



# TEDDY General Assembly

Donato Bonifazi

*Virtual Meeting*

April 8<sup>th</sup>, 2020

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

# AGENDA

- ✓ Update on the TEDDY activities
- ✓ Approval of the Financial Statements 2019
- ✓ Approval of the new Statute and the TEDDY name
- ✓ Appointment of the Board and the Chair

# TEDDY activities update

- TEDDY became new member of **Enpr-EMA Coordinating Group**



- Participation in several **Enpr-EMA WGs**:
  - ❖ WG on clinical trial preparedness
  - ❖ WG on ethics
  - ❖ WG on young patient advisory groups
  - ❖ WG on educational training for research staff on paediatric clinical trials
- TEDDY Health data WG: collaboration with the **WG 3 'Data Sources and Multi-source Studies' of ENCePP** in the revision and analysis of Post-Authorisation studies in paediatric population included in the EU PAS Register

# TEDDY participation in initiatives

**ePTRI**

EUROPEAN PAEDIATRIC TRANSLATIONAL RESEARCH INFRASTRUCTURE

Involvement as Third Party of the Coordinator in the the project coordination (WP1), the design of the governance model (WP2), the performing of the context analysis (WP3), the design of the activities aimed at underpinning paediatric studies to medicine development (WP9), the ethical revision of the planned activities (WP10) and the promotion of patients' engagement (WP11)



Involvement as Partner in Pillar 3 WP15, aimed to provide 'paediatric patient experts training courses' on the themes of rare diseases, and in the project Communication and Dissemination activities (Pillar 0 WP5)



TEDDY is involved as one of the 300 committed supporters from 26 countries

# TEDDY Publications in 2019

- Ruggieri L, Bonifazi D, Landi A, Bonifazi F, Bartoloni F, Costello M, Grazia Felisi M, Gasthuys E, Godo A, Martinon Torres F, Nadal D, Nuytinik L, Rocchi F, Turner M, Ceci A. Survey by TEDDY - European Network of Excellence for Paediatric Clinical Research demonstrates potential for Europe-wide trials. Acta Paediatr. 2019 Sep 18. doi: 10.1111/apa.15020. [Epub ahead of print] PubMed PMID: 31532836. Available at: <https://onlinelibrary.wiley.com/doi/abs/10.1111/apa.15020>
- Bueno-Campaña M, Sainz T, Alba M, Del Rosal T, Mendez-Echevarría A, Echevarria R, Tagarro A, Ruperez-Lucas M, Herreros ML, Latorre L, Calvo C. Lung ultrasound for prediction of respiratory support in infants with acute bronchiolitis: A cohort study. Pediatr Pulmonol. 2019 Jun;54(6):873-880. doi: 10.1002/ppul.24287. Epub 2019 Mar 5. PubMed PMID: 30838805. Available at: <https://onlinelibrary.wiley.com/doi/abs/10.1002/ppul.24287>
- Martín Del Valle F, Menasalvas Ruiz A, Cilla A, González AV, de Ceano Vivas M, Cabrerizo Sanz M, Calvo C. Neurodevelopment medium-term outcome after parechovirus infection. Early Hum Dev. 2019 May; 132:1-5. Doi: 10.1016/j.earlhumdev.2019.03.005. Epub 2019 Mar 22. PubMed PMID: 30908988. Available at: <https://www.sciencedirect.com/science/article/abs/pii/S0378378218306522?via%3Dihub>
- Intini A., Bonifazi D, Migliaccio G. Challenges and New Frontiers in the Paediatric Drug Discovery and Development (Book chapter). Drug Discovery and Development – New Advances. 2019 Apr 8. Publisher: IntechOpen. DOI: <http://dx.doi.org/10.5772/intechopen.85635>. Available at: <https://www.intechopen.com/online-first/challenges-and-new-frontiers-in-the-paediatric-drug-discovery-and-development>

# TEDDY Publications in 2019

- Calvo C, Millan C, Romero MP, Méndez-Echevarría A. Could human bocavirus be a causative agent of parotitis in children? *Enferm Infecc Microbiol Clin*. 2019 Mar;37(3):207-208. doi: 10.1016/j.eimc.2018.04.001. Epub 2018 May 8. English. Spanish. PubMed PMID: 29751940. Available at: <https://www.sciencedirect.com/science/article/pii/S02130005X18301691?via%3Dihub>
- Benavides-Nieto M, Méndez-Echevarría A, Del Rosal T, García-García ML, Casas I, Pozo F, de la Serna O, Lopez-Granados E, Rodriguez-Pena R, Calvo C. The role of respiratory viruses in children with humoral immunodeficiency on immunoglobulin replacement therapy. *Pediatr Pulmonol*. 2019 Feb;54(2):194-199. doi: 10.1002/ppul.24214. Epub 2018 Dec 21. PubMed PMID: 30575324. Available at: <https://onlinelibrary.wiley.com/doi/abs/10.1002/ppul.24214>

## TEDDY new Publication submitted in 2020

- Annagrazia Altavilla, Viviana Giannuzzi, Mariangela Lupo, Donato Bonifazi, Adriana Ceci, “Ethical, legal and regulatory issues of paediatric translational research call for an adequate model of governance”.

# TEDDY Consultation

TEDDY provided its own contribution to the Horizon Europe Co-design survey launched by EC to collect inputs about the document “

Orientations towards the first Strategic Plan implementing the research and innovation framework programme Horizon Europe” aimed to inform and stimulate the process to shape the European research and innovation investments in the coming years.

TEDDY provided its input in the design of the next European programme drawing attention on the paediatric issues that need stronger investments in order to deliver more benefits to the paediatric population. The paediatric topic is not specifically mentioned in the “Orientations” document and not considered as a global challenge as it is! TEDDY provided its perspective underlining the need for a paediatric centred vision to guarantee efficacious and safe drug for children.

# Public involvement

- TEDDY has promoted the creation of KIDS Bari and KIDS Albania

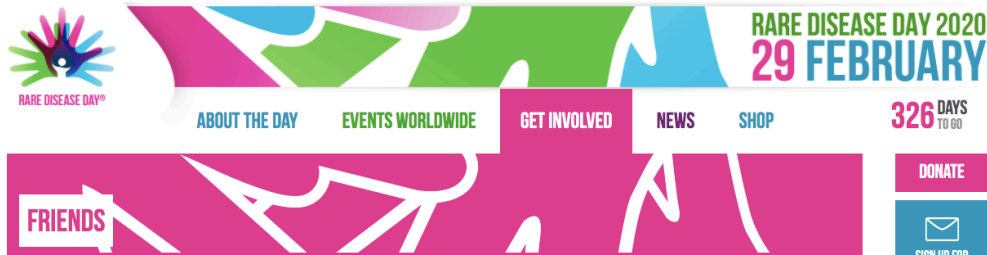


- Both groups have been involved in meetings to train the kids on topics that belong to paediatric basic and clinical trials (biomedicine, basic research, clinical research, humanization of healthcare) and in a series of practical activities during the last year, such as:
  - Presentation at meetings and conferences to raise awareness on the importance to involve children and their family in issues related to health, medicine, research and innovation (EPTRI General Assembly March 2019 in Madrid).
  - Awareness campaigns on different topics (Rare disease day, World Kidney Day, World Asthma Day)
  - Participation in consultation activities (within the project “Consultation on civic participation in healthcare system”)



# Communication activities

**TEDDY newsletter** (new structure: update on the TEDDY initiatives, news on paediatric medicines, across the world section, TEDDY publications)



TEDDY support for the **RARE DISEASE DAY** initiative through the official social profiles

# New TEDDY mission

To bring together subjects involved in paediatric drugs development processes, to share ideas about paediatric research, to contribute to the implementation of paediatric initiatives by:

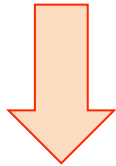
- raising and analysing **children diseases specificities and unmet needs** with a multidisciplinary approach
- promoting initiatives for **secondary use of paediatric data** to accumulate clinical evidence without additional clinical studies
- identifying and taking part to **initiatives on safe and cost-effective use** of health products in children
- promoting **integration of basic and developmental research with clinical research** to accelerate the availability of paediatric medicines, devices and innovative therapies on the market
- addressing **ethical, legal, social and regulatory issues** of research, from the preclinical phase to clinical evaluations and medicines utilization, access policies and education
- **engaging children and young patients** in decisions related to clinical research and healthcare
- **enhancing the awareness** of the main stakeholders including authorities and public, on the still unmet needs of paediatric research

# TEDDY Statute

The Association's Bodies are:

- General Assembly
- Board of Directors
- Chair
- Young Persons Advisory Group

TEDDY is an Italian Association that can not have profit and perform activities of promotion and social utility



**BOARD and CHAIR  
TO BE APPOINTED**



TEDDY activities are addressed to national, European and international Authorities, public and private Institutions and Companies, researchers, professionals and Patients' Associations

# New TEDDY name



European Network of Excellence  
for Paediatric Research

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