

TEDDY Working Group on Paediatric Research Methodologies

**Working Group Chair:
Giorgio Reggiardo**



TEDDY WG on Paediatric Research Methodologies supports researchers for design, analysis and reporting paediatric clinical trial protocols.

This WG is in charge to support the TEDDY's membership in several EU and international initiatives, such as the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA), Accelerating Clinical Trials in the European Union (ACT-EU) Multi Stakeholder Platform, and the SPIRIT | CONSORT initiative.

Mission

To promote paediatric clinical research through the development of innovative methodologies, from study design to statistical analysis.



Objectives

The main goal of this working group is to **facilitate the adoption of innovative designs and advanced methodologies in paediatric research**, promoting a more efficient and innovative approach to clinical trials. This can be achieved through the following specific objectives:

- Develop and share innovative methodologies applied to paediatric clinical research.
- Promote the sharing of best practices and guidelines for drafting protocols and clinical reports in pediatric research.
- Support TEDDY's participation in networks and strategic initiatives - European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA), Accelerating Clinical Trials in the European Union (ACT-EU) Multi Stakeholder Platform, and the SPIRIT | CONSORT initiative.
- Strengthen cooperation among European and international stakeholders.

Main Activities

- Design innovative studies in paediatric clinical research.
- Provide expertise for applying innovative methodologies in defining the statistical approaches.
- Promote topics for participation in the ACT-EU Multi-Stakeholder Platform Advisory Group.
- Participate in collaborative projects and/or public consultations to promote innovative research in the pediatric research sector.
- Join international working groups for the development of methodological guidelines. Prepare publications with a methodological focus.
- Promote training through the organization of workshops dedicated to innovative methodologies in clinical research.

Benefits for Participants

- Access to specialized knowledge Gain insights into the most advanced methodologies in paediatric research.
- International networking Connect with experts and researchers from different countries.
- Future collaborations Opportunities to collaborate on joint projects and scientific publications.
- Continuous updates Stay aligned with the latest guidelines and innovations in the field.
- Professional visibility Showcase your work in international contexts and enhance your profile.



Key Elements for Planning Efficient Paediatric Clinical Trials

To ensure successful and innovative paediatric clinical research, the following elements have been identified as crucial:

- Adaptive Study Design & Master Protocols.
- Flexible approaches that allow modifications based on interim analysis results, improving efficiency and relevance of clinical trials.
- Leveraging existing data (Real-World Data & Historical Control Arm) to complement clinical findings and reduce patient burden.
- Surrogate endpoints used as substitutes for target clinical outcomes.
- Early indicators that predict clinical outcomes, accelerating trial timelines.
- Innovative Statistical Methodologies.
- Advanced techniques to enhance data interpretation and decision-making.
- Model- and Simulation-Informed Drug Development.
- Using predictive models to optimize trial design and dosing strategies.



How to Join the Working Group

If you're interested in joining this working group, please contact

Emanuela Crea at
scientificsecretariat@teddynetwork.net
and

Giorgio Reggiardo at
greggiardo@teddynetwork.net



www.teddynetwork.net



info@teddynetwork.net
scientificsecretariat@teddynetwork.net



Registered office: Via Nicolò Putignani, 178
70122 Bari, Italy



+39 380 4651073

