



# **TEDDY** EUROPEAN NETWORK OF EXCELLENCE FOR PAEDIATRIC CLINICAL RESEARCH

## *Scientific Meeting and General Assembly*

**The paediatric theme in the  
forthcoming clinical research scenario**

**19th December, 2016**

**Padiglione Salviati, III Floor  
Ospedale Pediatrico Bambino Gesù  
Piazza Sant'Onofrio 4 - Rome**





Paediatric population has been long-time neglected from the clinical research scenario. As a direct consequence of this, in the pharmaceuticals field despite the great contribution done by the biomedical science, innovative medicines are available to children only after years respect to adults and the off-label use of the existing medicines is still a widespread phenomenon in all the countries and in almost all therapeutic areas.

The Paediatric Regulation has highlighted the specific of paediatric patients in terms of drug disposition, drug activity and response to therapy. For this reason, ad hoc paediatric drug development plans have to be prepared and performed. However, many scientific, methodological, economical and ethical factors still complicate the performance of clinical trials in children.

New funding strategies, focused on long-term self-sustainable Paediatric Networks and Research Infrastructures, represent a key to address the forthcoming challenges of paediatric clinical research.

TEDDY is the European Network of Excellence for Paediatric Clinical Research, funded in 2005 to "structure efforts devoted to the development of medicines tailored for children".

To date, after 12 years from the launch of TEDDY activities, it has a crucial role in the European and global scenario of clinical research, as it has been also acknowledged by the recent inclusion in the category 1 EnprEMA networks.

TEDDY annual General Assemblies are the occasion to discuss relevant achievements, forthcoming novelties in paediatric clinical research landscape and to plan TEDDY Network's activities and priorities.

In the occasion of its General Assembly, TEDDY Network, in collaboration with INCiPiT (the Italian Network for Paediatric Clinical Trials) organises a scientific session in which the most recent advancements in paediatric research at European and National level will be discussed and shared with the academy and other stakeholders interested in the field. In addition, the most recent TEDDY initiatives will be presented together with concrete and realistic plans to address some of the most relevant priorities in the paediatric research agenda.

The initiative is organised in the framework of and acknowledges the collaboration of the GRiP Project (Global Research in Paediatrics), funded by the FP7, grant agreement no. 261060.

8:45	Participants' registration	13:15	Q&A and discussion
9:00-13:30	<b>Clinical research in adult and children: commonalities and specificities</b> <i>Chairs: A. Ceci - P. Rossi</i>	13:30	Lunch
9:00	The experience of ISS - Italian Institute for Health in the European Research Infrastructures scenario <i>G. Migliaccio, EATRIS Scientific Director</i>	15:00-16:00	<b>General Assembly - TEDDY Network activities and plan of action</b> <i>Chairs: M. Turner - A. Ceci</i>
9:15	Research Infrastructures in biomedicine: a system pipeline to support biomedical research <i>M. Lavitrano, BBMRI-ERIC Management Committee Co-Chair</i>		The TEDDY Working Group on Off Label Use in Paediatrics: current status and next actions <i>S. de Wildt, TEDDY GOLUP Working Group coordinator</i>
9:30	The new clinical trials regulation to improve the clinical research in Europe: the ECRIN contribution <i>J. Demotes, ECRIN General Director</i>		The TEDDY survey to identify paediatric trials competences and capacities at site level <i>L. Ruggieri, TEDDY Network Scientific Secretariat</i>
9:45	Paediatric clinical trials: challenges and opportunities The contribution of PedCRIN <i>M. Turner, EnprEMA Chair</i>		TEDDY Inventory of procedures for obtaining Paediatric Clinical Trials approvals <i>C. Manfredi, TEDDY Network</i>
10:00	Scientific expertise and specialty level needed to design scientifically-sounded paediatric trials and research <i>C. Giaquinto, GRiP-PENTA - N. Ruperto, PRINTO - P. Telfer, DEEP - O. Della Pasqua (Dose selection and innovative study design) - F. Bonifazi (HTA and disease Registries)</i>		TEDDY contribution to ENCePP - European Network of Centres for Pharmacoepidemiology and Pharmacovigilance <i>K. Verhamme, TEDDY representative in ENCePP, via Teleconference</i>
11:15	Q&A and discussion	16:00	<b>General Assembly - Paediatric clinical trials sustainability in the framework of the paediatric regulation</b> <i>Chair: D. Bonifazi</i> <i>Discussants: A. Altavilla, C. Giaquinto, E. Jacqz-Aigrain, M. Mellado, M. Migdal, A. Neubert, S. de Wildt.</i>
11:30	Coffee Break		
12:00	National networks and initiatives contributing to the European Paediatric Clinical Trial Research Infrastructure (EPCT-RI) <i>Chair: C. Giaquinto</i> <i>E. Jacqz-Aigrain (INSERM, France) - P. Rossi (INCiPiT, Italy) - F. Martinon (RECLIP, Spain) - A. Godo (Albania) - M. Migdal (Poland)</i>	17:00	<b>General Assembly - TEDDY commitments, membership and boards</b>
		17:30	Goodbye cocktail



## List of Chairs and Speakers



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

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

**Fedele Bonifazi**, Vice President of the Gianni Benzi Pharmacological Research Foundation, Italy

**Adriana Ceci**, Scientific Coordinator of the TEDDY Network, President of the Gianni Benzi Pharmacological Research Foundation, Scientific Director of Consorzio per Valutazioni Biologiche e Farmacologiche, Italy

**Oscar Della Pasqua**, Professor, Chair of Clinical Pharmacology and therapeutics, University College London, United Kingdom

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

**Carlo Giaquinto**, President of Fondazione Penta, Global Research in Paediatrics (GRiP) Project Coordinator, University of Padua, Italy

**Anila Godo**, Professor in paediatrics, Head of the Paediatric Department at the University Hospital Center "Mother Teresa", Head of Onco-Hematology Service, President of Albanian Paediatric Association, Albania

**Evelyne Jacqz-Aigrain**, Professor of paediatric pharmacology, clinical pharmacologist, University Descartes, Paris, France

**Maria Luisa Lavitrano**, Professor of pathology University Milano-Bicocca, co-chair BBMRI-ERIC Management Committee, president of CNRB, Italy

**Cristina Manfredi**, Consorzio per Valutazioni Biologiche e Farmacologiche, Italy

**Federico Martinon**, Head of Pediatrics, Hospital Clínico Universitario de Santiago de Compostela, Spain, Coordinator of Red Española de Ensayos Clínicos Pediátricos (RECLIP) Hub, Spain



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**Maria Mellado**, Jefe Servicio de Pediatría Hospitalaria, E. Infecciosas y Tropicales, Associate Professor at the Autónoma University of Madrid, Hospital Universitario Infantil LA PAZ, Madrid, Spain

**Marek Migdal**, Deputy Head of the Paediatric Intensive Care Unit in the Children's Memorial Health Institute, PDCO EMA member, Poland

**Giovanni Migliaccio**, Scientific Director of EATRIS, the European infrastructure for translational medicine, the Netherlands

**Antje Neubert**, PhD, Pharmacist, Head of Paediatric Clinical Study Centre of University Hospital of Erlangen, member of the PDCO, Germany

**Paolo Rossi**, Coordinator of the Italian Network for Paediatric Clinical Trials (INCiPiT), Head of the Paediatric Department at the University Hospital Bambino Gesù, Italy

**Lucia Ruggieri**, TEDDY Network Scientific Secretariat, Gianni Benzi Pharmacological Research Foundation in Bari, Italy

**Nicolino Ruperto**, MD, MPH, IRCCS G. Gaslini, PRINTO, Genoa, Italy

**Paul Telfer**, Queen Mary University of London, Barts Health NHS Trust, United Kingdom

**Mark Turner**, EnprEMA Chair, Senior Lecturer at the Liverpool University, United Kingdom

**Katia Verhamme**, TEDDY representative in the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), The Netherlands

**Saskia de Wildt**, Coordinator of the Working Group on Off Label Use in Paediatrics (GOLUP), Professor of Clinical Pharmacology, Paediatric Intensivist, clinical pharmacologist, at the Radboud University Nijmegen & Erasmus MC, The Netherlands



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