TEDDY - European Network of Excellence for Paediatric Clinical Research

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TEDDY in a nutshell

TEDDY was born in the context of the FP6 (start date: 1st June **2005**, duration: 60 months)

Since **2010** TEDDY has revised its organisation and gathered new research centres and groups willing to be engaged in developing paediatric clinical research

TEDDY today is a category 1 Network Member of Enpr-EMA
… is continuing working at facilitating the performance of good quality paediatric studies and research thanks to the voluntary efforts of its members.

TEDDY lifeline

TEDDY funded as a consortium responding to a call of the EU aimed at “structuring efforts devoted to the development of medicines tailored for children”

Network of Excellence for Paediatric Clinical Research and Member of Enpr-EMA with partners agreement

A Network with a legal status to be fully represented in the European paediatric research framework

2005 → 2011 → 2018

Between 2005-2010, the FP6 TEDDY project (LSHB-CT-2005-005216) played a critical role in the start-up of paediatric activities in Europe, in parallel with the introduction of the new European Paediatric Regulation.

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TEDDY mission

- **Valorize the results and keep on the activities of TEDDY** (FP6 project) and consolidate the Network created at the end of the project with the denomination TEDDY – NETWORK OF EXCELLENCE FOR PAEDIATRIC CLINICAL RESEARCH (TEDDY Network)
- **Support activities** for the paediatric medicines development
- **Promote informative actions** for a more effective and safer use of paediatric drugs

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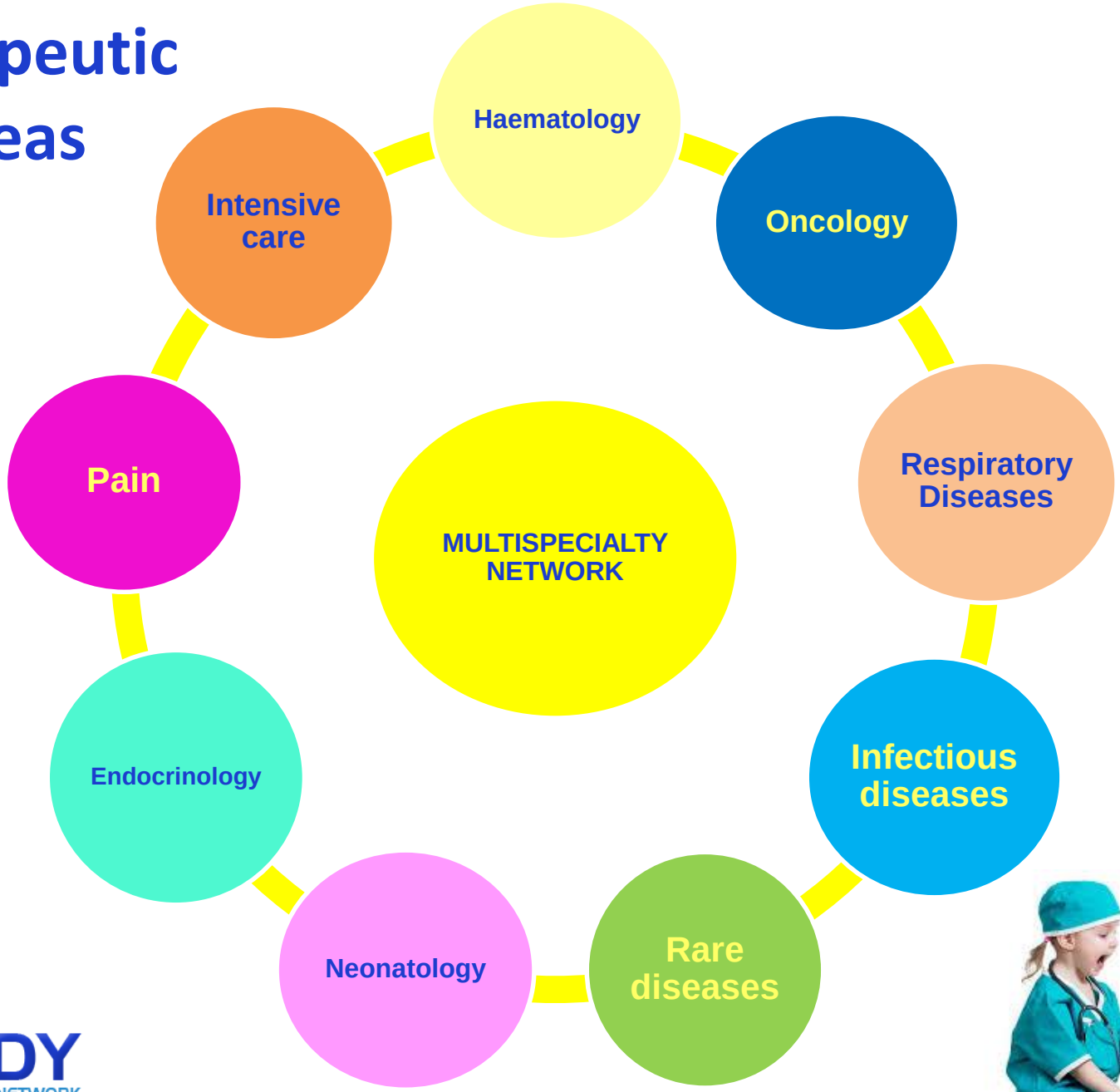
The association does not have profit and perform activities of promotion and social utility with a European dimension

Therapeutic Areas



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TEDDY Objectives

- **Implement good practices and tools to develop studies and research** on medicinal products in children in compliance with EU legislation and guideliness.
- **Promote, participate in and provide methodological expertise** to set up, develop and conduct paediatric national or multinational clinical trials and other paediatric studies.
- **Collaborate with existing paediatric networks and research organisations** in the framework of the Enpr-EMA and other international initiatives.
- **Develop informative tools** in order to **increase awareness** on the topics of paediatric research.
- **Develop communication and educational tools** tailored **for children** in order to **facilitate their participation in all the relevant experimental procedures** including assent and consent forms preparation.

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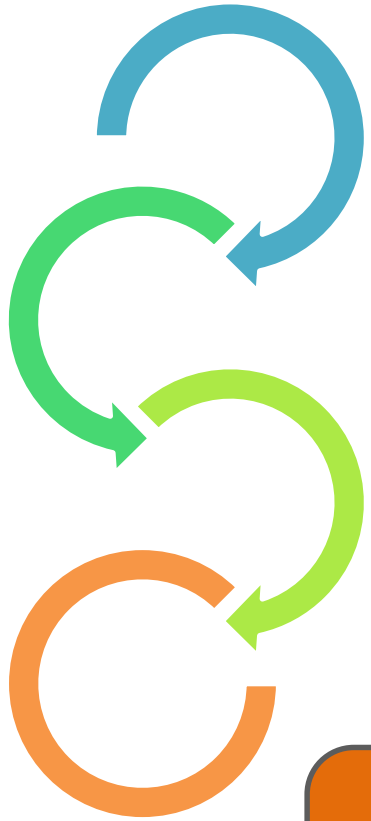
TEDDY activities

Participate in or promoting new EU **initiatives** in the paediatric fields (Enpr-EMA, FP7 and H2020 projects, EPCTRI, PedCRIN, EPTRI, c4c)

Inform the Network participants about new initiatives and circulate regulatory documents and scientific publications

Develop educational, informative and empowerment **tools** for children and families



Contribute to the scientific and regulatory **debates** promoted by EU Institutions by stimulating participation and by submitting written contributions

Plan and execute **surveys** on specific themes and provide publications on the results

Manage and mantain useful **databases** on paediatric medicinal products and related trials, studies, PIP, PUMA or paediatric variations

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TEDDY's activities

2011 — CVBF-TEDDY IS PARTNER OF **GRIP**

2014/2016 — TEDDY IS MEMBER OF ENPREMA **CAT. 4** (FIRSTLY) AND **CAT. 1** (CURRENTLY)

2017/2018
- TEDDY IN **PEDCRIN, EPTRI**
- TEDDY AS FUNDER PARTNER OF **EJP-RD**

5 completed

8 ongoing

clinical trails conducted

In 2018
7 Working Groups

- Standard Operating Procedures for the conduct of paediatric CTs
- Ethical Issues and interactions with Ethic Committees
- Off-label medicines use in paediatrics
- Regulatory procedures for paediatric clinical trials
- Pharmacovigilance
- Active engagement of children and adolescents in the themes of clinical research
- Advanced therapies in paediatrics

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What TEDDY expertise can offer?

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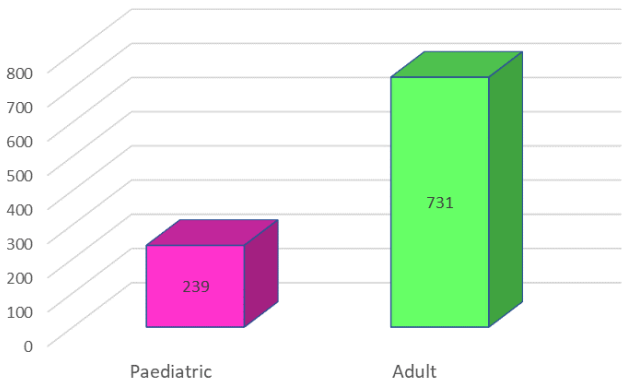
EPMD – European Pediatric Medicines database

A database containing information on paediatric drugs authorised by the European Medicine Agency (EMA) under the centralised procedure. It is aimed to create a ***harmonised, integrated and reliable European source of information*** *on paediatric medicines in Europe*

After 10 years from the entry into force of the Paediatric Regulation, the number of paediatric medicines has tripled, but they remain ~ 1/3 of all the centrally authorised medicines

Medicines approved up to 2017



European Paediatric Medicines Database, October 2017

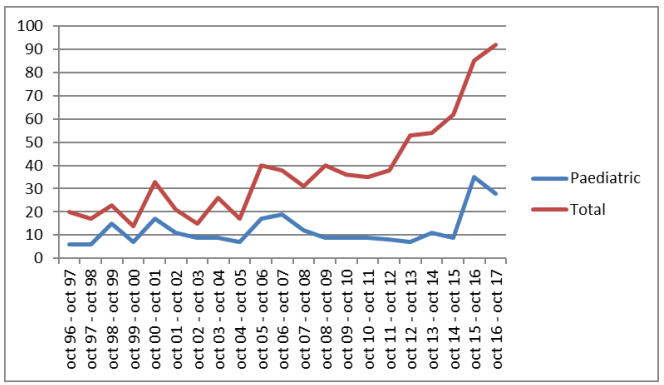
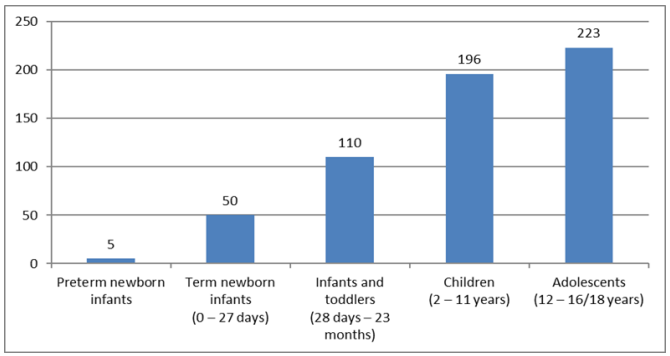


Figure 1 - Medicinal products authorised by EMA divided by year (Oct. 1995 – Oct. 2017)

Not a constant increase for paediatric medicines approval



Still few medicines approved for term and preterm newborns

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SOPs availability

RATIONALE

The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with *written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).*

The TEDDY Network has produced some procedures in the context of the FP7 trials that have been conducted with the involvement of many TEDDY partners.

A plan for SOPs update is now ongoing within the WG

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Sites inventory

In **2016** TEDDY has set up and developed a survey aimed to map paediatric clinical centers and services. The survey contents and results were agreed and shared with EnprEMA and promoted together with other EnprEMA networks (FinPedMed, RECLIP, etc.).

Following this collection, the TEDDY survey was additionally used and implemented to map EU infrastructure and service needs for paediatric and neonatal trials (developed in the framework of the **PedCRIN project**) in order to better understand the real needs of the scientific and users' community and to ensure that future PedCRIN tools will respond to them (April-May 2017).

The survey has been correctly submitted online by a total of **147** users from 30 different countries. The questionnaires were mainly filled out by paediatricians (57), specialty paediatricians (58), medical doctors (36) and researchers (39), 81% of whom actively took part as Investigators in at least one clinical trial involving paediatric subjects (0-18 years), mainly as PI (39%) or co-investigator (41%).

ePTRI
European Paediatric Translational Research Infrastructure

Currently the **ID-EPTRI survey** has been implemented with the aim to identify potential service providers to be included in the future European Paediatric Translational Research Infrastructure (April- May 2018)

PedCRIN

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Informative documents

The GAPP (GAbapentin in Paediatric Pain) project intends to improve the therapeutic perspectives of children who suffer from chronic pain, providing them with the drug " Gabapentin"

- **3 different BOOKLETS for each study** (GABA-1 e GABA-2) for different age groups
- **2 different ASSENT FORMS** for patients from 7 to 11 and from 12 to 17 years of age

Available in the 7 languages of the project (Albanian, French, Greek, English, Italian, Dutch and German)

The objective of the DEEP project is the marketing of a new formulation of deferiprone for the treatment of iron overload in paediatric patients affected by congenital anaemias

- 3 different BOOKLETS explaining CTs aims and procedures and what they are going to experience
- 2 different ASSENT FORMS

Available in the 6 project languages (Albanian, Arabic, English, French, Greek, Italian)

Patient diary for each study (GABA-1 and GABA-2)

Two animated videos have been developed:

- presenting general information on clinical trials for young children
- presenting general information on clinical trials for teenagers

Participation in public consultations/ contribution in other initiatives

ICH E11 (R1) guideline on clinical investigation of medicinal products in the pediatric population (April 2017)

Public consultation on the revision of "Ethical Considerations for Clinical Trials on Medicinal products conducted with Minors" (August 2016)

Ethical Considerations for Clinical Trials Performed in Children (2007)

Public consultation on “Concept paper paediatric addendum of the guideline on clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic disease” (January 2018)

Evaluation of the legislation on medicines for children and rare diseases (medicines for special populations) (January 2018)

Public consultation to gather stakeholders' experiences of the EU Paediatric Regulation (February 2017)

Stakeholder consultation for Horizon 2020 Societal Challenge "Health, demographic change and wellbeing" for the programming exercise 2016/2017 (September 2014)

Contribution to amendments proposed by GRiP to the draft Regulation on Clinical Trials on medicinal products for human use (May 2013)

Public consultation on the concept paper on the Revision of the 'Clinical Trials Directive' 2001/20/EC (February 2011)

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Participation in public consultations/ contribution in other initiatives

Survey of Young Persons Groups (YPAG) in Europe (January 2017)

Public consultation on "Summary of Clinical Trial Results for Laypersons" (August 2016)

Survey for Enpr-EMA networks regarding Young Persons Groups (April 2016)

Contribution to EnprEMA Working Group for preparedness in paediatric clinical trials

Contribution to EnprEMA WG4 Ethics (Comments on the revision of EC Ethical Recommendations 2008 (2017); Harmonised consent / assent template; Risk / benefit assessment in paediatrics)

On 8-9 March 2018, TEDDY selected as **EMA stakeholder** and invited to participate in the “the Second International Awareness Session for international regulators, academia and non-governmental organisations” (March 2018)

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TEDDY's Members

2005
19 Partners
12 Countries

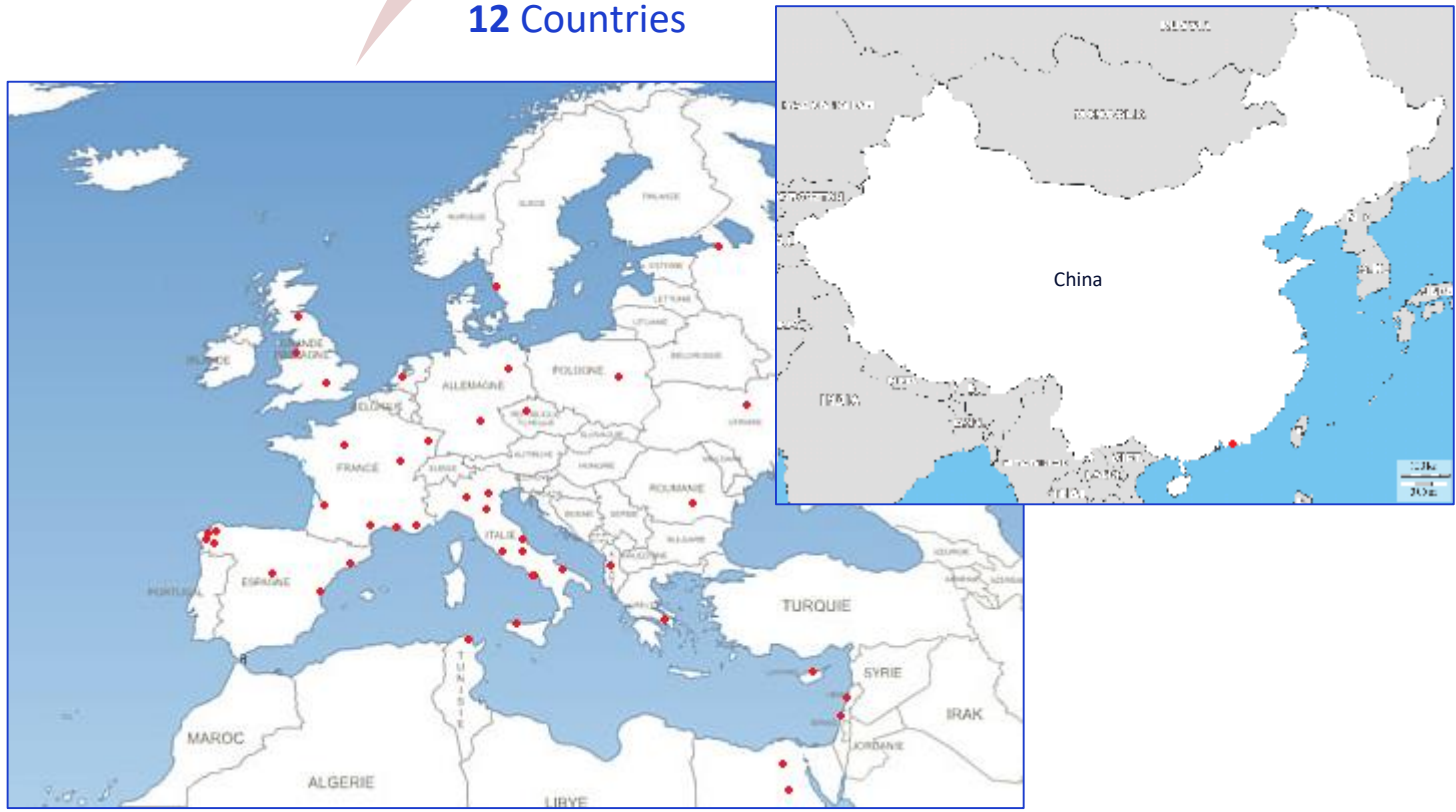
2013
25 Partners
12 Countries

2017
42 Partners
14 Countries

2018

50 Members

21 Countries



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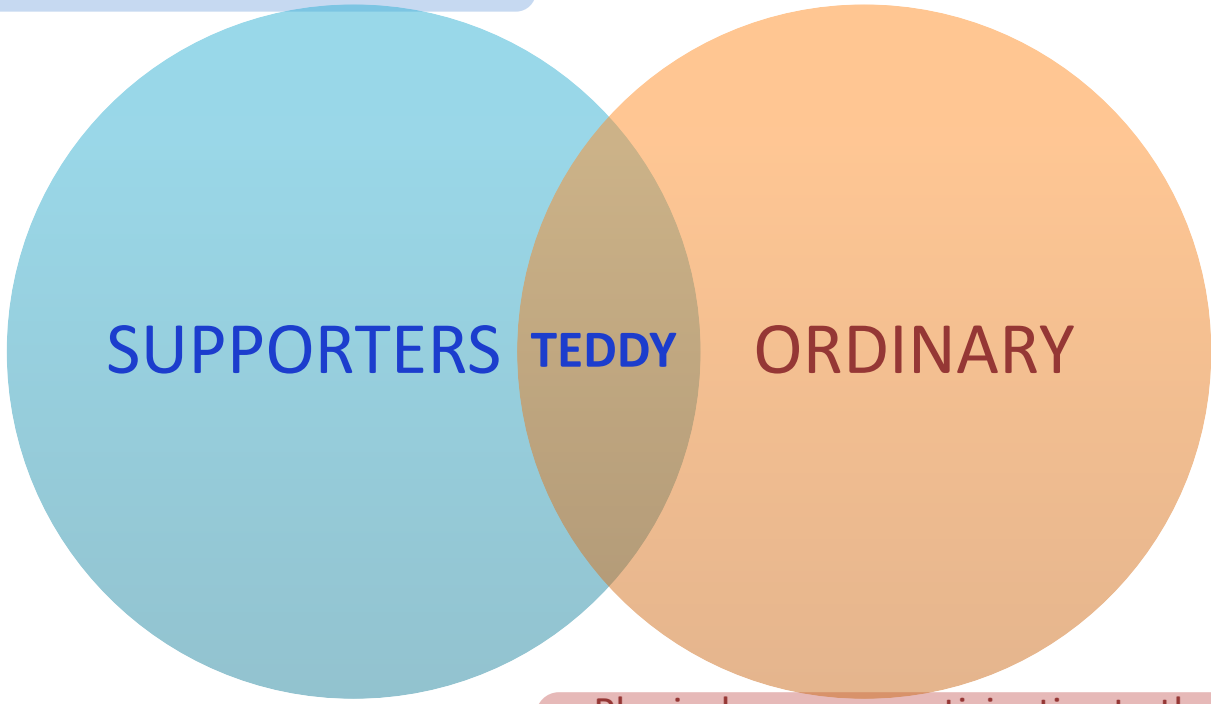
Two categories of associated

The 50 legal entities **already members of** the **TEDDY** network and their affiliated physical persons are recognized as being associated after a simple request, having already shared the purposes

Legal entities contributing to the activities and assuring extraordinary voluntary contribution



Physical persons participating to the collaborative groups and paying the association fee, annually established by the Assembly

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TEDDY future plans and ambition

Through an **autonomous representativeness we aim to**

- Have a **consolidated role** in the European paediatric research community framework

- Enlarging the participation of Members **actively taking part in new EU projects**

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