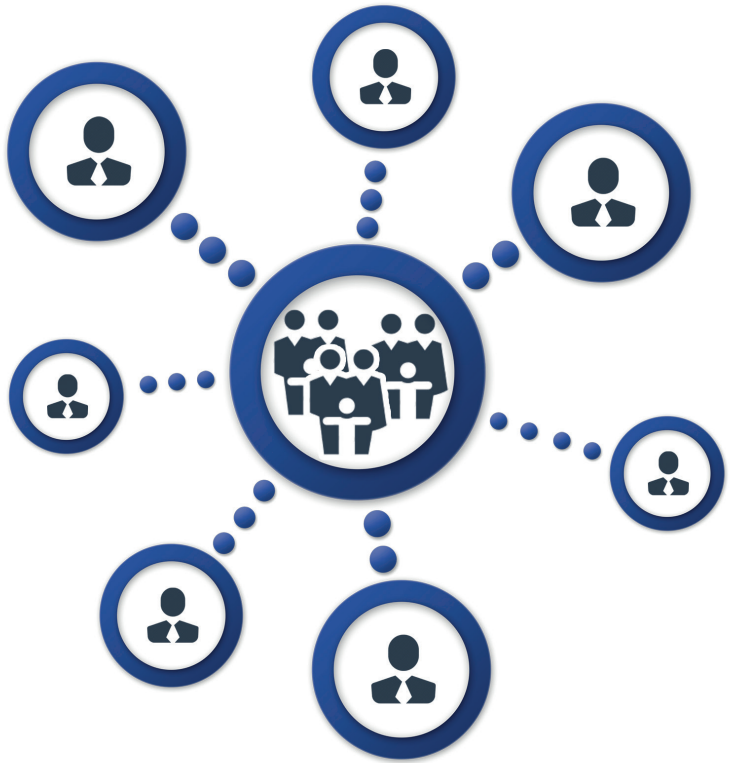
TEDDY
NETWORK
European Network of Excellence
for Paediatric Clinical Research



TEDDY NETWORK

European Network of Excellence for Paediatric Clinical Research

TEDDY is an **independent multidisciplinary and multinational research Network**, composed by partners from EU and non-EU countries aimed at facilitating the performance of good quality paediatric studies and research and **coordinated by CVBF - Consorzio per Valutazioni Biologiche e Farmacologiche**.

It was launched in 2005 as Network of Excellence (NoE) under the Sixth Framework Programme for Research and Technological Development (FP6) in response to a EU call with the aim of “structuring efforts devoted to the development of tailor made medicines for children”.

At the end of the funding period, TEDDY has revised its organisation and has collected research centres and groups willing to be engaged in developing paediatric clinical research as requested by the new regulatory scenario.

TEDDY is today a **category 1 member of Enpr-EMA** (the European Network of Paediatric Research at the European Medicines Agency) and a **registered network at ENCePP** (the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance).

TEDDY is also a **founder member of INCiPiT** (Italian Network for Paediatric Clinical Trials), a Network composed by the main Italian paediatric hospitals and scientific institutes for research, hospitalisation and health care (IRCCS) and other institutions which operate at different level in paediatric research.

MISSION

Promoting the performance of good quality paediatric studies and research

- To **plan, design and perform paediatric clinical trials (CTs) and studies** at national and international level covering different specialty area.
- To **implement good practices, Standard Operating Procedures (SOPs) and tools** to develop studies and research on medicinal products in an international framework.
- To **provide methodological expertise** to set up and manage paediatric clinical trials and other paediatric research.
- To **develop educational, informative and empowerment tools** for children and families.

INFORMATIVE TOOLS

TEDDY is now performing an online survey to collect general information on investigational centres in EU and non-EU countries participating in paediatric research. Results will be made available to Enpr-EMA and to all the national networks supporting its dissemination.

The European Paediatric Medicines Database (EPMD), containing information on paediatric drugs authorised by the European Medicines Agency (EMA) under the centralised procedure, has been created since 2007 and is constantly updated.

An Inventory of the Ethical and Regulatory procedures for paediatric clinical trial (CT) approval and conduction in EU and non-EU countries has been performed. It includes information on the relevant local and national requirements and procedures to apply Ethics Committees and Competent Authorities.

ACTIVITIES AND EXPERTISE

Having paediatric research as utmost priority, the TEDDY NETWORK can count on the expertise and collaboration of researchers, scientists, health experts and paediatric clinical research centres working together to identify the most appropriate research tools and procedures that reflect the specificity of the paediatric patient population. TEDDY is also particularly engaged in favouring awareness on the topics of paediatric research, to spread information on the rational use of paediatric medicines and to identify unmet medical needs in paediatrics.

It is a paediatric multispecialty Network which partners cover the following main therapeutic areas:

Haematology

Infectious diseases

Respiratory diseases

Intensive care

Pain

Endocrinology

Rare diseases

Neonatology

PROJECT MANAGEMENT

The project management area at TEDDY represents a support structure for ensuring high quality research and its implementation through managerial and administrative expertise. TEDDY started as a FP6 funded project and promoted, together with its members, several FP7 projects including research-driven paediatric clinical trials: CloSed, DEEP, GAPP, NeoMero, NeoVanc.

In the new Horizon 2020 framework, two projects have been funded: SMART - Small Medicines Advanced Research Training, a Twinning project started in 2016 which gathered 4 TEDDY members, and PedCRIN - Paediatric Clinical Research Infrastructure Network, an INFRADEV-3 project coordinated by ECRIN (European Clinical Research Infrastructure Network - ERIC) that involves CVBF-TEDDY as a partner.

CLINICAL TRIAL MANAGEMENT

The Network has the expertise to perform project and trial management activities and to monitor their performance, thanks to the setting up of a 'trial management infrastructure' including SOPs, data management and drug management plans, pharmacovigilance and monitoring plans, in order to deal with the complexity of multinational and multi-centre clinical trials.

It is also used to implement for each clinical trial submission a regulatory and ethical procedure including a unique Clinical Trial Application (CTA) 'package of documents', all in compliance with Good Clinical Practice (GCP) and CTs Regulation.

CLINICAL TRIAL MONITORING

All studies conducted under the TEDDY umbrella are submitted to monitoring procedures in accordance with GCP and other relevant rules related to each specific study, as specified in the Study's Monitoring Plan. A Site Initiation Visit is performed before the first patient is enrolled in order to ensure that everything is ready at each clinical site. Regular monitoring visits are performed to verify that the patients safety and well-being are protected, the reported trial data are accurate, complete and verifiable from source documents, and the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP and with the applicable regulatory requirement(s). Once all patients have concluded the study and the database is locked and ready for statistical analysis, a close-out visit occurs.

PLANNING AND DESIGN OF CLINICAL TRIALS

TEDDY is committed to setting up and implementing appropriate methodologies to conduct clinical research, with reference to innovative and traditional studies including population PK study, Modeling & Simulation, extrapolation. To this aim, TEDDY is both involved in the scientific discussion (as member of the GRiP - Global Research in Paediatrics Project) to prepare and disseminate recommendations and publication on this issue and in the practical development and conduction of paediatric national or multinational clinical trials using innovative methodologies.

CLINICAL TRIAL START-UP

Site feasibility is assessed case by case on the basis of a 'feasibility questionnaire' prepared according to the peculiarities and needs of each specific trial. Screening and participants' recruitment is carried out via participating centres and for each clinical trial, a feasibility study is carried out to evaluate centres' recruitment capacity and their compliance to the protocol requirements.

CLINICAL TRIAL CONDUCTION

TEDDY has implemented many SOPs for implementing and maintaining quality assurance and control systems on data management, drug management, monitoring, pharmacovigilance and clinical trial management as well as strategies for clinical trials conduction and patients recruitment optimization.

SOPs are aimed at ensuring that trials are conducted and data are generated, documented, and reported in compliance with the protocol, GCP, and the applicable regulatory requirement. A consistent and meaningful communication with site personnel is promoted and established and study progresses for each trial are timely communicated through regular newsletters and updates and alerts on the Network and projects websites.

REGULATORY AND ETHICS

The regulatory activity includes the preparation and supervision of dossiers and regulatory applications for European Medicines Agency (e.g. orphan designation, Paediatric Investigation Plans), including authorisation to perform national and multinational clinical trial activities. TEDDY contributes to face the regulatory burdens and the ethical issues aiming at reaching the European standards also in non-European countries. The activities of the TEDDY NETWORK also address aspects related to ethics in clinical research and are concerned with the granting of adherence to Good Clinical Practice in paediatric trials, also implementing the 2008 European Ethical Recommendations.

TEDDY NETWORK's support is provided for the preparation and submission of ethical, scientific and legal documentation to the Ethics Committees and European / National Authorities as well as for the implementation of European ethical and methodological high level standards. Protocols contents and procedures are shared with patients associations and all studies conducted under TEDDY NETWORK umbrella have received the ethical approval by ECs and CAs. Indeed, provisions highlighted in the 'Ethical considerations' document, including acceptable blood volumes and frequency of sampling in children, have been taken into account in all studies.

PHARMACOVIGILANCE

TEDDY has large experience in the conduction of pharmacovigilance activities from Serious Adverse Events (SAEs) handling to Development Safety Update Report (DSUR) preparation and submission as well as in the conduction of post-marketing studies. It is a registered network at the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) since September 2015. ENCePP is an initiative coordinated by the EMA with the aim of strengthening post-authorisation research, pharmacoepidemiological research and risk-benefit monitoring of medicines.

COMMUNICATION

The TEDDY NETWORK pays particular attention to the theme of empowerment of paediatric patients in the healthcare field. Children's active participation in the decision-making process is needed not only in the daily clinical practice, but also and especially in all the activities related to the development and use of drugs. TEDDY has a longlasting experience in the development of age-appropriate informative material to improve knowledge on the topics of paediatric research to layman people and promote the empowerment of paediatric patients involved in clinical trials. Patients and families are involved in the preparation of information packages for patients and parents (videos, leaflets, etc.) also through the organisation of focus groups as well as in the definition of therapeutic needs. TEDDY is also investigating the possibility to establish an YPAG (Young Persons Advisory Group) to be involved in the design of pediatric studies and in the preparation of consent/assent forms. In this sense, the TEDDY NETWORK will play a crucial role in contributing to raise awareness amongst the general public and decision-makers about paediatric diseases and their impact on patients' lives.

EDUCATION

TEDDY as GRiP member has actively participated in the setting up of the "Master Programme in Paediatric Medicines Development and Evaluation", leading the Training Module "Experimental Drug Evaluation in Paediatrics". In addition, through its own e-learning TEDDY platform, 19 e-learning courses on paediatric medicines and paediatric research are available for healthcare professionals interested to increase their knowledge and expertise to conduct GCP paediatric trials. The courses are regularly updated to take into account the evolving of the scientific and regulatory framework in paediatric research.

A special attention has been dedicated to the preparation of educational materials targeted to patients, aimed to contribute to make them able to directly participate in the decisions on their own health.

NEXT STEPS...

Towards the european paediatric clinical trials research infrastructure

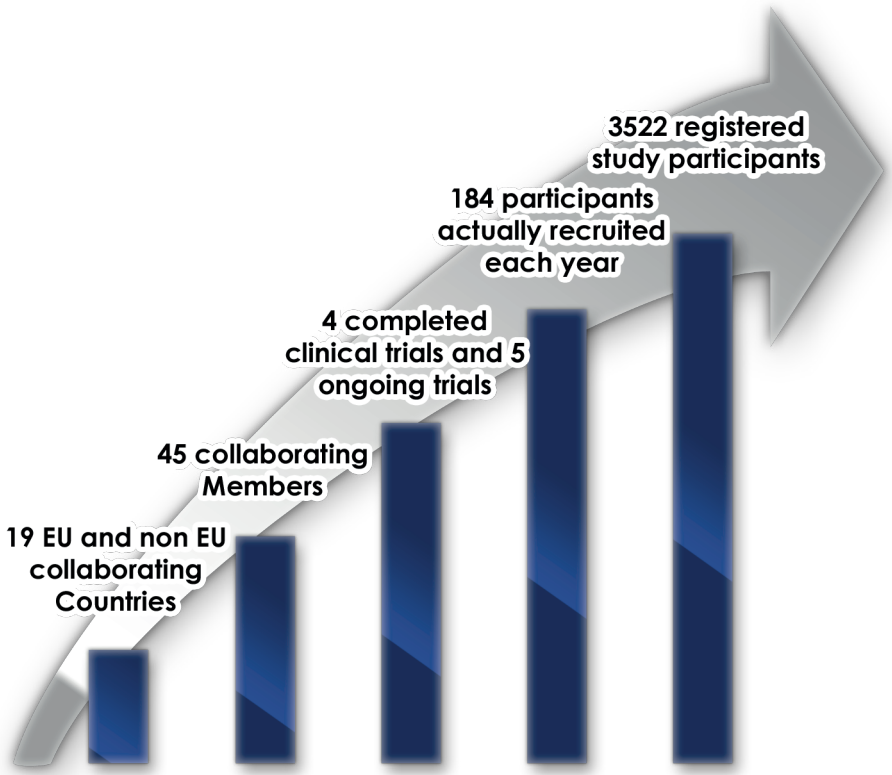
TEDDY is contributing to propose at European level the establishment of EPCT-RI (the European Paediatric Clinical Trials Research Infrastructure), a research infrastructure addressing the paediatric research theme all across Europe with innovative scientific and methodological strategies.

It will provide an integrated system for the conduct of paediatric clinical trials by facilitating the delivery and design of these trials, thus contributing to enhance industrial capacities and business in the field of paediatric medicines.

In this scenario, an online survey for the mapping of centres dealing with paediatric clinical research has been developed by several experts referring to the TEDDY Network (European Network of Excellence for Paediatric Clinical Research) with particular input from FINPEDMED (the Finnish Investigators Network for Paediatric Medicines), and agreed with Enpr-EMA, which includes 43 paediatric networks.

The information will be used to attract funding for national and specialty networks and will help mapping the European scenario of paediatric clinical research in the light of the research infrastructure setup for the conduction of paediatric clinical trials.

TEDDY NUMBERS



TEDDY MEMBERS

Assistance Publique - Hopitaux de Paris, France
Azienda Ospedaliera Antonio Cardarelli, Italy
Azienda Ospedaliera di Padova, Italy
Azienda Ospedaliera Ospedali Riuniti Villa Sofia-Cervello, Italy
Azienda Ospedaliero Universitaria Consorziale Policlinico di Bari, Italy
Azienda Ospedaliero-Universitaria di Modena, Italy
Barts Health NHS Trust, United Kingdom
Cairo University, Egypt
Centre National de Greffe de Moelle Osseuse, Tunisia
Charité - Universitätsmedizin Berlin, Germany
Childhood Cancer International, The Netherlands
Consorzio per Valutazioni Biologiche e Farmacologiche, Italy
Consorzio per Valutazioni Biologiche e Farmacologiche - Branch of Albania, Albania
Erasmus Universitair Medisch Centrum Rotterdam, The Netherlands
Erasmus MC Sophia Children's Hospital, The Netherlands
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Fondazione PENTA Onlus, Italy
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Hospital Universitario 12 de Octubre, Spain
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Medical and Public Health Services of the Cyprus Ministry of Health, Cyprus
National and Kapodistrian University of Athens, "AGIA SOPHIA" Children's Hospital, Greece
Ospedale Pediatrico Bambino Gesù, Italy
PharmaSich, LLC, Ukraine
PHARM – PHArmaceutical Research Management Srl, Italy
Phoenix Clinical Research, Lebanon
Romanian Angel Appeal Foundation, Romania
Società Servizi Telematici Srl, Italy
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University of Edinburgh, United Kingdom
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University of Liverpool, United Kingdom

Join the TEDDY NETWORK!

For more information, please contact the Network Coordinator at

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or visit our website

www.teddynetwork.net