The TEDDY survey to identify paediatric trials competences and capacities at site level

Lucia Ruggieri

Outline

- *Aims*
- *Topics, items and structure*
- *Recipients and reference contact points*
- *Preliminary results and perspectives*

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

Survey – key points

- To collect information about sites that would like to join paediatric trials networks and research initiatives
- To design networks and to attract funding for national, international and specialty networks
- Prepared by several experts referring to:
  - TEDDY Network
  - FINPEDMED
- Agreed with EnprEMA

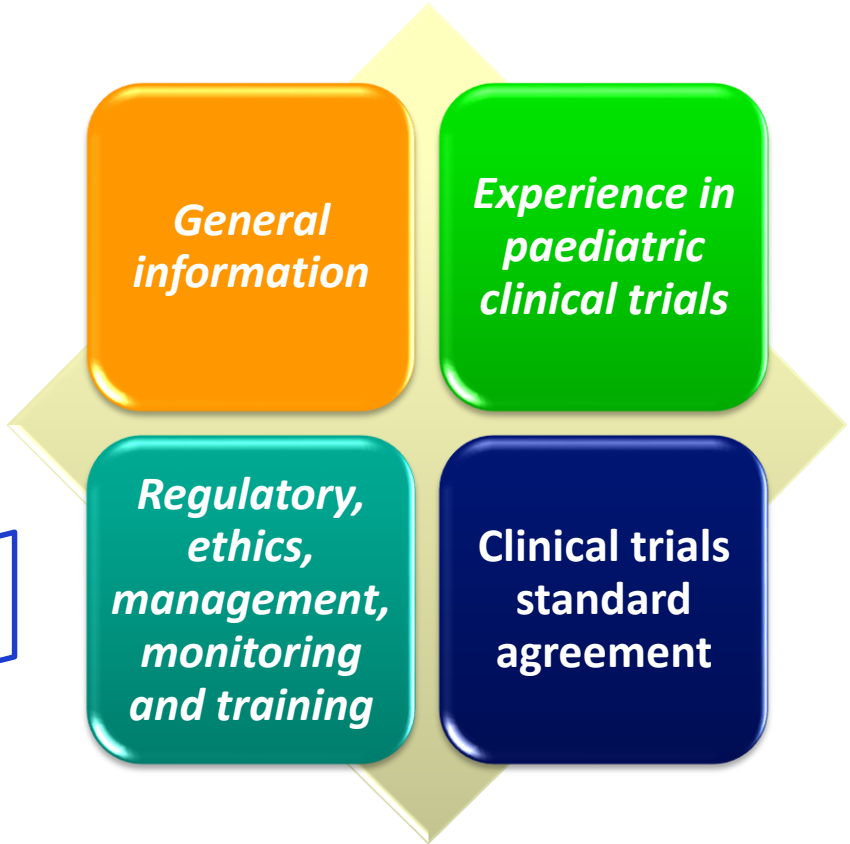
TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

Teddy Survey – Topics

~ 60 questions grouped in several sections that will allow to have a clear picture on sites

Expertise of centres performing paediatric clinical trials, available services, equipment and the centralised services supporting clinical trials in each site

Indicators for performance metrics



TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

ITEMS

CLINICAL TRIALS STANDARD AGREEMENTS:

- availability of standards for CT agreements definition
- master documents provided by companies/networks

performance metrics

insurance for CTs

GENERAL INFORMATION:

- Type of organization
- Nr of beds for hospitalization/day hospital admissions
- Nr of paediatric patients yearly hospitalised and/or visited
- Therapeutic area(s) covered by the institution

EXPERIENCE OF THE INSTITUTION IN PAEDIATRIC CLINICAL TRIALS

- *clinical trial centre details*
- *public/private funded projects*
- *type/nr of paediatric CTs*
- *Trials by therapeutic areas*
- *pharmacy service*
- *PK evaluation unit*
- *staff for paediatric clinical trials*
- *technical facilities*
- *eCRF availability*
- *biobanks*

REGULATORY, ETHICS, MANAGEMENT, MONITORING AND TRAINING

experience in:

PIP/PSP preparation

protocol design

CRF design

EC/CA documents submission

data management

technical aspects

IMP management

Pharmacovigilance

Quality Assurance

Monitoring

GCP training

collaboration with Patients Associations and YPAGs

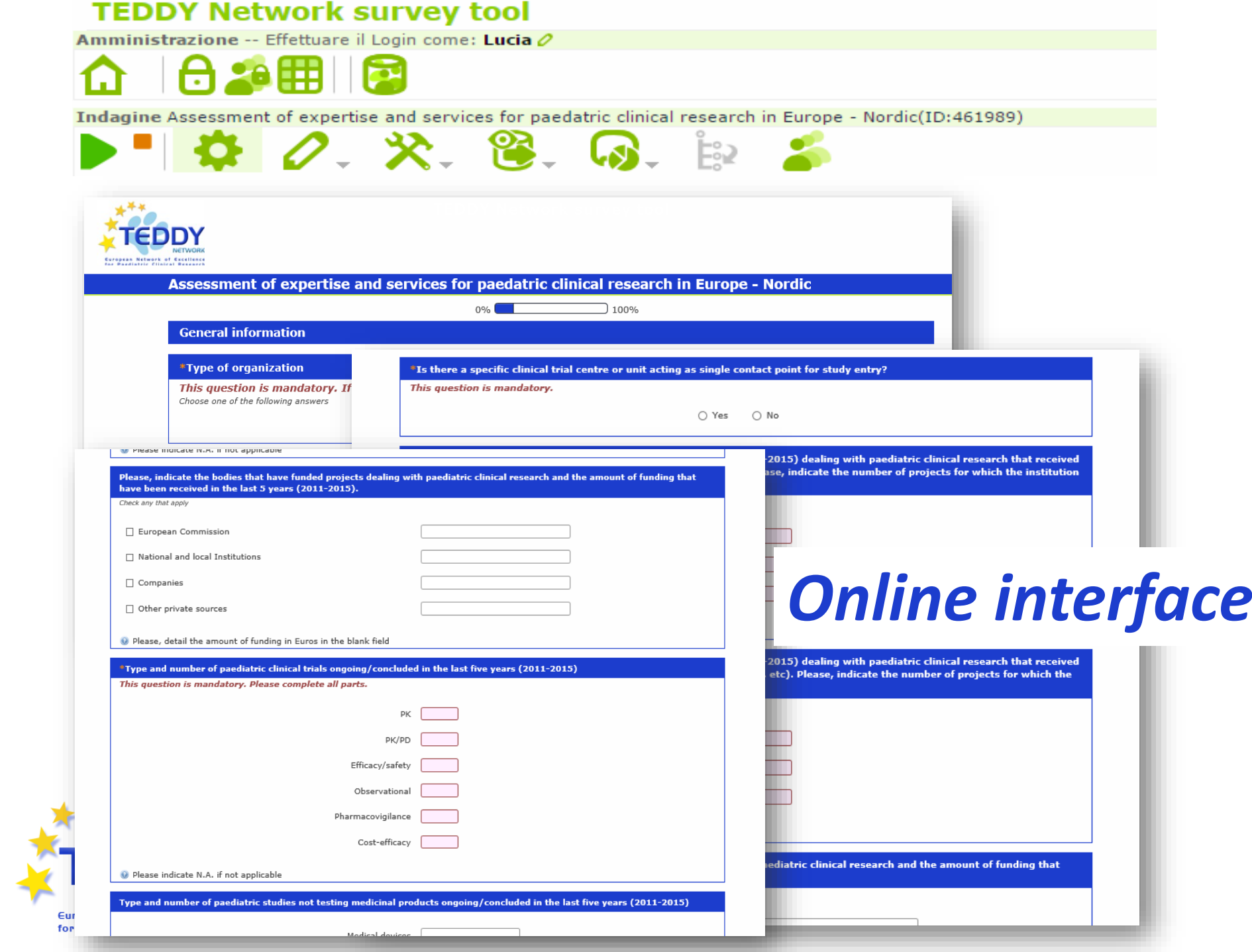
AUDITS/INSPECTIONS RECEIVED

Teddy Survey – Structure

- *Open-source survey tool*
- *All data (answers, mail recipients and all other personal information) are password protected*
- *Participants can access the survey for data entry using a customized URL provided by LimeSurvey, containing a unique token*
- *Filled form available after completion*

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

Technical manager: Franco Bartoloni


TEDDY Network survey tool
Amministrazione -- Effettuare il Login come: Lucia
Indagine Assessment of expertise and services for paedatric clinical research in Europe - Nordic(ID:461989)
TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research
Assessment of expertise and services for paedatric clinical research in Europe - Nordic
0%
100%
General information
*Type of organization
This question is mandatory. If
Choose one of the following answers
*Is there a specific clinical trial centre or unit acting as single contact point for study entry?
This question is mandatory.
Yes
No
Please, indicate the bodies that have funded projects dealing with paediatric clinical research and the amount of funding that have been received in the last 5 years (2011-2015).
Check any that apply
European Commission
National and local Institutions
Companies
Other private sources
Please, detail the amount of funding in Euros in the blank field
*Type and number of paediatric clinical trials ongoing/concluded in the last five years (2011-2015)
This question is mandatory. Please complete all parts.
PK
PK/PD
Efficacy/safety
Observational
Pharmacovigilance
Cost-efficacy
Please indicate N.A. if not applicable
Type and number of paediatric studies not testing medicinal products ongoing/concluded in the last five years (2011-2015)
Online interface

Recipients and reference contact points

Centres and reference contacts to be identified through contacts with national/regional representatives:

- Italy: INCiPiT national network
- Nordic countries: FINPEDMED
- Spain: RECLIP
- Other Teddy Network members
- Others to be identified

INCiPiT
Italian Network for Paediatric Clinical Trials

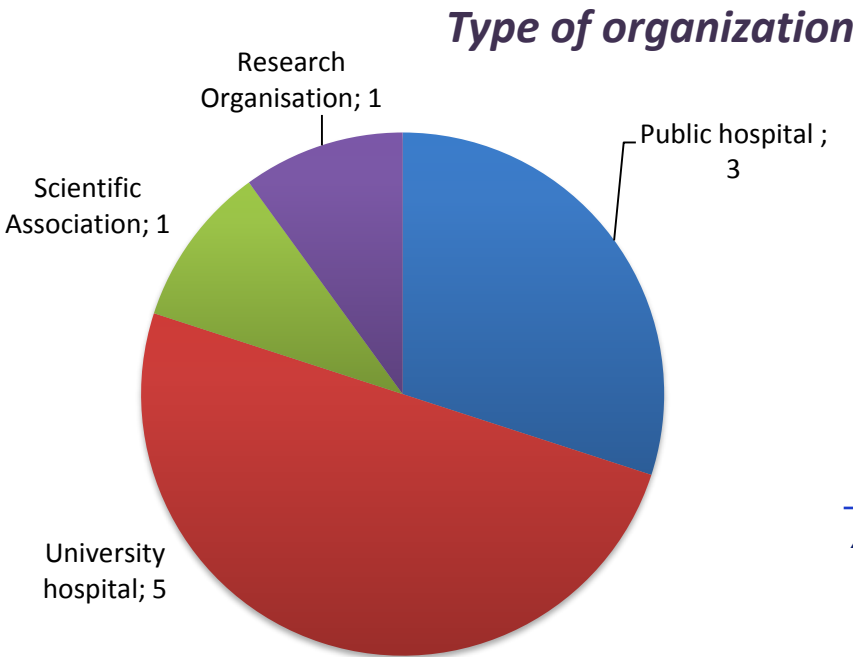
FINPEDMED
Finnish Investigators Network for Pediactric Medicines

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

Some results from the Italian survey…

- *To date, 30% respondents (10 out of 32 requests sent)*



Size of clinical centres

	Beds for hospitalisation	Beds for DH admissions	Paediatric pts hospitalised/ visited yearly
Average Nr. (±SD)	210±196	27,7±22	47525±58834
Range	20-607	2-69	1000-153748

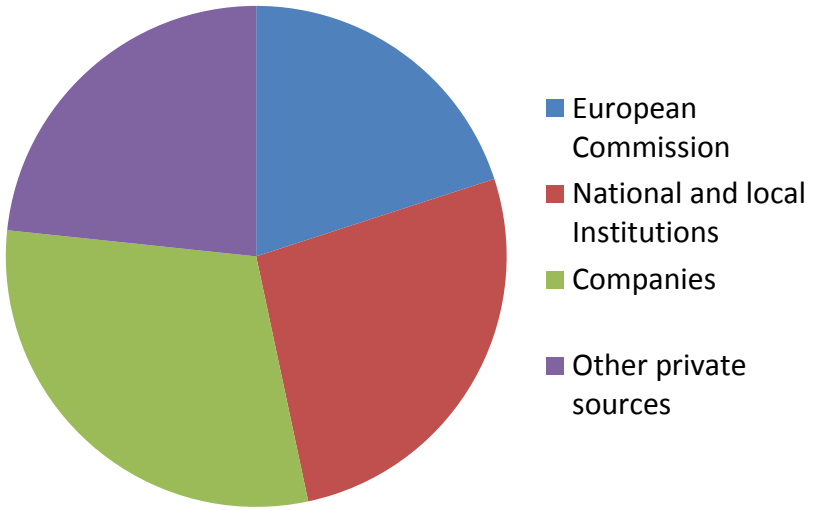
TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

Experience in paediatric clinical research

		Nr. of publicly-funded projects	*Nr. of privately-funded projects*
Role of the institution in the project	Project coordinator	168	100
	Project partner	195	539
	Third party	16	-

ongoing/concluded in the last five years

Funding bodies



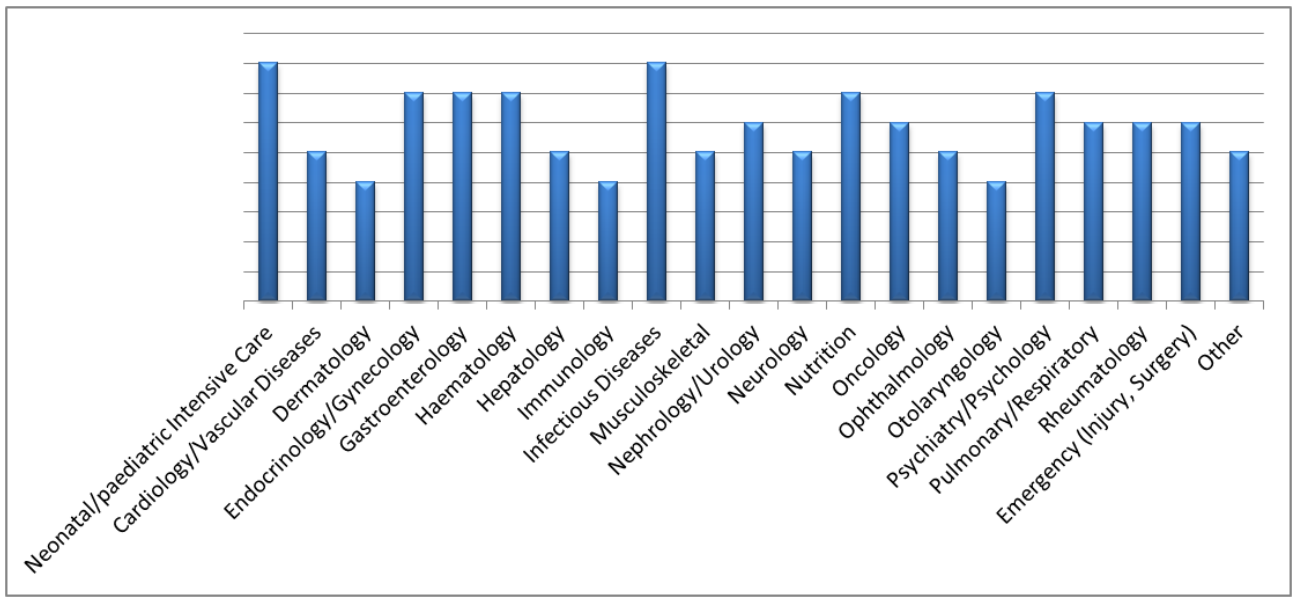
TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

Paediatric clinical trials

Paediatric clinical trials	Nr.
PK	36
PK/PD	97
Efficacy/safety	697
Observational	352
Phamacovigilance	41
Cost-efficacy	2
Medical devices	39
Alimentary products/dietary supplements	12
Other	152

Paediatric clinical trials	Nr.
Research-driven trials	592
Industry-funded trials	430
Regulatory trials	261

Therapeutic areas



TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

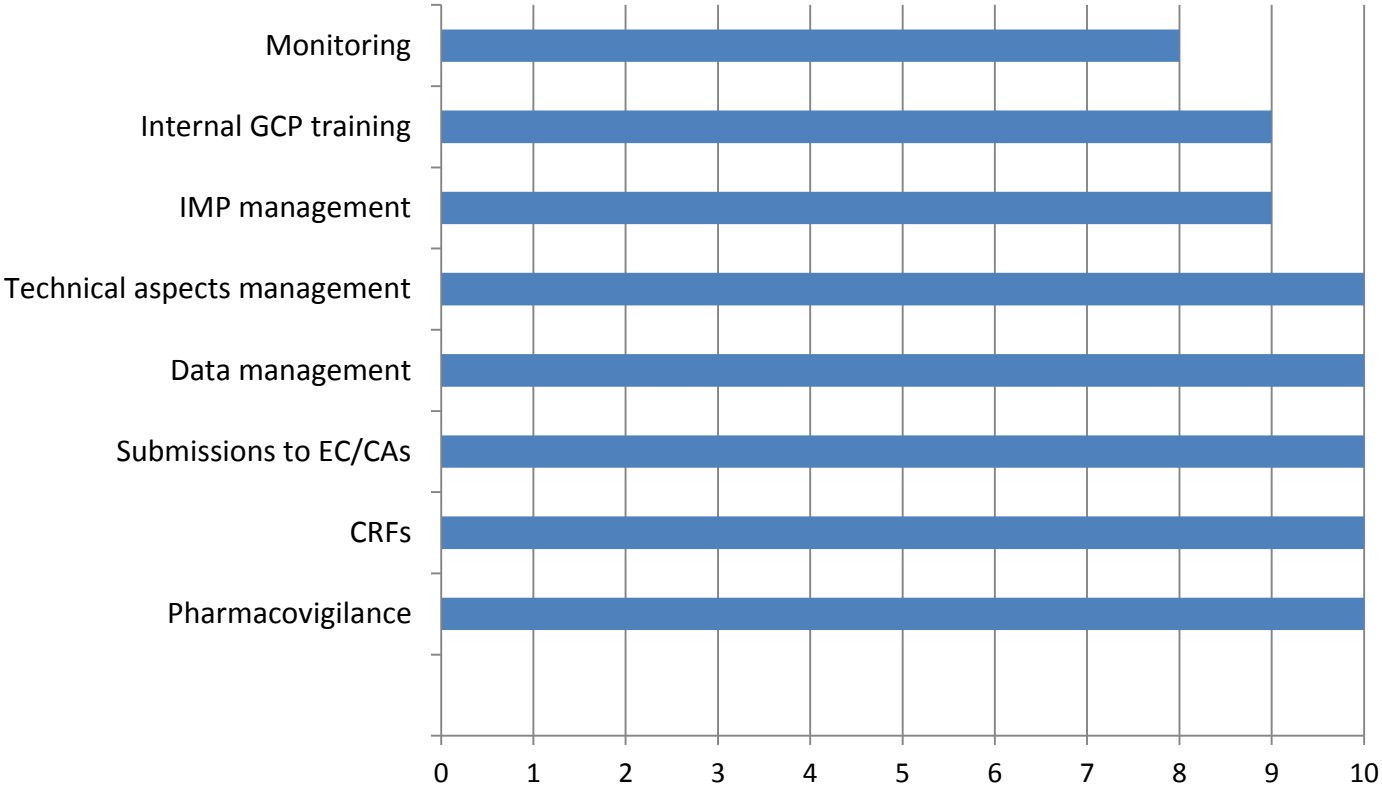
Nr of institutions

10/10	• *Electronic health records and eCRFs*
9/10	• *Availability of pharmacy service and experienced personnel*
9/10	• *Contributing to scoping and feasibility work*
9/10	• *GCP-compliant technical facilities*
6/10	• *Staff able to move among different departments*
5/10	• *Availability of a dedicated unit for PK evaluation*
5/10	• *Biobanks of human samples*

Staff dedicated to paediatric clinical trials	*Nr.*
Medical personnel	*209*
Non-medical	*169*

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

Experience of institutions in…



- All the respondents have established collaborations with Patients Associations and YPAGs
- 3/10 institutions received inspections from European Commission, AIFA, EMA and FDA. Only in 1 case, criticisms have been found

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

Survey – pros and cons

- *Completeness of the information to be collected*
- *Possibility to reach all Eu countries through national contacts*
- *Easy-to-use online system*

- *Length of the survey*
- *Difficulty to check mistakes in the completion*
- *Self-report*
- *Need for help-desk service*

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

What's next?

- *To cover other Eu countries → identify national contact points and get results*
- *To increase response rate → support for survey completion*
- *Check for inconsistencies → follow-up with centres to avoid mistakes*

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research

TEDDY NETWORK
European Network of Excellence for Paediatric Clinical Research