



European Network of Excellence
for Paediatric Clinical Research

General Assembly

**A new phase for paediatric clinical research:
a role play for TEDDY?**

January 14th, 2018

Hotel Ripa

Via degli Orti di Trastevere, 3

Rome - Italy



The TEDDY Network of Excellence arose from the Task-force in Europe for Drug Development for the Young, a consortium funded in 2005 as a Network of Excellence within the EC Sixth Framework Programme with the aim to favour the integration of the paediatric pharmacological research activities, the implementation of adequate health policies and the social awareness on the importance of the paediatric medicines across Europe covering different specialties.

At the end of the 5-years funding period, the TEDDY Network was further renewed and is still running today on a voluntary basis with valuable and internationally recognised efforts provided by its members' resources, with many partners collaborating on a case by case basis.

To consolidate the work carried out up to date as well as to expand the future perspective of the Network, the Boards Members have taken the decision to provide TEDDY with an autonomous legal status. This will allow the Network to be fully represented and consolidated in the European paediatric research community framework, to actively take part in new EU projects and to have a well identified role as an International subject.



A new Statute has also been prepared, allowing the adhesion of both persons and institutions interested in continuing TEDDY activities and some operating groups have been improved and/or created.

Providing TEDDY with a legal entity is aimed to valorise the results and continue the activities of the TEDDY - European Network of Excellence for Paediatric Clinical Research also in its role of category 1 Network Member of Enpr-EMA (the European Network of Paediatric Research at the European Medicines Agency).

As decided by the TEDDY Boards Members, the 2018 TEDDY General Assembly is planned to:

- share ideas and plans for the future activities of the TEDDY Network,
- consolidate groups involved in specific paediatric research topics,
- identify the way in which TEDDY could further serve in disseminating principles and good practices to promote paediatric research.

9:00	Participants' registration	14:30-15:30	The evolution of the paediatric research at European level: projects and initiatives in which TEDDY could participate <i>Chairs: P. Rossi - A. Ceci</i>
9:30-13:30	The future perspective of the Network as International subject in the European scenario <i>Chairs: M. Mellado - O. Della Pasqua</i>	14:30	The PedCRIN project: promoting high-quality clinical research in children through strengthened international collaboration <i>J. Demotes</i>
9:30	The present, the past and the future of TEDDY <i>A. Ceci</i>	14:50	Conect4children Network: the big challenge of EFPIA and European Commission to optimise the delivery of clinical trials in children <i>C. Giaquinto</i>
9:45	TEDDY Statute and legal framework <i>D. Bonifazi</i>	15:10	EPTRI project to underpin medicines development to paediatric clinical studies <i>M. Turner</i>
	Presentation of TEDDY operative groups and plans of action:	15:30	Coffee Break
	<ul style="list-style-type: none"> • 10.00 <i>Standard Operating Procedures for the conduct of paediatric CTs</i> • 10.15 <i>Ethical Issues in paediatric research</i> • 10.30 <i>Off-label medicines use in paediatrics</i> • 10.45 <i>Regulatory procedures for paediatric clinical trials</i> 	16:00-17:30	Towards better cooperation between scientific research communities, companies, regulators and Networks <i>Chairs: C. Fracasso - M. Migdal</i>
11:00	Coffee Break	16:00	The European landscape of Research Infrastructures for the promotion of health: integration without overlapping <i>G. Migliaccio</i>
	<ul style="list-style-type: none"> • 11.30 <i>Inventory of clinical sites and facilities for clinical trial feasibility</i> • 11.45 <i>Health data/ Pharmacovigilance</i> • 12.00 <i>Active engagement of children and adolescents in the themes of clinical research</i> • 12.15 <i>Advanced therapies in paediatrics</i> 	16:15	Enpr-EMA WG on Clinical Trial Preparedness <i>A. Siapkara</i>
12:30	Lunch Break	16:30	Child centred paediatric research: legal and ethical considerations under the new regulatory framework <i>A. Altavilla</i>
13:30	Discussion and appointment of the TEDDY Bodies	16:45	The role of Enpr-EMA in facilitating paediatric research and the results of the WG4-Ethics activities <i>P. Lepola</i>

17:00 **How multispecialty, national and international Networks cooperate for the promotion of clinical research in paediatrics: the Spanish experience**

C. Trasorras, M. Mellado

17:15 **The coordination of rare diseases research in Europe: the European Joint Programme on Rare Diseases**

D. Julkowska

17:30-18:45 **The contribution of TEDDY in paediatric trials and research**

Chairs: E. Jacqz-Aigrain - S. de Wildt

17:30 **Re-purposing of off-patent drugs for children – TEDDY to create a bridge between Europe and Asia**

I. Wong

17:45 **The contribution of INCiPiT in the mapping of paediatric research expertise and units**

F. Rocchi

18:00 **The GAPP Project at the end of the FP7 funding period**

F. Kaguélidou

18:15 **PROMISE: a pragmatic trial in paediatric patients affected by multiple sclerosis**

L. Margari, M. Simone

18:30 **DEEP-2 preliminary results: a best practise in FP7**

A. Kattamis

18:45 **Wrap up, closing and thank you**

D. Bonifazi

19:00-23:00 **Rome by night - Social event including dinner**



List of Chairs and Speakers



Annagrazia Altavilla, Espace Ethique Méditerranéen, Aix-Marseille Université, France

Donato Bonifazi, Chief Executive Officer, Consorzio per Valutazioni Biologiche e Farmacologiche, Italy

Adriana Ceci, President, Gianni Benzi Pharmacological Research Foundation, Italy

Oscar della Pasqua, Clinical Pharmacology and Therapeutics, University College London, UK

Jacques Demotes-Mainard, General Director, European Clinical Research Infrastructure Network (ECRIN), France

Saskia de Wildt, Clinical Pharmacology, Radboud University Nijmegen and Erasmus MC Rotterdam, the Netherlands

Claudio Fracasso, Global Pediatric Medical Director at Pfizer Pediatric Center of Excellence, Italy

Carlo Giaquinto, President, Penta Foundation, Italy

Daria Julkowska, Scientific Coordinator E-Rare, EJP on Rare Diseases, INSERM, Thematic Institute of Genetics, Genomics & Bioinformatics, France

Florentia Kaguélidou, Clinical Pharmacology, Assistance Publique-Hôpitaux de Paris and University Paris Diderot, France

Antonis Kattamis, Pediatric Hematology-Oncology, National & Kapodistrian University of Athens, Greece

Pirkko Lepola, Executive Secretary, Finnish Investigators Network for Paediatric Medicines, Finland

Lucia Margari, Basic Medical Science, Neuroscience and Sense Organs, University of Bari, Italy

María J. Mellado, Paediatric, Infectious and Tropical Diseases, LA PAZ Children's University Hospital and Autonomous University of Madrid, Spain

Marek Migdal, Member of the Paediatric Committee (PDCCO) at EMA, Paediatric Intensive Care Unit, Children's Memorial Health Institute, Poland

Giovanni Migliaccio, Senior Advisor, EATRIS-ERIC, Italy

Francesca Rocchi, Italian Network for Paediatric Clinical Trials (INCiPiT), Italy

Paolo Rossi, Head of the Paediatric Department at Bambino Gesù Children Hospital, Italy

Angeliki Siapkara, Member of the Paediatric Committee (PDCCO) at EMA, co-Chair of the Clinical Trial Preparedness Enpr-EMA Working Group, UK

Mark Turner, EnprEMA Chair, Liverpool University, UK

Cristina Serén Trasorras, RECLIP - Spanish Pediatric Clinical Trials Network, Spain

Ian Wong, University College London and University of Hong Kong, UK



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