

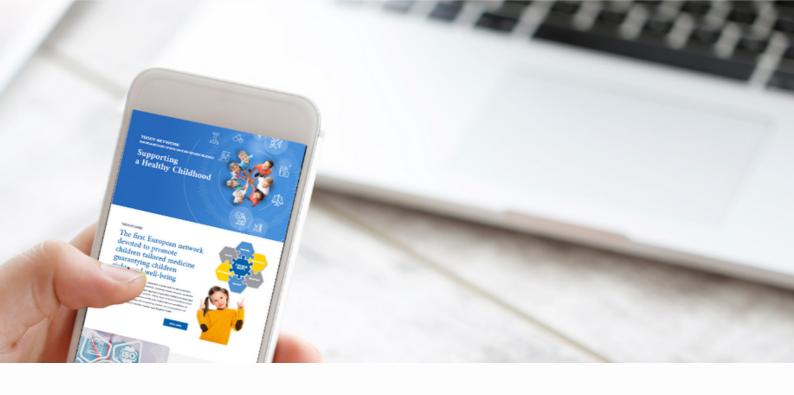
**TEDDY European Network of Excellence for Pediatric Research** is a non-profit scientific research organisation.

It delves into paediatric therapeutic areas where suitable medicines are lacking, promoting safe and effective therapies for children, while fostering "regulatory grade" paediatric studies and safeguarding children's fundamental rights.

As a member of the European Network of Pediatric Research (EnprEMA) appointed at EMA, Teddy operates on a voluntary basis as an independent, multidisciplinary, and multinational research framework entity and consolidates its actions within the European research community by constantly taking part in new and innovative European projects.

Teddy's statute, the network bodies, and members, along with the main results achieved, are available on the institutional website

www.teddynetwork.net



## The main objectives of the TEDDY network

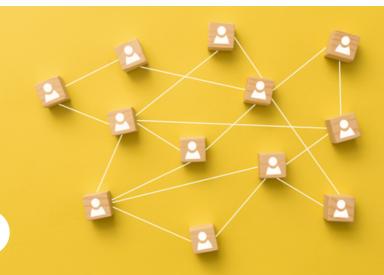
- a promoting children well-being and ensuring children's fundamental rights protection including health;
- b promoting paediatric research and accelerating the availability of paediatric medicines, devices and advanced therapies for their use;
- c ensuring equal access to health products for children's prevention, diagnosis and therapies;
- d providing training on the risks and benefit of medicines utilisation;
- e engaging children and young patients in decisions related to participation in clinical research and healthcare;
- f enhancing awareness among key stakeholders including authorities, general public, health professionals and sponsors about the persistent unmet needs of paediatric research and on paediatric health protection.

# TEDDY's experience develops at European and international level

- member of the European Network of Paediatric Research at the European Medicines Agency-EMA and of the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance-EMA;
- partner of "conect4children (c4c)", the largest European network for paediatric clinical research which aims to facilitate the development of new medicines and therapies;
- partner of EPTRI-AISBL, the only paediatric research infrastructure covering all phases of paediatric biomedical research;
- partner of the European Joint Program on Rare Disease (EJP RD), that provides training and communication tools dedicated to paediatric patients with rare diseases and their special needs;
- scientific partner of the Council of Europe in the elaboration of the "Strategic Action Plan for children rights in the biomedical field" (2020-2025).

### TEDDY's experience is also national and local

- membrer of INCiPit (Italian Network for Paediatric Clinical Trials) the national network of paediatric clinical centers and universities involved in clinical research and advanced paediatric therapies;
- partner of Consorzio Valutazioni Biologiche e Farmacologiche (CVBF), a research organization that has coordinated the TEDDY project during the funded period.



#### **TEDDY main skills**



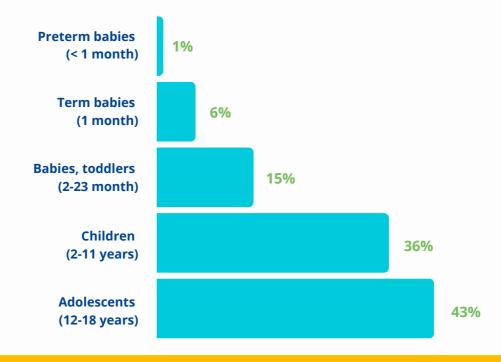
#### **Paediatric Therapeutic needs**

Promoting Paediatric research is one of the priorities of TEDDY Network. It's necessary to concentrate efforts and resources on the unmet needs.

In this context, TEDDY has delved into the analysis of therapeutic areas and the paediatric age group, where appropriate medicines are lacking. The European Paediatric Medicines Database (EPMD) was created in 2007, to collect data on medicinal products available for children in many therapeutic areas.

It emerges that the majority of paediatric medicines approved are antiinfectives, whereas cardiovascular medicines remain scarce. In addition, considering different children's age-groups, a limited percentage of these medicines have been approved for use in preterm babies, term babies and toddlers, in contrast to a higher number of medicines for older children and adolescents.

Data from EPMD are continuously updated and available for patients, researchers and health authorities.



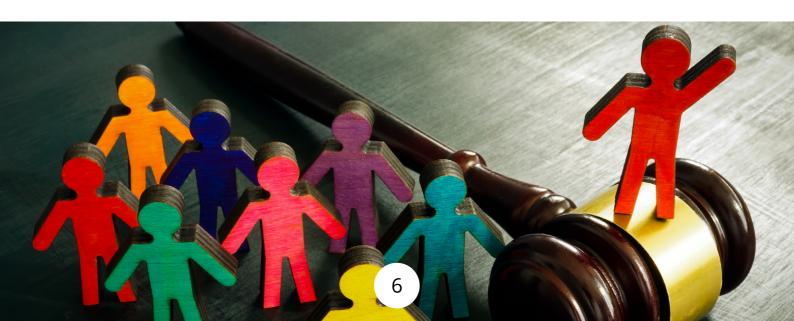


# Expertise in paediatric research with a particular focus on ethics, regulatory issues and children's rights

TEDDY has gained relevant experience on ethical, legal, regulatory and social issues related to research, access and correct use of medicines considering the paediatric age.

In particular, TEDDY:

- provides methodological and management support to paediatric trials, including the preparation of informative consent/assent forms;
- provides advice on data protection and children's rights in the application of the GDPR in paediatric research;
- has participated in the drafting process of the European Regulation on Clinical Trials and actively collaborates with the European institutions, including the Paediatric European Network at EMA (EnprEMA);
- collaborates with the Council of Europe in the development of the "Strategic Action Plan for children rights in the biomedical field" (2020-2025), contributing to the elaboration of the "Guide to the participation of children in decision-making processes regarding their health";
- participates in the European Joint Programme on Rare Diseases (EJP RD) project as provider of workshops for paediatric expert patients dedicated to European children with chronic rare diseases.





#### **Empowerment and advocacy of the paediatric population**

TEDDY promotes a child-friendly healthcare and research approach through the empowerment of paediatric population.

The active participation of children in decision-making process, according to their age and maturity, is crucial in routine clinical practice, but also in the development of innovative medicines and therapies.

Empowering children and young individuals by incorporating their perspectives in health-related decision-making is a fundamental right. Moreover, when children and young people participate in the processes regarding their health, they develop valuable skills and self-esteem, and acquire the ability to manage their condition and treatments more effectively.

To promote children empowerment and effective partnerships with health professionals, TEDDY set up two Young Persons Advisory Groups (YPAG), KIDS Bari and KIDS Albania, and supporting the organisation of other KIDS groups in Europe. TEDDY Kids are part of ICAN, the International Children's Advisory Network, a worldwide consortium of children's advisory groups.





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