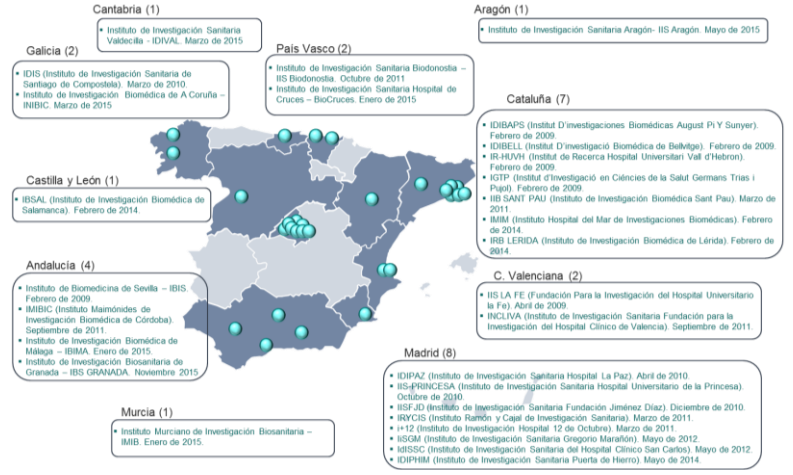
- To increase capacities of the research groups.
- To encourage the development of multidisciplinary projects.
- To improve the access to competitive funding sources.

COOPERATION AMONG TECHNOLOGICAL AGENTS (TECHNOLOGICAL CLUSTERS AND PLATFORMS)

biocat
Madrid Network
bioga
Cluster Tecnológico Empresarial das Ciencias da Vida
BIOVAL
Bioregión de la Comunidad Valenciana
Plataforma de Mercados Biotecnológicos
BASQUE BIOCLUSTER
Andalucía BIORegión
AraBioTech
The Aragón Biotechnology Cluster

HEALTH RESEARCH INSTITUTES

Association of hospitals with universities, public research institutions and other public or private research centres.



Objectives of RECLIP

The main objective of RECLIP is to provide a fully developed and professionalized network of reference national clinical trial units, ensuring an appropriate infrastructure for conducting safe and effective paediatric clinical trials.

HOW?

Through a **coordinated and super-specialized network** and a **professionalized, multidisciplinary and organized stable structure**, integrating the **most important paediatric clinical research units** across the country, located in the most important hospitals in Spain.

WITH WHOM?

RECLIP develops its activity through the **cooperation with key stakeholders** inside and outside the network. The network joins strong and experienced national paediatric clinical and academic institutions with a long history of cross-collaboration with each other and the pharmaceutical industry.

WHY?

The collaboration between reference entities in RECLIP allows to **reduce the uncertainty** and the risk inherent to the development of paediatric trials and **helps to accelerate** the process. All partners offer their expertise and best practices for the achievement of the aim of RECLIP.

Who we are: founders of RECLIP

The Spanish Paediatric Clinical Trials Network (RECLIP), formally constituted on November 21, 2016, is created on the basis of the clinical strength of major paediatric hospitals, combined with primary health care centres and thematic research networks that develop relevant activity in paediatric clinical research.

CURRENT PARTNERS OF RECLIP

- HOSPITAL CLÍNICO UNIVERSITARIO DE SANTIAGO DE COMPOSTELA
- HOSPITAL UNIVERSITARIO 12 DE OCTUBRE
- HOSPITAL UNIVERSITARIO LA PAZ
- HOSPITAL UNIVERSITARIO VALL D'HEBRON
- HOSPITAL UNIVERSITARIO CLÍNICO SAN CARLOS
- HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESÚS
- HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN
- HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE
- HOSPITAL UNIVERSITARIO RAMÓN Y CAJAL
- HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO
- HOSPITAL REGIONAL UNIVERSITARIO DE MÁLAGA
- HOSPITAL SANT JOAN DE DÉU
- FUNDACIÓN PARA EL FOMENTO DE LA INVESTIGACIÓN SANITARIA Y BIOMÉDICA DE LA C. VALENCIANA
- RED DE INVESTIGACIÓN TRALACIONAL EN INFECTOLOGÍA PEDIÁTRICA (RITIP)
- RED DE SALUD MATERNO INFANTIL Y DESARROLLO (SAMID)
- SOCIEDAD ESPAÑOLA DE REUMATOLOGÍA PEDIÁTRICA (SERPE)
- SOCIEDAD ESPAÑOLA DE HEMATOLOGÍA Y ONCOLOGÍA PEDIÁTRICA (SEHOP)
- RED EUROPEA DE NEUROPSICO-FARMACOLOGÍA DEL NIÑO Y DEL ADOLESCENTE (ECAPN)
- SOCIEDAD ESPAÑOLA DE ERRORES INNATOS DEL METABOLISMO (SEEIM)

INTEGRATING CHARACTER

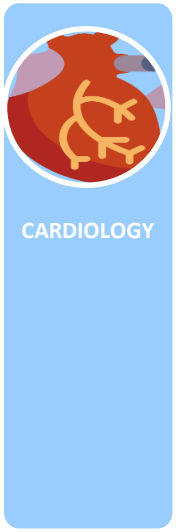
RECLIP is an integrated network open to all the centres and networks that want to join the initiative. RECLIP will be coordinated by Complejo Hospitalario Universitario de Santiago.

Thematic networks and Scientific societies

SEHOP – Sociedad Española de Hematología y Oncología Pediátricas; RITIP; ECAPN; RED SAMID; Sociedad Española de Errores Innatos del Metabolismo; SERPE

Scientific capabilities

TRANSVERSAL THEMATIC AREAS



CARDIOLOGY

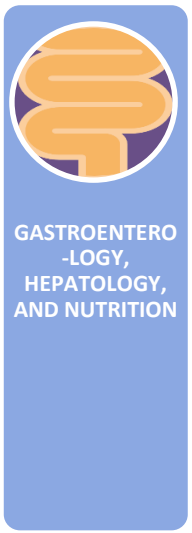
INTENSIVE CARE

ENDOCRINO-LOGY

INFECTIOUS DISEASES AND VACCINES

RITIP

Dra. Cristina Calvo

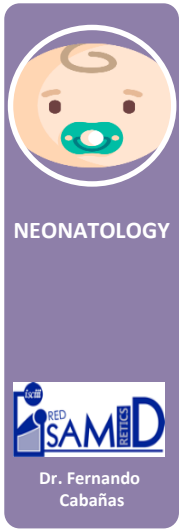


GASTROENTERO-LOGY, HEPATOLOGY, AND NUTRITION

INBORN ERRORS METABOLISM

Sociedad Española de Errores Innatos del Metabolismo

Dra. Mari Luz Couce



NEONATOLOGY

RED SAMID

Dr. Fernando Cabañas

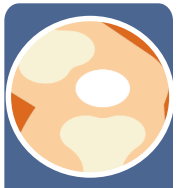
PNEUMOLOGY AND ALLERGY

NEUROLOGY

ONCO-HEMATOLOGY

SEHOP

Dr. Lucas Moreno



RHEUMATO-LOGY

SERPE

Dr. Jordi Antón López

PSYCHIATRY

ECAPN

Dra. Carmen Moreno

OTHER

RECLIP endorsements and collaborative entities (under way)

INSTITUTIONAL ENDORSEMENTS

INSTITUTO DE SALUD CARLOS III (ISCIII)
CARLOS III HEALTH INSTITUTE

AGENCIA ESPAÑOLA DEL MEDICAMENTO Y PRODUCTOS SANITARIOS (AEMPS)
MEDICINES AND HEALTHCARE PRODUCTS AGENCY

FARMAINDUSTRIA
NATIONAL TRADE ASSOCIATION OF THE SPANISH BASED PHARMACEUTICAL INDUSTRY

COLLABORATIVE ENTITIES / SOCIETIES

PLATAFORMA DE UNIDADES DE INVESTIGACIÓN CLÍNICA Y ENSAYOS CLÍNICOS
SPANISH CLINICAL RESEARCH NETWORK (SCReN)

PAEDIATRIC RHEUMATOLOGY INTERNATIONAL TRIALS ORGANISATION (PRINTO)

EUROPEAN CHILD AND ADOLESCENT CLINICAL PSYCHOPHARMACOLOGY NETWORK

OTHERS: SPANISH PEDIATRIC SEPCIALTIES SOCIETIES, …

Network capabilities

The information has been requested to the centres by a questionnaire that reflects their activity in paediatric research lines through specific quantitative and qualitative indicators.

QUALITATIVE INDICATORS

- ✓ Main scientific areas
- ✓ Resources and infrastructures
- ✓ Staff
- ✓ Research Studies:
  - Clinical Trials
  - Observational Studies

QUANTITATIVE INDICATORS

- ✓ Paediatric Clinical Trials:
  - Non-commercial clinical trials
  - Commercial clinical trials
  - Phases
- ✓ Observational studies
  - EPA observational studies
  - Non-EPA observational studies
- ✓ Patients recruited
- ✓ Value of captured funding

NOMBRE DEL CENTRO:

	DATOS GENERALES	*Pequeña descripción, reflexión*
1	¿Cuáles, de las siguientes, son sus principales áreas científicas de acuerdo al desarrollo de su actividad?	
	CARDIOLOGÍA	*Enumerar las líneas de investigación fundamentales del centro en este recuadro. Añadir tantas filas como sean necesaria*
	CUIDADOS INTENSIVOS	*Enumerar las líneas de investigación fundamentales del centro en este recuadro. Añadir tantas filas como sean necesaria*
	ENDOCRINOLOGÍA	*Enumerar las líneas de investigación fundamentales del centro en este recuadro. Añadir tantas filas como sean necesaria*
	ENFERMEDADES INFECCIOSAS Y VACUNAS	*Enumerar las líneas de investigación fundamentales del centro en este recuadro. Añadir tantas filas como sean necesaria*
	GASTROENTEROLOGIA Y NUTRICIÓN	*Enumerar las líneas de investigación fundamentales del centro en este recuadro. Añadir tantas filas como sean necesaria*
	NEONATOLOGÍA	*Enumerar las líneas de investigación fundamentales del centro en este recuadro. Añadir tantas filas como sean necesaria*

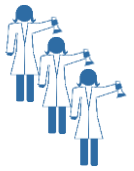
ANÁLISIS CUANTITATIVO													
			DESGLOSE POR ÁREAS/TEMÁTICAS DE LOS ENSAYOS CLÍNICOS (ESTAS CONSIDERADAS U OTRAS NO CONTEMPLADAS)										
1	Capacidades	TOTAL	CARDIOLOGÍA	CUIDADOS INTENSIVOS	ENDOCRINOLOGIA	ENFERMEDADES INFECCIOSAS Y VACUNAS	GASTROENTEROLOGÍA Y NUTRICIÓN	NEONATOLOGÍA	NEUMOLOGIA	NEUROLOGÍA	ONCOLOGIA	REUMATOLOGIA	INDICAR OTRAS ÁREA NO ESPECIFICADAS
	EECC pediátricos nuevos iniciados												
	- EECC pediátricos no comerciales												
	- EECC pediátricos comerciales												
	EECC pediátricos iniciados anteriormente a 2011 pero activos en 2011												
	EECC pediátricos donde el centro haya actuado como coordinador												
	EECC pediátricos en Fase I												
	EECC pediátricos en Fase II												
	EECC pediátricos en Fase III												
	EECC pediátricos en Fase IV												
	Pacientes pediátricos reclutados por el centro												
	- Pacientes pediátricos reclutados por el centro (Fase I)												
	- Pacientes pediátricos reclutados por el centro (Fase II)												
	- Pacientes pediátricos reclutados por el centro (Fase III)												
	- Pacientes pediátricos reclutados por el centro (Fase IV)												
2	Valor de financiación												
	EECC pediátricos												

ANÁLISIS CUANTITATIVO								
1	Capacidades	TOTAL	DESGLOSE POR AÑOS					
			2011 y anteriores	2012	2013	2014	2015	2016
	Estudios observacionales EPA							
	Estudios observacionales no EPA							
2	Valor de financiación							
	Estudios observacionales (NA si se corresponden con investigacion independiente)							

RECLIP CAPABILITIES (2011-2016)

MEMBERS

STAFF TEAM



6089

TOTAL STAFF

34,29%

PhD Researchers

18,39%

Doctors

35,15%

Nurses

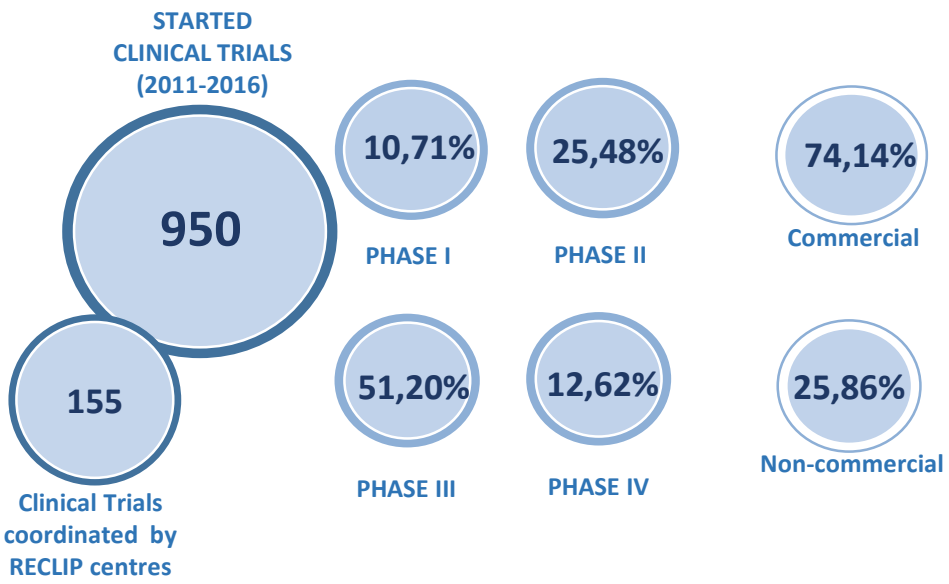
12,17%

Others

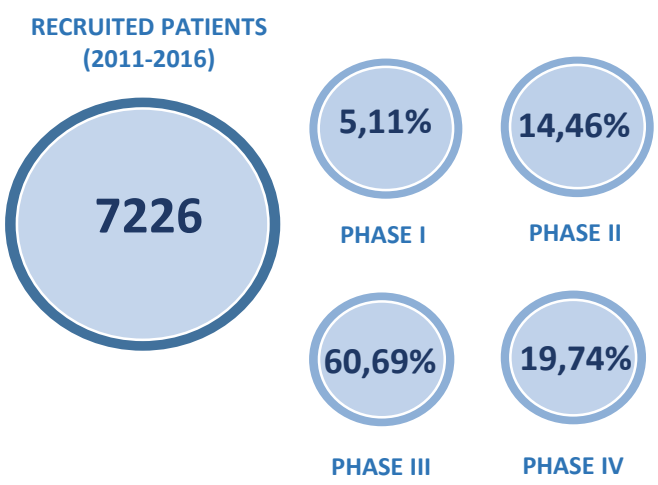
(Coordinators, monitors, data managers, technical and statistical staff)

RECLIP CAPABILITIES (2011-2016)

CLINICAL TRIALS

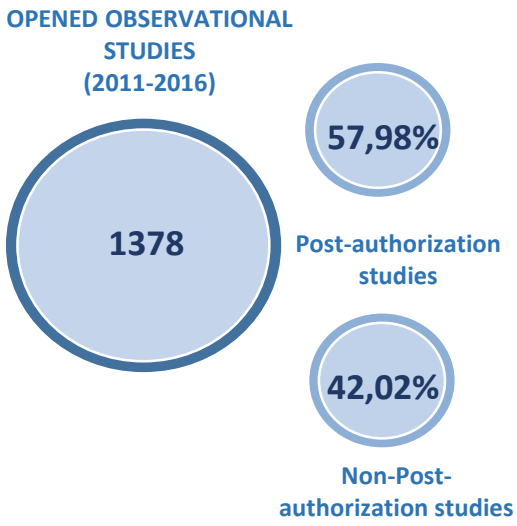


RECRUITED PATIENTS

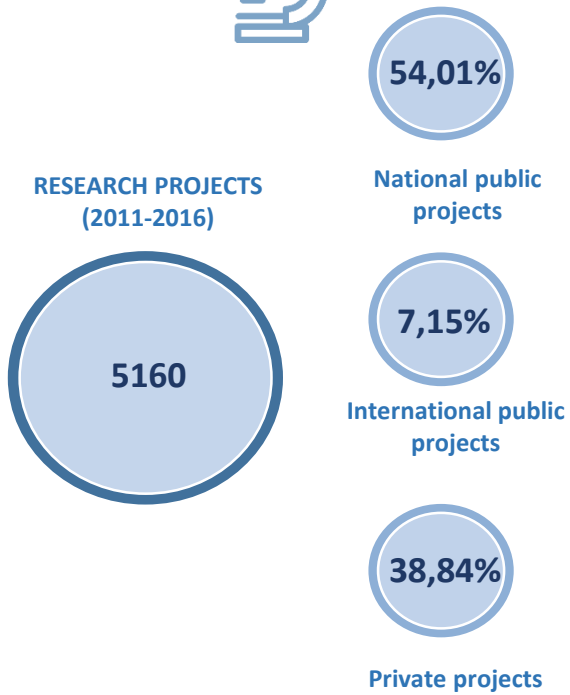


RECLIP CAPABILITIES (2011-2016)

OBSERVATIONAL STUDIES



RESEARCH PROJECTS



Centres capabilities: Classification criteria of centres and networks

To become a RECLIP centre, signature of the adherence document by the head of pediatrics (or equivalent) and by the institution, and submission of the requested information to assess centre capability is mandatory. According to this, centres will be classified as:

CENTRES

CONSOLIDATED centres

- ✓ Fully dedicated staff and structure for paediatric clinical trials (nurses, project managers, coordinators…)
- ✓ At least 5 active trials per thematic area / year in the last 4 years
- ✓ 3 or + thematic areas including previous criteria

THEMATIC centres

- ✓ Similar to previous, but at least 5 active trials in one single thematic area in the last 4 years

EMERGING centres

- ✓ Not fulfilling previous criteria but at least +2 active trials / year

NETWORKS

CONSOLIDATED THEMATIC networks

- ✓ + 5 coordinated centres
- ✓ Proven track record of successful network collaborationship in PCT in the last 2 years
- ✓ + 5 active trials / year in the last 4 years

EMERGING THEMATIC networks

- ✓ Similar to previous but less than 5 centres and/or 5 active trials /year in the last 4 years

Centres capabilities

✓✓ At least 5 opened trials per year in the last 4 years

✓ At least 1 opened trial per year in the last 4 years

	CARDIOLOGY	ENDOCRINOLOGY	GASTR. AND NUTRITION	INFECT DIS. AND VACCINES	INTENSIVE CARE	NEONATOLOGY	NEUROLOGY	ONCOLOGY	PNEUMOLOGY	RHEUMATOLOGY	OTHER
HOSPITAL UNIVERSITARIO 12 DE OCTUBRE		✓	✓✓	✓✓		✓	✓	✓	✓✓	✓	
HOSPITAL UNIVERSITARIO CLÍNICO SAN CARLOS			✓	✓✓	✓	✓	✓				✓ Surgery ✓ Hematology
HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN	✓✓			✓	✓✓	✓			✓		✓ Dermatology ✓ Psychiatry ✓ Inmunoallergy ✓✓ Hemato-oncology ✓✓ Allergy
HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE	✓		✓✓	✓✓		✓	✓	✓✓	✓✓	✓✓	✓ Dermatology ✓ Nefrology ✓ Hematology ✓ General Pediatics ✓ Neumology and allergy
HOSPITAL UNIVERSITARIO LA PAZ	✓	✓	✓	✓✓	✓	✓✓	✓✓	✓	✓✓	✓✓	✓ Dermatology ✓ Surgery ✓ Nefrology ✓ Ginecology ✓ General Pediatrics ✓ Biochemistry ✓ Medical and molecular genetics ✓ Ophthalmology ✓✓ Hematology ✓✓ Hemato-oncology ✓✓ Allergy ✓✓ Hepatology ✓✓ Pain Unit ✓ HIV Unit ✓ Clinical pharmacology ✓ Pediatric Urgencies
HOSPITAL REGIONAL UNIVERSITARIO DE MÁLAGA	✓	✓	✓	✓		✓		✓	✓	✓	

Centres capabilities

✔✔ At least 5 opened trials per year in the last 4 years

✔ At least 1 opened trial per year in the last 4 years

	CARDIOLOGY	ENDOCRINOLOGY	GASTR. AND NUTRITION	INFECT DIS. AND VACCINES	INTENSIVE CARE	NEONATOLOGY	NEUROLOGY	ONCOLOGY	PNEUMOLOGY	RHEUMATOLOGY	OTHER
HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESÚS	✔	✔	✔		✔		✔✔	✔✔	✔✔	✔	
HOSPITAL UNIVERSITARIO RAMÓN Y CAJAL	✔✔	✔		✔	✔		✔	✔	✔	✔✔	
HOSPITAL SANT JOAN DE DÉU	✔	✔✔	✔	✔✔	✔	✔	✔✔	✔✔	✔	✔	✓ Dermatology ✓ Psychiatry ✓ Surgery ✓ Anesthesia ✓ Nefrology ✓ Rehabilitation ✓✓ Gynecology ✓✓ Hematology ✓✓ Inmunoallergy ✓ Neurosurgery ✓ Otolaryngology
HOSPITAL CLÍNICO UNIVERSITARIO DE SANTIAGO DE COMPOSTELA (HUB)		✔	✔	✔✔	✔	✔		✔			✓ Surgery ✓ Nefrology
HOSPITAL UNIVERSITARIO VALL D'HEBRON							✔✔		✔✔		✓ Nefrology ✓✓ Hematology-oncology ✓ Hospital pediatrics ✓ Obstetrics
HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO	✔	✔	✔	✔	✔	✔	✔	✔✔	✔✔	✔	✓ Nefrology ✓ Rare diseases
FUNDACIÓN PARA EL FOMENTO DE LA INVESTIGACIÓN SANITARIA Y BIOMÉDICA DE LA C. VALENCIANA (FISABIO)				✔✔							

RECLIP Centres classification *(as of Dec 2016)*

CENTRE	TYPE (Consolidated, Thematic or Emerging)	THEMATIC AREAS (With at least 5 active trials per thematic area / year in the last 4 years)	
HOSPITAL UNIVERSITARIO 12 DE OCTUBRE	CONSOLIDATED	INFECTIOUS DISEASES AND VACCINES PNEUMOLOGY	GASTROENTEROLOGY AND NUTRITION
HOSPITAL UNIVERSITARIO CLÍNICO SAN CARLOS	THEMATIC	INFECTIOUS DISEASES AND VACCINES	
HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN	CONSOLIDATED	CARDIOLOGY HEMATO-ONCOLOGY	INTENSIVE CARE ALLERGY
HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE	CONSOLIDATED	INFECTIOUS DISEASES AND VACCINES PNEUMOLOGY RHEUMATOLOGY	GASTROENTEROLOGY AND NUTRITION ONCOLOGY
HOSPITAL UNIVERSITARIO LA PAZ	CONSOLIDATED	INFECTIOUS DISEASES AND VACCINES PNEUMOLOGY RHEUMATOLOGY HEMATO-ONCOLOGY HEPATOLOGY	NEONATOLOGY NEUROLOGY PAIN UNIT ALLERGY PAIN UNIT
HOSPITAL REGIONAL UNIVERSITARIO DE MÁLAGA	EMERGING		
HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESÚS	CONSOLIDATED	PNEUMOLOGY ONCOLOGY	NEUROLOGY
HOSPITAL UNIVERSITARIO RAMÓN Y CAJAL	THEMATIC	CARDIOLOGY RHEUMATOLOGY	
HOSPITAL SANT JOAN DE DÉU	CONSOLIDATED	ENDOCRINOLOGY NEUROLOGY GINECOLOGY	INFECTIOUS DISEASES AND VACCINES HEMATO-ONCOLOGY INMUNOALLERGY
HOSPITAL CLÍNICO UNIVERSITARIO DE SANTIAGO DE COMPOSTELA (HUB)	THEMATIC	INFECTIOUS DISEASES AND VACCINES	
HOSPITAL UNIVERSITARIO VALL D'HEBRON	CONSOLIDATED	PNEUMOLOGY HEMATO-ONCOLOGY	NEUROLOGY
HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO	THEMATIC	PNEUMOLOGY ONCOLOGY	
FUNDACIÓN PARA EL FOMENTO DE LA INVESTIGACIÓN SANITARIA Y BIOMÉDICA DE LA C. VALENCIANA (FISABIO)	THEMATIC	INFECTIOUS DISEASES AND VACCINES	

Networks capabilities: the example of ID& vaccines - RITIP

RITIP is constituted by four fundamental structures: the thematic networks, the research groups, the paediatric clinical trials arm and an educational program and chairs the infectious diseases & vaccines thematic area of RECLIP.

Two Keys Areas

Modifying clinical practice in paediatric infectious diseases *(epidemiology, pathophysiology, diagnosis, treatment, and prevention), avoiding infections through prevention and improving their prognosis through better diagnosis and treatment.*

Unify all assistance levels*, from Primary Care to Hospital assistance, including Neonatology, and Paediatric Intensive Care,* ***always from an infectious disease point of view.***

Research Group

9

Clinical Trials

264

Education Program

2

Thematic Networks

8

Networks capabilities: the example of neonatology - SAMID

SAMID conducting multicentre clinical trials through a network of collaborating hospitals and participates in European networks in which we have institutional representation. SAMID chairs the neonatal area of RECLIP

Two Keys Areas

The factors causing brain injury in Childhood and thus affecting ***neurodevelopment.***

The early nutritional factors related to the latter development of the ***metabolic syndrome in preadolescent children****.*

Research Group

12

Clinical Trials

70

Education Program

3

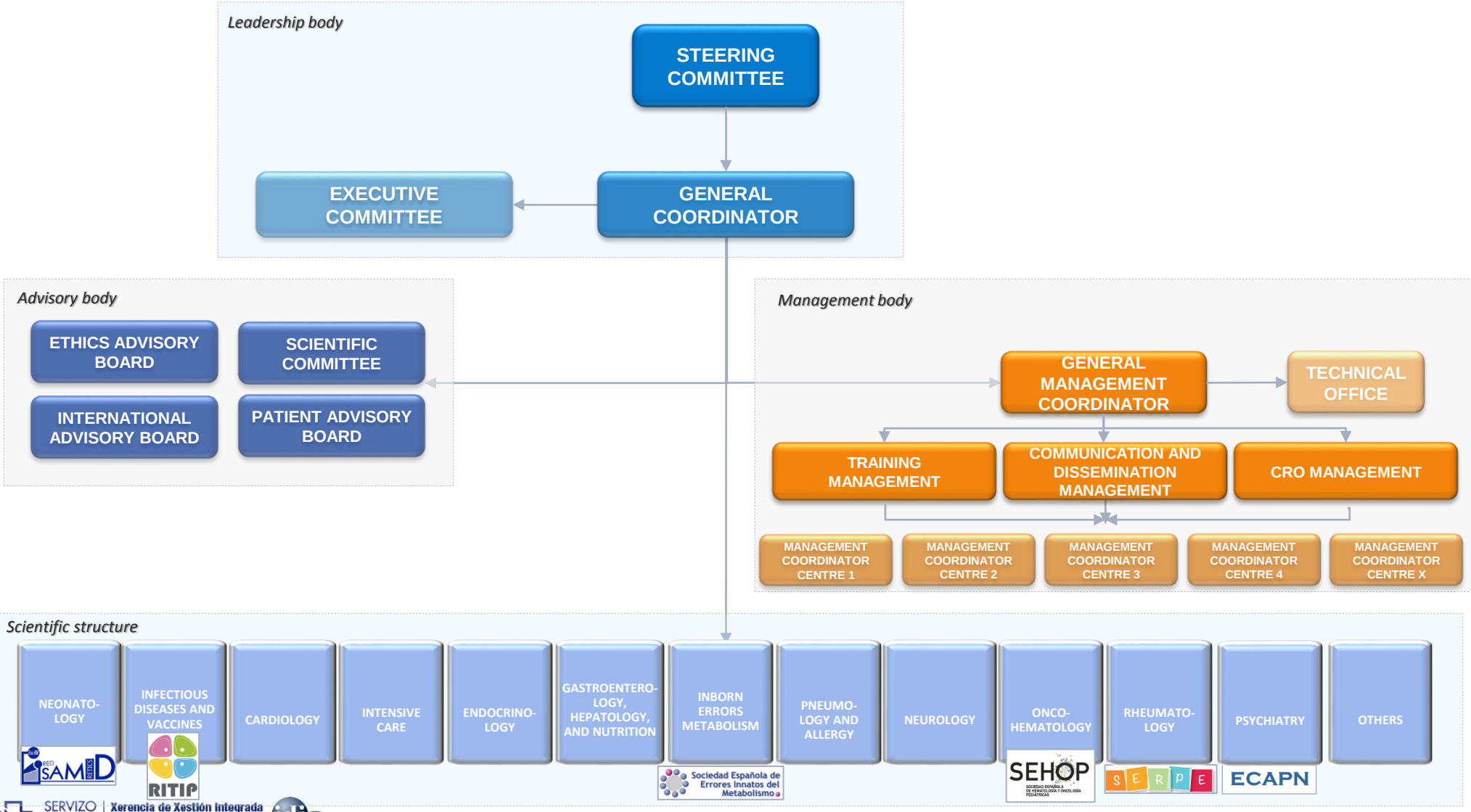
- ✓ Epidemiological methodologies.
- ✓ Analytical methodologies.
- ✓ Experimental models.

Thematic Networks

Close collaboration with other networks and CIBERER. Additionally, SAMID has joined with SCReN-ISCIII national platform and is a EnprEMA member.

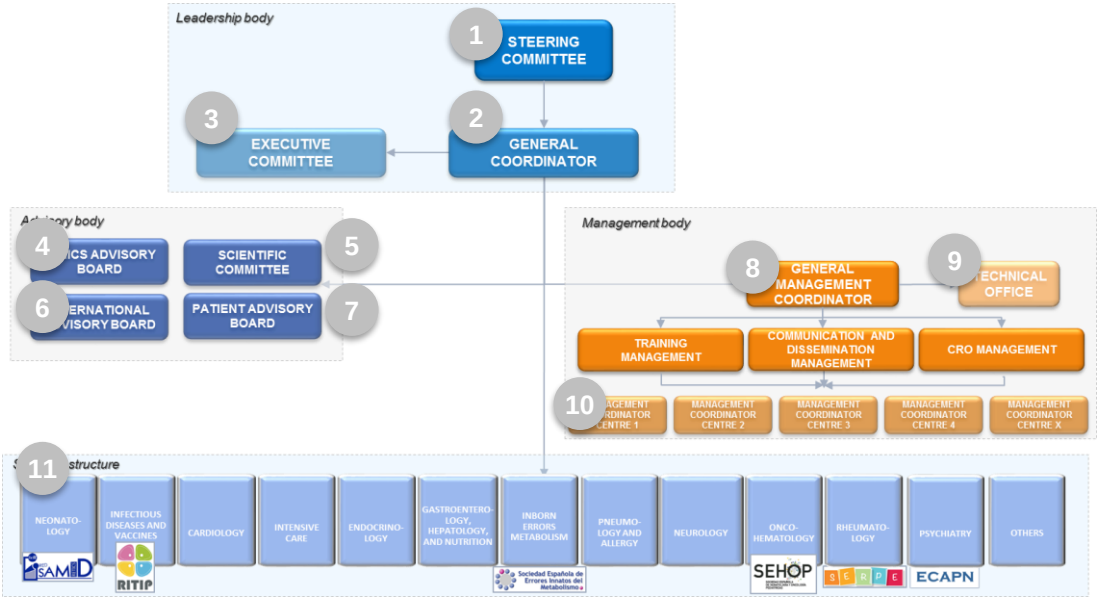
Organization and governance

GENERAL ORGANIZATION CHART



Organization and governance

GENERAL ORGANIZATION CHART



Leadership body

1 ***Steering Committee***: Steering Committee is the supreme organ responsible of making decisions by consensus of all participants of RECLIP.

2 ***General Coordinator:*** General Coordinator ensures that RECLIP activities are performed in accordance with global strategies and organizational structure and management.

3 ***Executive Committee:*** Executive Committee helps the General Coordinator to make decisions on urgent matters that are then reported to the STEERING COMMITTEE.

Advisory body

4 ***Ethics Advisory Board:*** EAB ensures ethics adequacy in pediatric linical research performed at RECLIP and advices on any related subject to the leadership body.

5 ***Scientific Committee:*** Scientific Committee is the scientific advisory body for research activities developed by RECLIP and composed by clinicians of participant centres.

6 ***International Advisory Board:*** International Advisory Board is a group of international experts that provides external scientific advice and expertise.

7 ***Patient advisory Board:*** Patients Advisory Board ensures the implication of patients and families in the design and processes that will take place during the clinical trial.

Management body

8 ***General Management Coordinator:*** General Management Coordinator is the responsible for the administrative, economic and financial management of the activities in RECLIP.

9 ***Technical Office***: Technical Office provides technical support in the economic, administrative and human resources areas of RECLIP .

10 ***Management Coordinator Centres***. Each centre will have a management coordinator in charge of the integral management of the clinical trials activity of the centre.

Scientific structure

11 ***Scientific Programs:*** Specific scientific programs defined for each research areas of RECLIP (e.g. Neonatology, Vaccines&Infections, Oncology, Neurology, Cardiology, etc.) supported by Thematic Networks and centres of RECLIP.

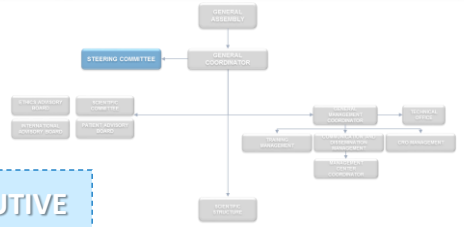
Organization and governance

EXECUTIVE COMMITTEE

EXECUTIVE COMMITTEE

MEMBERS OF EXECUTIVE COMMITTEE:

- *The General Coordinator of RECLIP, who acts as the **Chairman** of the EXECUTIVE COMMITTEE.*
- ***4 clinical representatives of consolidated and/or thematic centres** integrated in RECLIP, who will be elected by the STEERING COMMITTEE.*
- ***3 representative of managerial organization** (as default, 1 will be the managerial general coordinator).*
- ***Up to 2 representatives of the thematic networks** that support scientific programs in RECLIP elected by vote by STEERING COMMITTEE.*



COMPOSITION OF EXECUTIVE COMMITTEE

CHAIRMAN OF EXECUTIVE COMMITTEE

GENERAL COORDINATOR
Federico Martinón
Complexo Hospitalario Universitario de Santiago de Compostela

CLINICAL LEADERS OF CONSOLIDATED/THEMATIC CENTRES

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE
Daniel Blázquez
Hospital Universitario 12 de Octubre

HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE
Eduardo Montesinos
La Fe

HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESÚS
Lucas Moreno
Hospital Infantil Universitario Niño Jesús

HOSPITAL UNIVERSITARIO VALL D'HEBRON
Carlos Rodrigo
Vall d'Hebron

MANAGEMENT LEADERS

HOSPITAL UNIVERSITARIO LA PAZ
José Luis Narro
Hospital Universitario La Paz

HOSPITAL SANT JOAN DE DÉU
Joana Claverol
Sant Joan de Déu

HOSPITAL CLÍNICO UNIVERSITARIO DE SANTIAGO DE COMPOSTELA
María Gómez Reino
Complexo Hospitalario Universitario de Santiago de Compostela

THEMATIC NETWORKS

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

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

Plan for the integration of new members

Since its implementation RECLIP has a representative number of centres that provides all the capacities and operability necessary for its proper functioning.

Nevertheless, RECLIP behaves like an integrating network of all those centres and entities that want to join the initiative.

*For this purpose, RECLIP will define the **criteria and conditions for the incorporation** of new entities into the network structure.*

INTEGRATION PLAN
SYSTEM OF DECISION AND INCLUSION OF NEW ENTITIES THROUGH THE ESTABLISHMENT OF DEFINED REQUIREMENTS

***Signature of the adherence document** by the head of pediatrics (or equivalent) and by the institution*

→

*An **information questionnaire** will be requested with **specific quantitative and qualitative indicators** of the centre's activity and of their paediatric investigation lines.*

→

***Three categories of participation** in the network will be established based on the fulfillment of the requirements.*

- *Consolidated centres*
- *Thematic centres*
- *Emerging centres*

Plan for the integration of new members

Categories of participation in RECLIP.

INTEGRATION PLAN
Categories of participation in RECLIP

Consolidated centres

Centres with the following criteria:

- *Having an own management structure and clinical trials platform, dedicated staff with a Management Coordinator of the centre.*
- *Working in at least 2 scientific programs defined by RECLIP.*
- *Developing at least 5 clinical trials annually per theme.*

Thematic centres

Centres with the following criteria:

- *Having an own management structure and clinical trials platform, dedicated staff with a Management Coordinator of the centre.*
- *Working prominently in 1 scientific programs defined by RECLIP.*
- *Developing at least 5 clinical trials annually in the subject.*

Emerging centres

Centres with the following criteria:

- *Working in less than 2 scientific programs defined by RECLIP and/or less then 5 clinical trials per theme.*
- *Not having a clinical trials platform (or limited), being difficult the own management of clinical trials activity.*
- *The hub of RECLIP will provide support in the management of the clinical trials developed by emerging centres (offering support as a CRO).*
- *The hub of RECLIP will mainly offer advisory and training activities for emerging centres.*

The final decision on the integration of new centres or entities in RECLIP will depend on the Executive Committee.

Admissions of new centres or entities will be opened once a year.

NOW OPENED FROM 15 DEC-30 DEC 2016

RECLIP – ONGOING / NEXT steps

1. EOI for **new centres and networks** (15- 30 dec 2016)
2. Registration at **EnprEMA** (ongoing, end Dec)
3. Strong active involvement of RECLIP in **EU/IMI2** WPs
4. Further development/definition of **thematic areas**
5. Development of **sustainability plan** for RECLIP
6. Official **endorsment** acquisiton (ongoing)
7. TEDDY capabilities survey (Jan17)

Spanish Paediatric Clinical Trials Network (RECLIP)

Executive RECLIP Report

www.reclip.org - contact@reclip.org