

TEDDY Statute and legal framework

Donato Bonifazi

Consorzio per Valutazioni Biologiche
e Farmacologiche

European Network of Excellence for Paediatric Clinical Research

Aim of the statute



- to valorize the results and keep on the activities of TEDDY, Task force in Europe for the Drug Development for the Young –
 Network of Excellence (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)
- to support activities for the paediatric medicines development
- to promote informative actions for a more effective and safer use of paediatric drugs



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

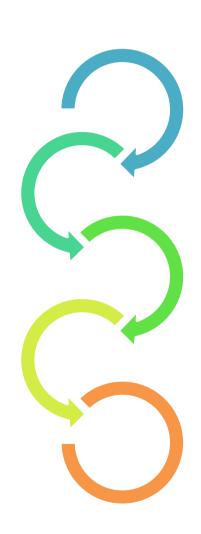
Finalities of the statute

Favor the creation of the infrastructural conditions to cover the existing gaps in paediatic drugs availability

Participate to projects, RI and European consortia that will be set up in order to respond to these needs

Inform the TEDDY Network participants about new initiatives and circulate documents and publications





Develop education and training programmes to favor the knowledge in the paediatric research field

Develop education and communication tools for children and teenagers in order to facilitate their participation to clinical research projects

Favor the access of the paediatric ages to the main finding of research in life sciences

Realize research projects at national, European and international level

TEDDY activities

Research and clinical studies, development and application of new methods in the CT field, setting up of SOPs, creation of tools for research and data banks

Networking and participation to public consultations

Participation, coordination and management of projects at national, European and international level



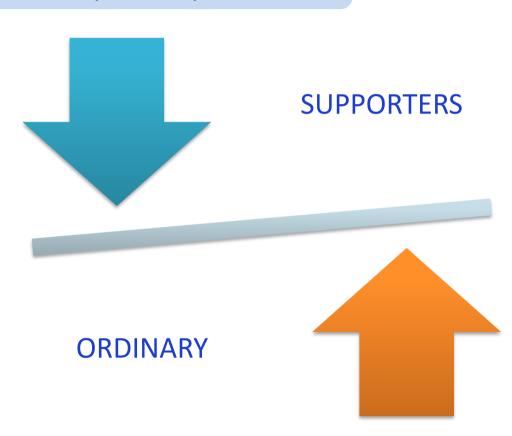
Scientific and regulatory advice

Education and communication

Two categories of associated

Legal entities contributing to the activities and assuring extraordinary voluntary contribution

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





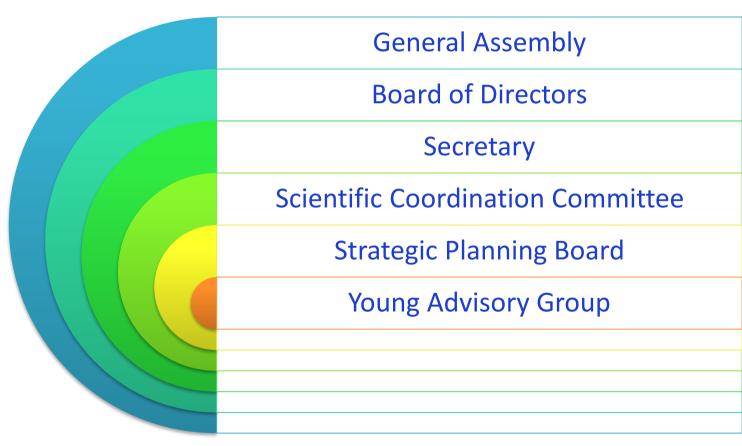
Physical persons participating to the collaborative groups and paying the association fee, annually established by the Assembly

Rights and duties of the Associated

- ➤ The admission is for an indefinite period, subject to the right of withdrawal and the continuation of the conditions of eligibility to the Association referred to in art. 3.
- The Associated has the **right to elect the TEDDY Network Bodies** and be elected in the same ones.
- ➤ The Associated has the right to be informed about the activities of the association and to be reimbursed for the expenses actually incurred in the performed activities.
- The Associated has to respect the statute and the internal regulation.
- ➤ The Associated will perform its activities in the association mainly in a personal, voluntary and free manner, without any profit, even indirect, on account of its personal availability.

opean Network of Excellence Paediatric Clinical Research

TEDDY Bodies





General Assembly

The General Assembly is the sovereign body of the TEDDY Network and consists of all the associated natural persons and legal representatives or their delegates of the associated legal persons.

The ordinary General Assembly resolutions are taken by a majority of the present.

The General Assembly must:

- approve the annual report on the activity of the TEDDY Network, the annual economic and financial statement and the forecast statement;
- determine the programmatic guidelines of the association's activity;
- approve the internal regulation;
- deliberate definitively on requests for new memberships and on the exclusion of members;
- elect the Association's Bodies;
- deliberate on what has been demanded by law or by statute, or subjected to its examination by the Board of Directors.



Board of Directors

The Board of di Directors is composed of a minimum of 3 and maximum 7 members elected by the Assembly among its components.

The Board of Directors performs all ordinary and extraordinary administration acts not expressly assigned to the Assembly; it prepares and presents to the Assembly the annual report on the activity of the association, the annual economic and financial statement and the forecast plan oc activities.

The Board of Directors is in office for two years and its components can be re-elected for two consecutive terms.





Secretary

The Secretary has the legal representation of the Association.

He/She is a member of and convenes the General Assembly and the Board of Directors.





Scientific Coordinating Commitee

The Scientific Coordination Committee (SCC) is set up to coordinate the scientific activities of the Network TEDDY and it is composed of at least 3 members appointed by the General Assembly.

The Committee will aim to monitor all the scientific aspects of the Network, share knowledge and experience among the associated, monitor and review the progress of scientific activities, and ensure that relevant scientific objectives are achieved. The Committee has the power to decide on the approval of scientific deliverables and the updating of the work plans.

At the initiative of one of its members, the Committee may also seek advice from experts on issues that require specific attention.





Strategic Planning Board

The Strategic Planning Board (SPB) is an advisory body whose purpose is to ensure consistency between the objectives of the TEDDY Network and the issues currently being discussed in the field of pediatric research.

It also plays a key role in the process of strategic planning of activities and projects, ensuring adherence to the high quality standards of the Network, including ethical principles, and establishing relationships with the Institutions involved and stakeholders.

It consists of at least 3 members appointed by the General Assembly.





Young Advisory Group

The Young Advisory Group (which may also be briefly referred to as "TEDDY Kids") is composed of 5 or more individuals aged 12 to 18, both patients and non-patients, recruited by the associated and selected based on their motivation and interest in clinical research.

Associated who are promoters of existing KIDS groups, will have the right to express at least one representative in the Young Advisory Group.

The Young Advisory Group has the following mission:

- peer support for young patients;
- support and information support for children, patients, and participants in pediatric clinical trials;
- training of the children on research;
- increase in public awareness.





