



INCiPiT Italian Network for
Paediatric Clinical Trials

THE CONTRIBUTION OF INCIPIT IN THE MAPPING OF PAEDIATRIC RESEARCH AND EXPERTISE

TEDDY GENERAL ASSEMBLY

Rome, 14/01/2018



INCiPiT - Italian Network for Paediatric Clinical Trials

Who we are

INCiPiT is a Consortium composed by the main Italian children's hospitals, the largest departments of paediatrics and national and international paediatric therapeutic networks coordinated by Italian institutions

Mission

The mission of INCiPiT is to foster and support the planning, conduct and completion of all types of clinical studies conducted in Italy in the paediatric population by all kinds of sponsor (industry sponsored and academic/research driven) according to high standard of quality and ethics

Objectives:

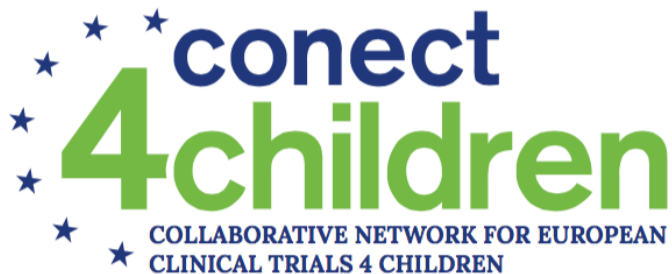
- To improve opportunities for performing paediatric CTs in Italy
- To provide training and create competences
- To harmonize joint national operational models in paediatric CTs
- To provide effective and timely communication/collaboration among INCiPiT Members
- To involve children and young people and their families in paediatric research



Activities

- Consortium Agreement signed by 17/23 Centers in Nov 2017: INCiPiT is a legal entity (President, Vice and BoD)
- Communication strategy: website, presentation to stakeholders (AIFA, Ministry of Health, Farmindustria, ad hoc meetings)
- Survey to map INCiPiT potentialities and application for EnprEMA
- Creation of SOPs and models to harmonize CTs in Italy
- Creation of Patients Database (condition/pathology)
- Set up collaboration with Regulators (AIFA)
- Participation in National Research projects (Calls AIFA 2016 and 2017): 2/40 projects involving INCIPIT founded + 3-4 projects proposed for the actual call
- 2-3 ongoing proposals for consultancy/CTs with Pharma
- Education and Training <http://incipitcourses.scuolaiad.it>

INCiPiT in European Projects



INCiPiT represents
the Italian Network

ID-EPTRI
EUROPEAN PAEDIATRIC
TRANSLATIONAL RESEARCH
INFRASTRUCTURE



INCiPiT involved

Surveys

TEDDY Survey

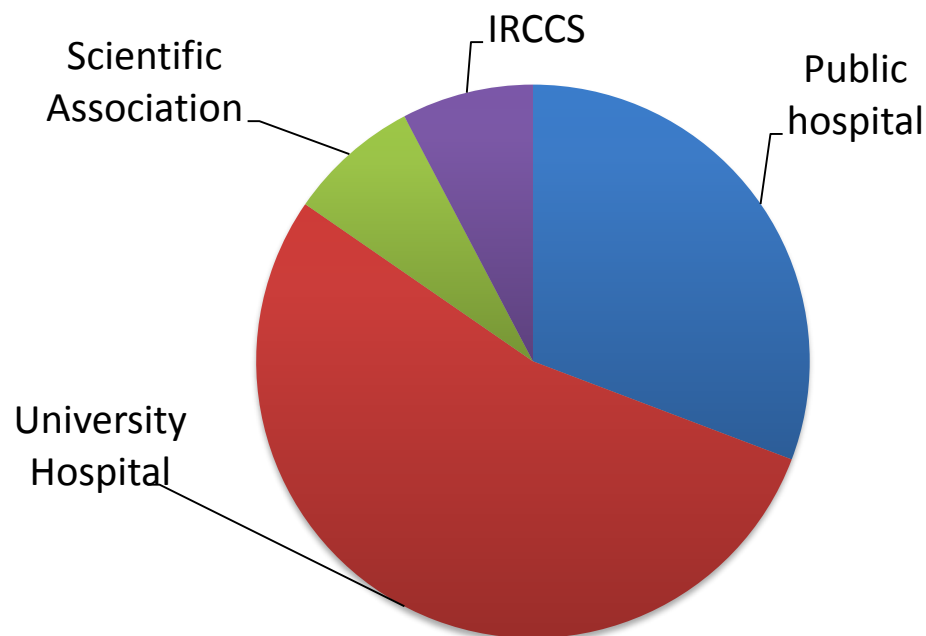
- When: Oct 2016 - Dec 2016
- Web survey
- 60 questions agreed with several stakeholders at EU level (Enpr-EMA)
- Sent to all INCiPiT Partners (20) to identify the level of expertise in paediatric clinical research
- Questions, grouped in sections, on:
 - General Info
 - Experience in paediatric CTs
 - Regulatory, ethics, management, monitoring and training
 - CTs standard agreement
- Limits:
 - Not appropriate for disease specific Network
 - Time
 - System self reporting

INCiPiT Survey

- When: March 2017 - May 2017
- Web survey
- 16 questions agreed between INCiPiT members
- Sent to all Partners (21) in order to map the capacities to plan and conduct paediatric CTs of high quality and complexity
- Questions on:
 - CTs - Therapeutic areas and patients enrolled
 - Type of drugs
 - Feasibility questionnaire and patients declared vs patients enrolled
- Limits:
 - Data cleaning needed
 - Not appropriate for disease specific Network
 - Time for providing results very long
 - System self reporting
 - Difficulties in finding the data
 - Difficult to verify data

TEDDY Survey:

13 Partners/20
provided data



	<i>Total number of beds for hospitalization</i>	<i>Total number of beds for day hospital admissions</i>	<i>Average number of paediatric patients hospitalised and/or visited per year</i>
<i>Media (±DS)</i>	188±175	45±61	11005±11647
<i>Range</i>	6-607	2-215	1000-33481

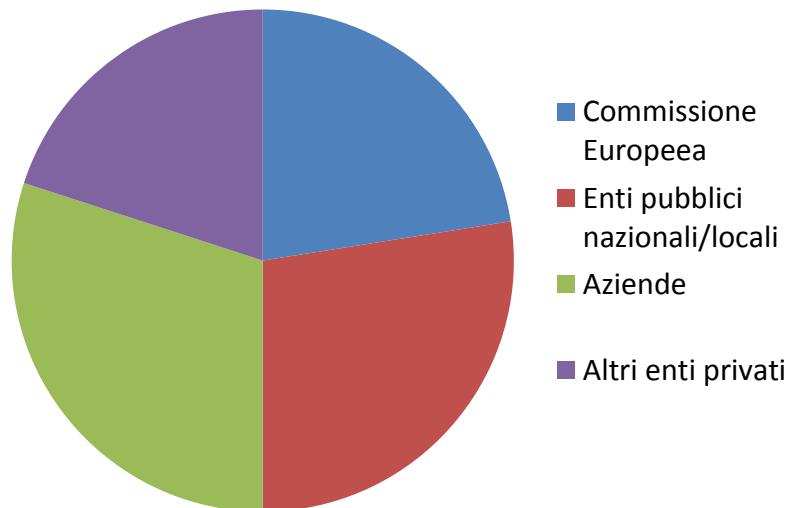
TEDDY Survey – results:

Experience in research projects (2011 – 2015)

		N. of projects funded by that public funds.	N. of projects funded by that private funds
Role in the project	Coordinator	465	382
	Partner	220	482
	Third party	10	-

Ongoing/concluded in the last 5 years

Funding bodies



	Total Funding (in Euro)
EC	18.765.534
Public Institutions	102.077.927
Companies	6.435.090
Other private	13.430.523

TEDDY Survey: results

Paediatric clinical trials (2011 -2015)

8 Partners have a dedicated Clinical Trial Centre

Paediatric CTs	Nr.
PK	168
PK/PD	107
Efficacy/safety	794
Observational	745
Pharmacovigilance	53
Cost-efficacy	3
Medical devices	80
Alimentary products/dietary supplements	41

Paediatric clinical trials	Nr.
Research-driven trials	1131
Industry-funded trials	607
Regulatory trials	247

5 Partners have experience in paediatric clinical trials in almost all therapeutic areas

TEDDY Survey: results

Facility, resources and experience

Dedicated staff to paediatric CTs	Nr.
Physicians	~313
Non-medical personnel for paediatric clinical trials	~189

- 11/13 Centers established collaborations with Patients associations and Young People Advisory Groups

- 4/10 Centers received inspections from EC, AIFA, EMA e FDA. In 1 case only a mayor finding outlighted

13/13

- *electronic health records and web-based systems (eCRF)*

11/13

- *Availability of a pharmacy service and experienced personnel dedicated to paediatric clinical trials*

12/13

- *contribute to scoping (preliminary analysis) and feasibility work*

12/13

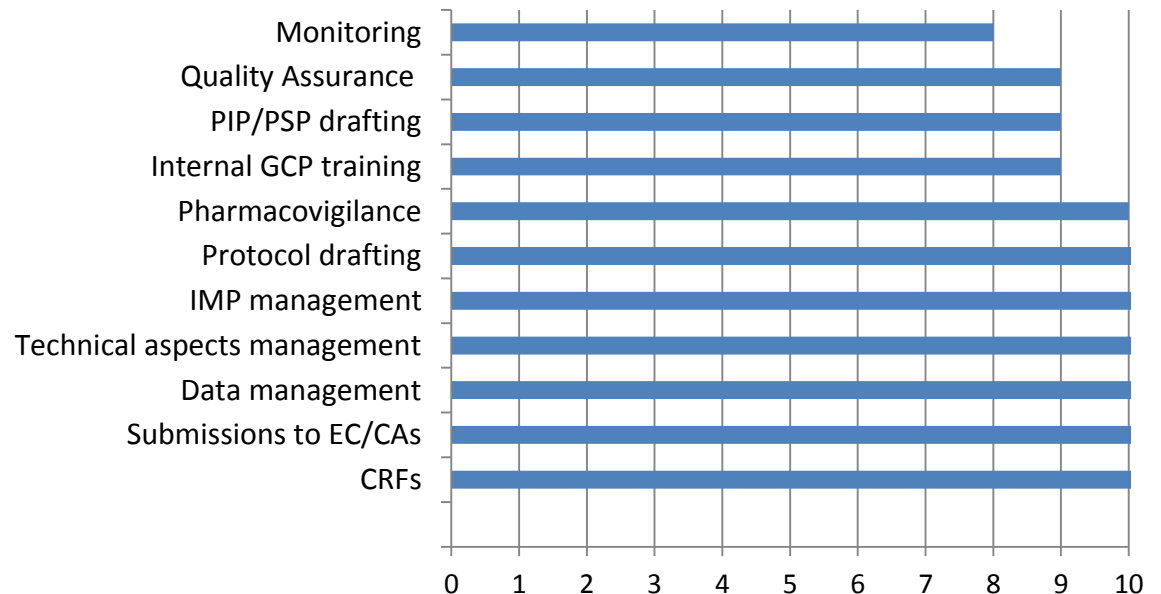
- *technical facilities and equipment adequate to conduct GCP CTs*

8/13

- *Dedicated unit for PK analysis*

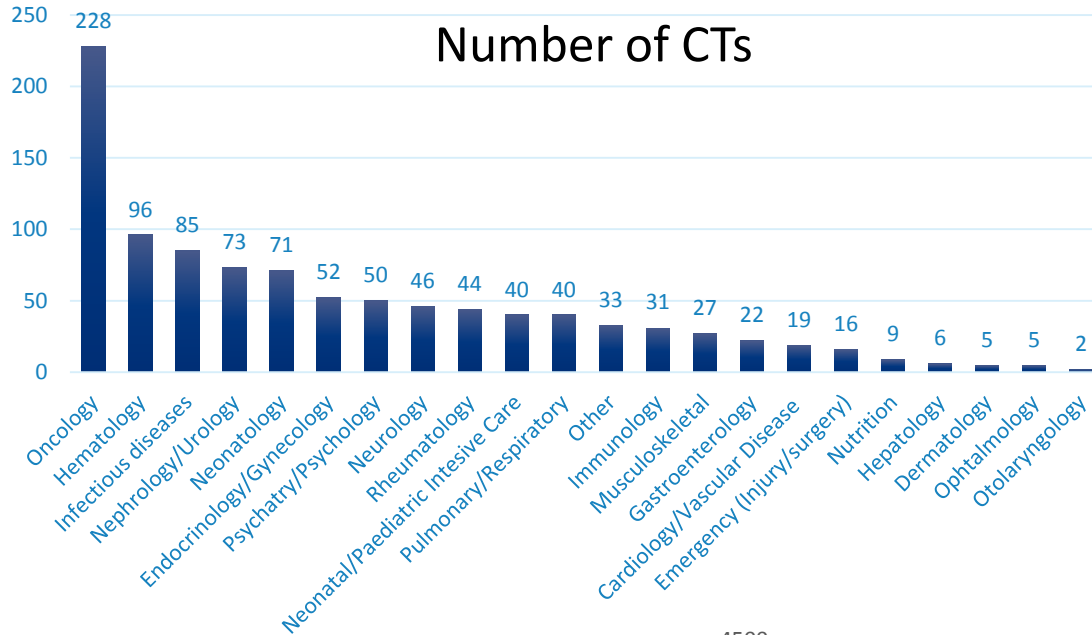
7/13

- *biobanks of human samples*



INCIPIT Survey

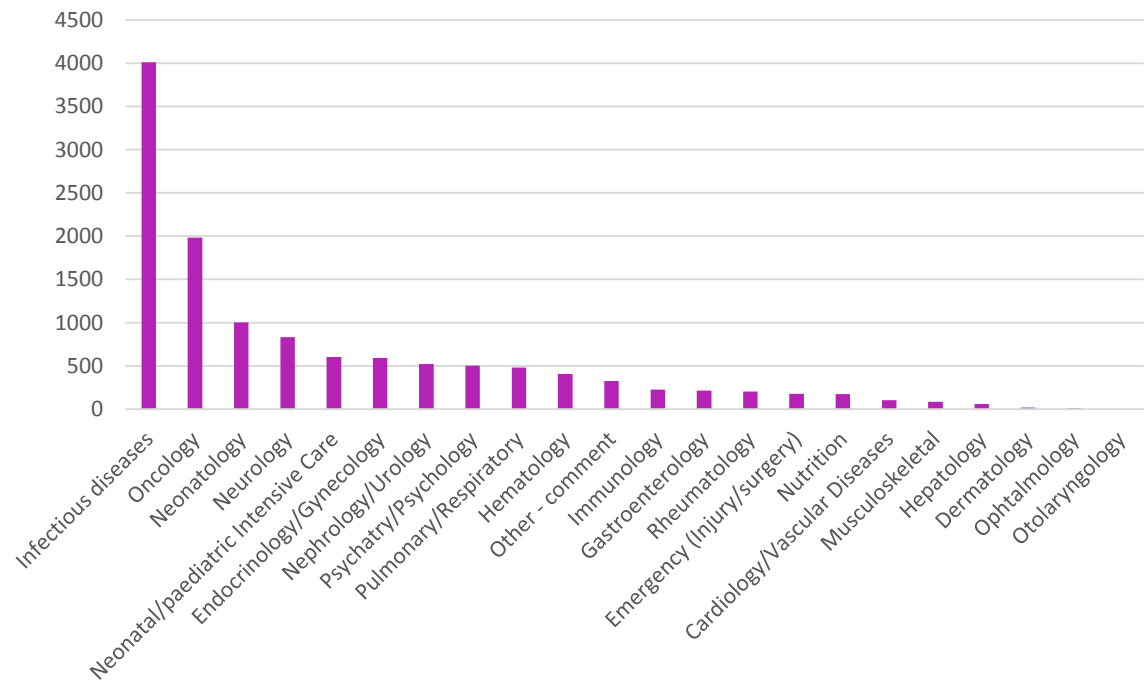
Number of CTs



*Paediatric CTs (ongoing + closed)
industry funded + research-driven
and patients enrolled by
therapeutic areas (2011-2015)*

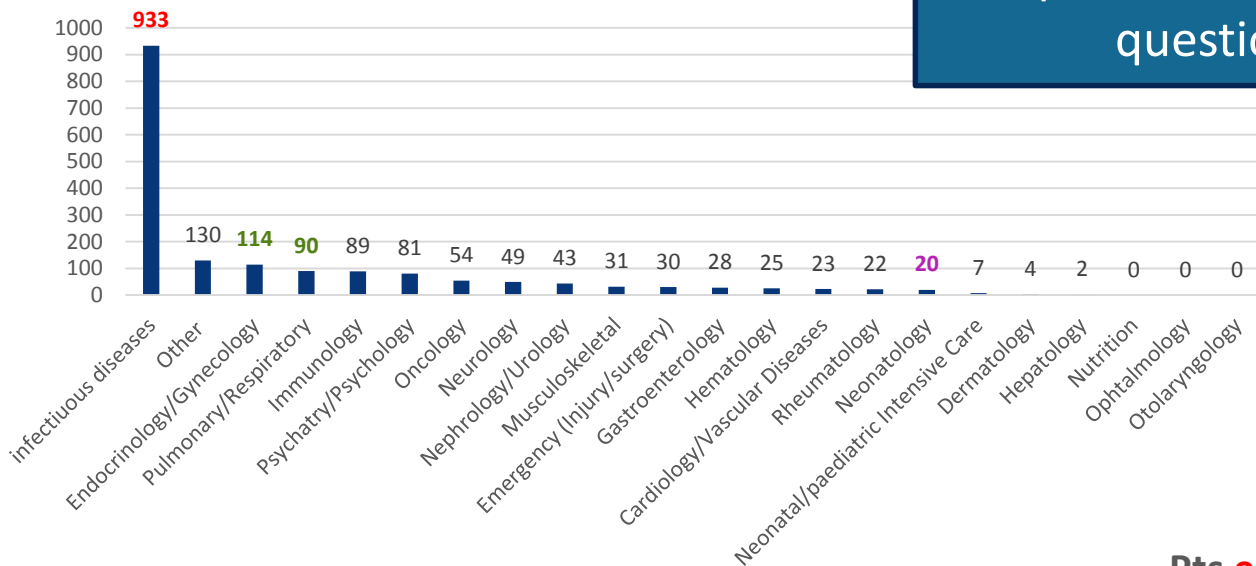
*Paed CTs started in 2016
analyzed → similar trend*

Patients enrolled

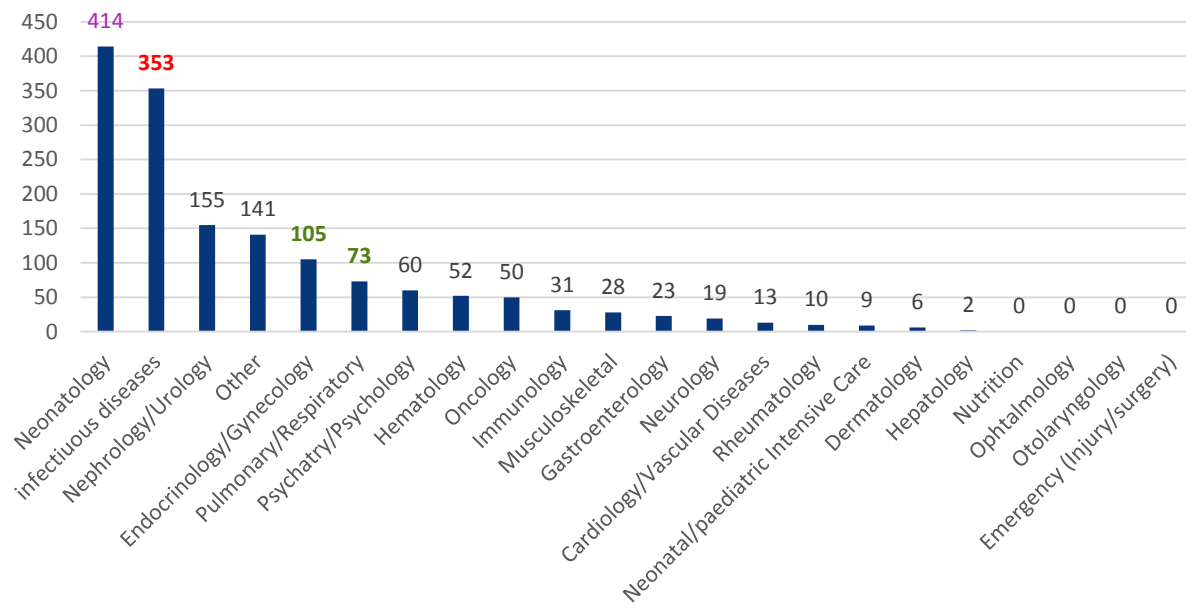


Already closed **INDUSTRY FUNDED** CTs:
patients declared in the feasibility
questionnaire (2014-2015)

Pts **declared** in the feasibility

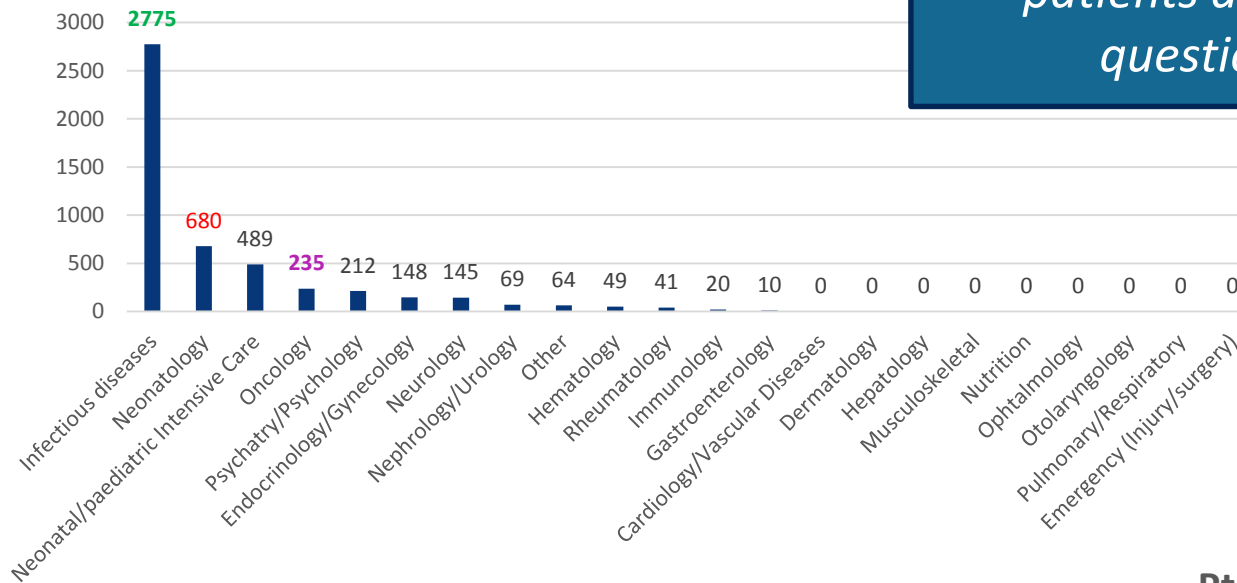


Pts **enrolled** (ICF signed)

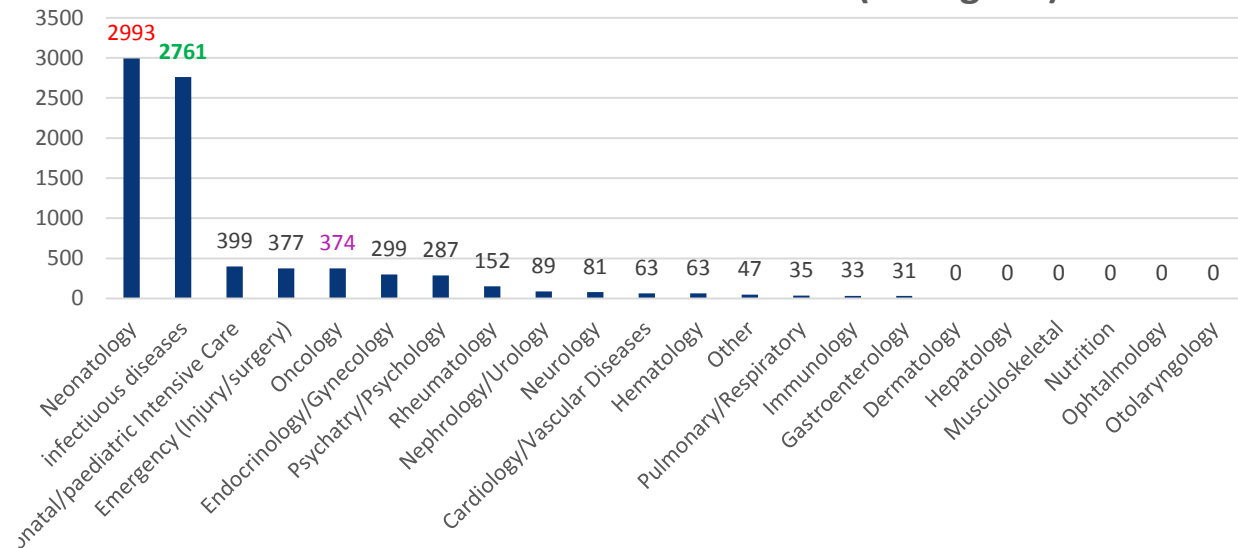


Already closed **RESEARCH DRIVEN** CTs:
patients declared in the feasibility
questionnaire (2014-2015)

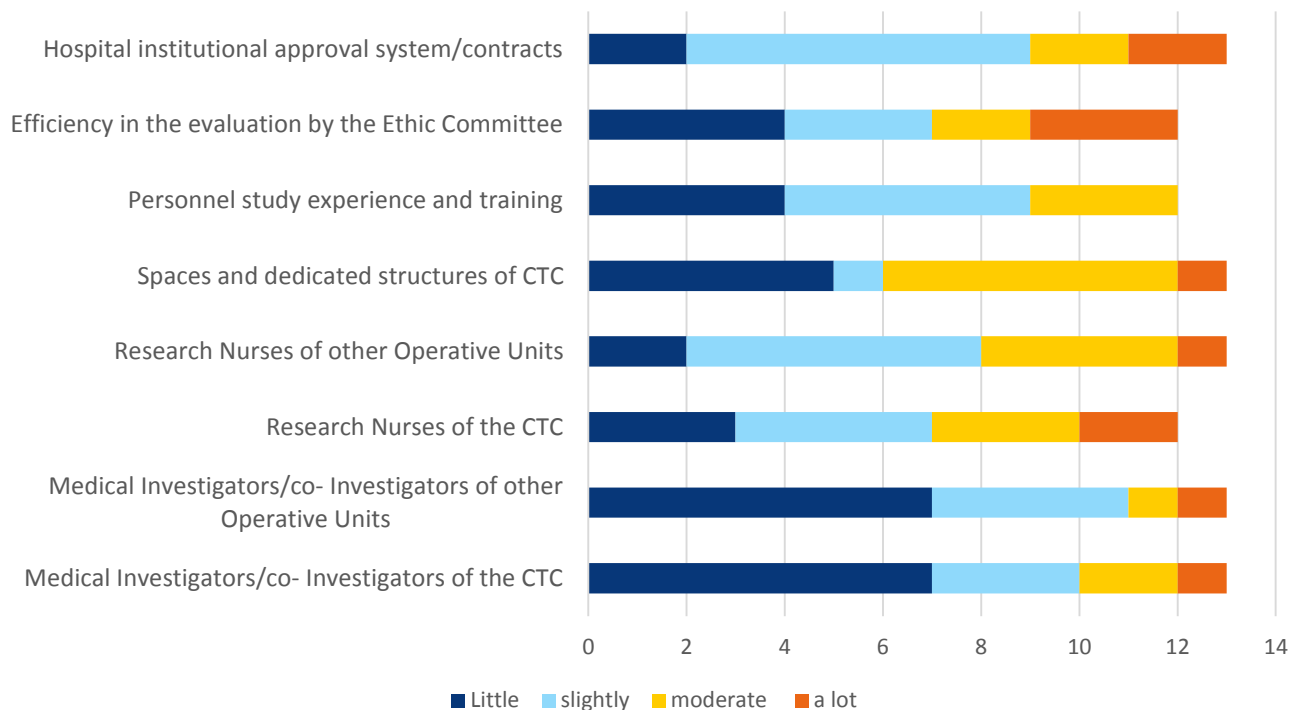
Pts **declared** in feasibility



Pts **enrolled** (ICF signed)



Factors limiting the number of CTs conducted in clinical sites



Average time Institution takes from the proposal of a new paediatric study by the Sponsor (i.e. pre study visit) to SIV

From 2 month to 3 months	4
From 3 months to 4 months	7
More than 5 months	2

What did the surveys tell?

- Overall picture of INCiPiT centers
- Overall evaluation of the potentialities in paediatric clinical research in Italy (projects and CTs) – great results but space for improvement
- Each center: mapping and auto-evaluation of the history and expertise in paediatric clinical research → useful exercise
- Surveys not appropriate for Network disease specific
- Time and limits
- Next step: Ranking of the centers (ranking scheme identified) and application to Enpr-EMA!

Keep calm and..... let's INCiPiT!

www.incipit-ped.it

info@incipit-ped.net