



European Network of Excellence  
for Paediatric Clinical Research



# General Assembly 2019

March 29<sup>th</sup>

Ministry of Health, Consumption and Social Welfare  
Paseo del Prado 18 - Madrid - Spain

## Meeting Agenda



**TEDDY Network**  
**European Network of Excellence for Paediatric Clinical Research**

**General Assembly meeting**  
**March 29<sup>th</sup>, 2019**

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.

In 2017, TEDDY network was provided with an autonomous legal status with a new Statute, to 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.

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). Moreover, the new Statute allows the adhesion of both persons and institutions interested in continuing TEDDY activities and some operating groups have been improved and/or created.

As decided by the TEDDY Boards Members, the 2019 TEDDY General Assembly is planned to:

- renew the interest and commitment of TEDDY partners and participants in TEDDY activities,
  - reopen useful discussion on mission, vision and governance model of this first multinational paediatric Research Network in EU into the changed scenario of Paediatric Research.
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## MEETING AGENDA

<b>09:00-09:15</b>	<b>REGISTRATION AND WELCOME COFFEE</b>	
<b>09:15-09:30</b>	<b>WELCOME ADDRESS</b>	<i>A. Ceci</i>
<b>9:30- 11:00</b>	<b>TEDDY NETWORK ACTIVITIES FROM LAST GENERAL ASSEMBLY UP TODAY</b>	<i>Chairs: O. Della Pasqua, M. Mellado M. Felisi</i>
	<ul style="list-style-type: none"> <li>▪ TEDDY Scientific activities and tools</li> <li>▪ New and ongoing activities: <ul style="list-style-type: none"> <li>○ Paediatric applications of ATMP <i>G. Migliaccio</i></li> <li>○ Off-label use in paediatrics <i>L. Ruggieri</i></li> <li>○ Young Patients Advocacy Groups activities <i>Kids Bari &amp; Kids Albania groups representatives F. Bonifazi – A. Landi</i></li> <li>○ WG Health Data Plan of Action <i>F. Bonifazi – A. Landi</i></li> </ul> </li> <li>▪ Discussion: Chairs and Members of WGs <i>All</i></li> </ul>	
<b>11:00- 13:00</b>	<b>TEDDY PLANS AND PERSPECTIVES IN THE LANDSCAPE OF PAEDIATRIC MEDICINES Participation in collaborative projects</b>	<i>Chairs: E. Jacqz-Aigrain, A. Altavilla</i>
	<ul style="list-style-type: none"> <li>▪ RESTORE: the wider community engagement in the definition of a European large-scale research initiative on Advanced Therapies <i>S. Benvenuti</i></li> <li>▪ Procedures for the set up and management of paediatric trials in the PedCRIN project <i>C. Manfredi</i></li> <li>▪ DEEP project: focus on paediatric patients' empowerment <i>M. Kreka</i></li> <li>▪ Young patients' engagement in the European Joint Programme on Rare Diseases EJPRD <i>M. Lupo</i></li> </ul>	

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**13:00-14:00 LUNCH**

**14:00-15:30 ROUND TABLE**

Participants will be asked to provide suggestions on the following aspects

- Mission and vision
- Needs to be covered by TEDDY and priorities
- Governance, resources and sustainability

A summary of the ROUND TABLE will lead the decisions taken by the TEDDY General Assembly

Discussion: Chairs and Members of WGs

*Chairs:*

*A. Ceci, M. Turner*

*SCC Members, SPB Members and WGs Chairs (all)*

*All*

**15:30-17:00 ACTIVITIES AND PROPOSALS FROM TEDDY SPAIN PARTNERS**

- Authorised Paediatric Clinical Trials in Spain
- Impact of the Spanish HIV HGM BioBank in the pediatric research
- Cell and advanced therapies for children with cancer

*Chairs:*

*D. Bonifazi, C. Calvo*

*M. J. Fernández Cortizo*

*M. Á. Muñoz Fernández*

*A. Pérez Martínez*

**17:00 END OF THE MEETING**

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## CHAIRS AND SPEAKERS LIST

**Annagrazia Altavilla**, Responsible of international relations, Espace Ethique Méditerranéen/Paca-Corse – APHM/ Aix-Marseille University, France

**Stefano Benvenuti**, Global partnerships manager, Fondazione Telethon, Italy

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

**Fedele Bonifazi**, Vice-president, Gianni Benzi Pharmacological Research Foundation, Italy

**Cristina Calvo**, Head Clinician, Pediatric and Infectious Diseases Department, Hospital Universitario La Paz  
Madrid, Spain

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

**Gabriele Ciavarella**, KIDS Bari representative, Italy

**Oscar Della Pasqua**, Chair of Clinical Pharmacology and Therapeutics, University College London, UK

**Antonio Di Pietro**, KIDS Bari representative, Italy

**Mariagrazia Felisi**, Clinical Director, Consorzio per Valutazioni Biologiche e Farmacologiche, Italy

**María Jesús Fernández-Cortizo**, Head of Service, Spanish Agency on Medicines and Healthcare Products, Spanish PDCO Alternate member, Spain

**Evelyne Jacqz-Aigrain**, Professor at Paediatric Pharmacology and Pharmacogenetics, Paris Diderot University, Hôpital Universitaire Robert Debré, France

**M. Kreka**, Medical Director, Consorzio per Valutazioni Biologiche e Farmacologiche, Albania

**Annalisa Landi**, Researcher, Gianni Benzi Pharmacological Research Foundation, Italy

**Denise Lieshaj**, KIDS Albania representative, Albania

**Mariangela Lupo**, Engagement of children and adolescents in research WG Leader, TEDDY Network – European Network of Excellence for Paediatric Clinical Research, Italy

**Cristina Manfredi**, Regulatory & Pharmacovigilance Area Coordinator, Consorzio per Valutazioni Biologiche e Farmacologiche, Italy

**María José Mellado**, Associate Professor of Universidad Autónoma de Madrid, Servicio Madrileño de Salud, Hospital University La Paz, Spain

**Giovanni Migliaccio**, Scientific Director, Consorzio per Valutazioni Biologiche e Farmacologiche, Italy

**Maria Angeles Muñoz-Fernández**, Scientific Director of the Spanish HIV HGM Pediatric BioBank, Spain

**Antonio Pérez Martínez**, Head of Paediatric Hemato-Oncology Service of the University Hospital La Paz, Spain

**Lucia Ruggieri**, Researcher, Gianni Benzi Pharmacological Research Foundation, Italy

**Nensi Semanaj**, KIDS Albania representative, Albania

**Mark Turner**, Enpr-EMA Chair, Liverpool University, UK

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Do you want to know more about TEDDY, visit the website at:

**[www.teddynetwork.net](http://www.teddynetwork.net)**

or write an email to

**[info@teddynetwork.net](mailto:info@teddynetwork.net)**