



"How multispecialty, national and international Networks cooperate for the promotion of clinical research in paediatrics: the Spanish experience"

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General Overview

The implementation of the European Paediatric Regulation in 2007 has led to a 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.



Datos Año 2015

Fuente: 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.

Overview of the Spanish scenario



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...but pediatric research has received limited specific support.

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.

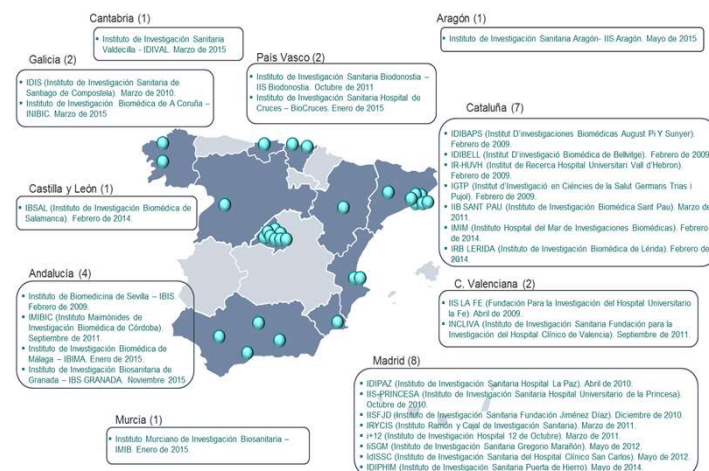


COOPERATION AMONG TECHNOLOGICAL AGENTS (TECHNOLOGICAL CLUSTERS AND PLATFORMS)



HEALTH RESEARCH INSTITUTES

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



Objectives



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 – Clinical Nodes

centres & classification criteria



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.



Who we are – Thematic Networks



The main objective is to contribute to the improvement of clinical practice in pediatric infectious diseases. Secondly, it is to avoid them by developing preventive measures and to improve the prognosis through an optimal diagnosis and treatment. Also, to obtain appropriate and suitable drugs for children. In other words, to improve the health of our children.



The main objective is to study the different pathological processes, nutritional and environmental conditions of perinatal and postnatal period, by addressing the study of factors of prematurity, prevention and patient safety, environmental and pathogenetic factors, nutrition and child development as well as promoting research into new products and therapeutic procedures.

Who we are – Thematic Networks



 SAMID	Direct Partners of RECLIP	Partners of RECLIP through SAMID
Hospital Universitario Cruces - IIS BIOCRUCES	X	
IIS Aragón		X
Hospital Sant Joan de Déu	X	
H. U. Vall d'Hebrón	X	
H. U. Clinic – H.U. del Mar		X
H. G. U. Gregorio Marañón	X	
H. U. de Valdecilla		X
H. U. Quirón Madrid	X	
H. U. La Paz	X	
H. U. 12 de Octubre	X	
H. U. La Fe	X	
H. U. de Granada		X
H. U. Murcia		X

Endorsements



INSTITUTIONAL ENDORSEMENTS

SPANISH AGENCY OF MEDICINES AND MEDICAL DEVICES



MEDICAL ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY



NATIONAL TRADE ASSOCIATION OF THE SPANISH BASED PHARMACEUTICAL INDUSTRY



SPANISH PAEDIATRIC SPECIALITIES ASSOCIATION

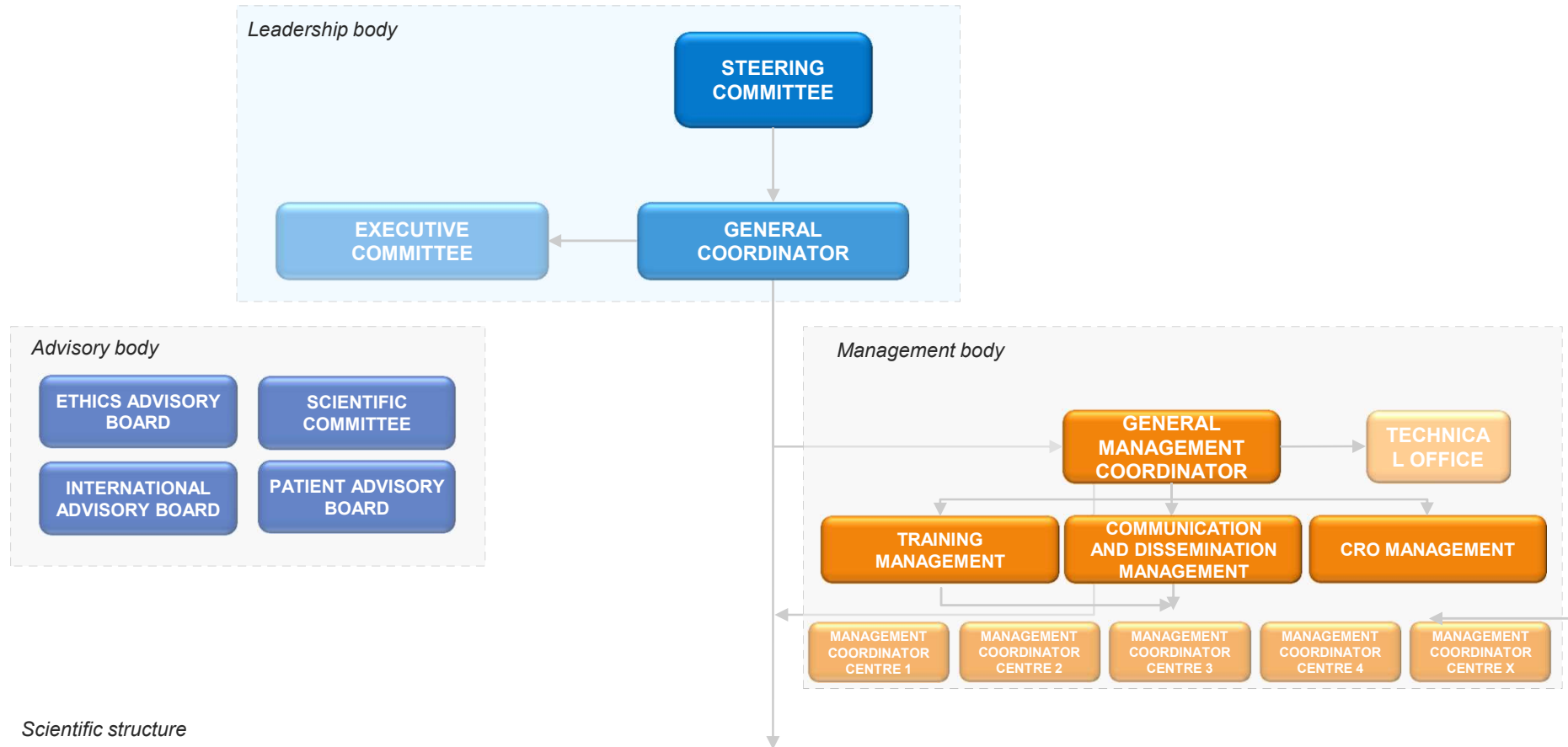


Enpr-EMA, European network of Pediatric Research at the European Medicines Agency



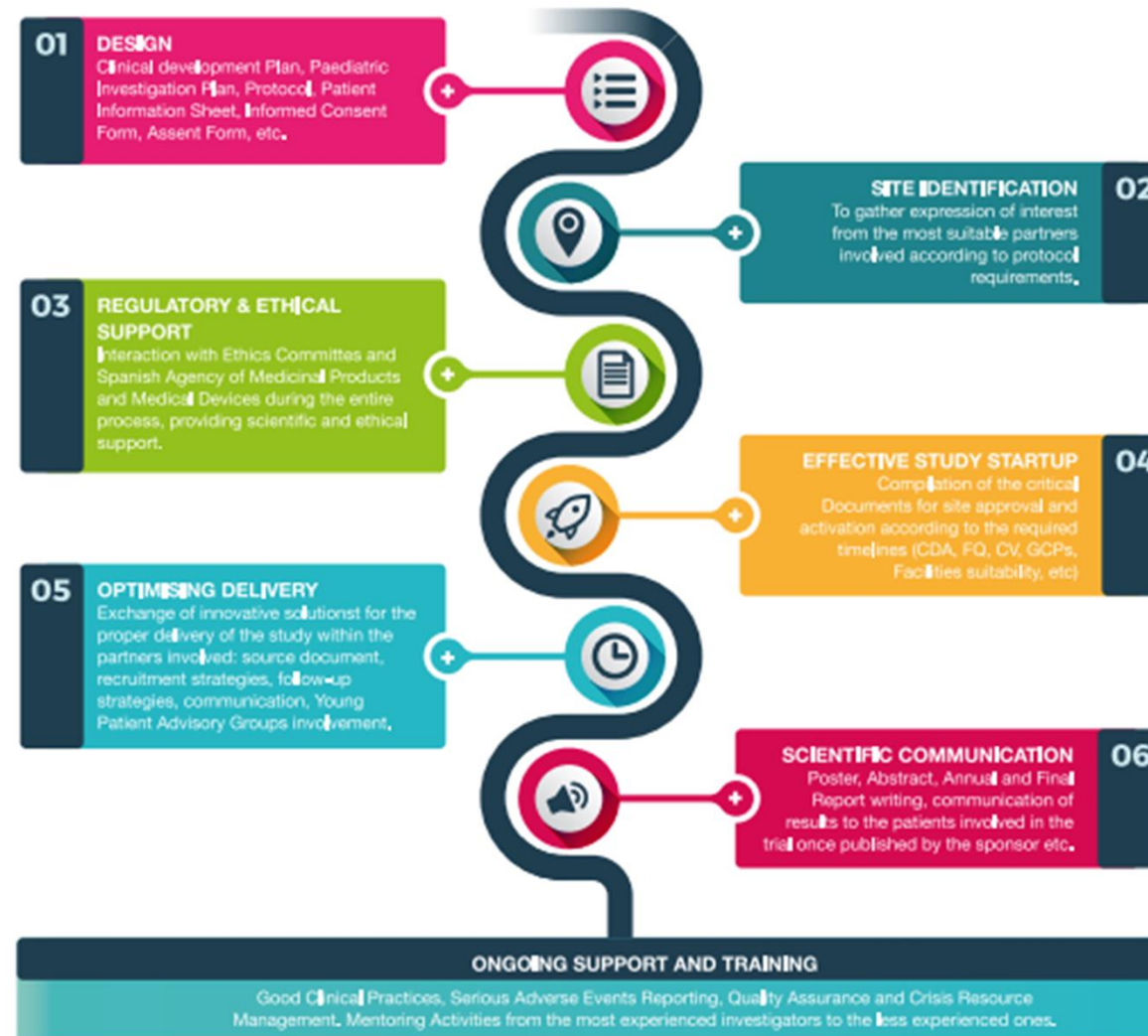
Governance

GENERAL ORGANIZATION CHART



Scientific structure

Services Portfolio



General organization



1.- Site and Key Opinion Leader
identification for new trials

2.- Site addition for ongoing trials

3.-Start-up activities support



Next steps



To get the **institutional support of the national entity ISCIII to guarantee sustainability**



To participate in the consortium of **IMI-2**



To build stable partnership with pharmaceutical industry



To increase the specialization, professionalization and integration of new members.



Grazie!

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