TEDDY involvement in the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

Annalisa Landi

Fondazione per la ricerca farmacologica Gianni Benzi – ETS

TEDDY General Assembly & Scientific Meeting

18 - 20 September, 2026, University of Bari Aldo Moro, Bari, Italy

TEDDY Health Data & Real-World Evidence WG

OBJECTIVE



- A dedicated TEDDY Working Group provides contribution to the **European Network of Centres for Pharmacoepidemiology and Pharmacovigilance** (ENCePP), in which TEDDY is represented and focused on the paediatric aspects

ENCePP ACTIVE WGs and SIGs

- Communications and Outreach
- Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology
- Independence and Transparency
- Artificial Intelligence (AI) in Pharmacoepidemiology and Pharmacovigilance
- Diversity and Health Equity
- Real-World-Data (RWD) sources in non-interventional studies
- Pragmatism in Clinical Trials
- Update of the ENCePP Checklist for Study Protocols
- Supplement to the Good Practice Guide for the use of the HMA-EMA Catalogues of real-world data (RWD) sources and studies
- Publication of selected chapters of the ENCePP Guide in Pharmacoepidemiology and Drug Safety and Value in Health

TEDDY NETWORK

TEDDY's involvement in ENCePP WGs and SIGs

Communications and Outreach

Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology

Independence and Transparency

Artificial Intelligence (AI) in Pharmacoepidemiology and Pharmacovigilance

Diversity and Health Equity

Real-World-Data (RWD) sources in non-interventional studies

Pragmatism in Clinical Trials

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TEDDY NETWORK

TEDDY's involvement in ENCePP WGs and SIGs

ENCePP WGs & SIGs



I. Revision of the ENCePP Guide on Methodological Standards in Pharmacoepidemiology

Chairs: Nhung Trinh (UiT – The Arctic University of Norway), Tania Schink (Leibniz Institute for Prevention Research and Epidemiology – BIPS)

TEDDY MEMBERS INVOLVED



MADLEN GAZARIAN

OBJECTIVES



- ✓ *Select and deliver revised (sub)chapters for Revision 12, for update of the **Guide on Methodological Standards in Pharmacoepidemiology** on the ENCePP website*
- ✓ *Develop a **strategy** for further periodic revisions and improvements*

TEDDY's involvement in ENCePP WGs and SIGs

ENCePP WGs & SIGs



II. Artificial Intelligence (AI) in Pharmacoepidemiology and Pharmacovigilance

Chair: Maurizio Sessa (Drug Safety Group, University of Copenhagen)

TEDDY MEMBERS INVOLVED



ANNALISA LANDI
CLAUDIA PANSIERI

OBJECTIVES



- ✓ *Map current **uses and perceptions of AI** within **PE and PV** across the ENCePP network and related stakeholders*
- ✓ *Critically **appraise available AI tools** relevant to the field*
- ✓ *Foster **collaboration and knowledge exchange** with other ENCePP groups*
- ✓ *Disseminate learnings through **targeted educational activities***
- ✓ *Define subsequent deliverables following completion and evaluation of the **initial mapping phase***

TEDDY's involvement in ENCePP WGs and SIGs

ENCePP WGs & SIGs



III. Real-World-Data (RWD) sources in non-interventional studies

Chairs: Christos Kontogiorgis (Democritus University of Thrace), Martín Solórzano (Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol)

TEDDY MEMBERS INVOLVED



ANNALISA LANDI

OBJECTIVES



- ✓ *Develop **metadata templates and feasibility tools** that can be directly applied during study planning*
- ✓ *Provide **fitness-for-purpose frameworks** to support the selection of data sources aligned with specific study objectives*
- ✓ *Clarify how **existing catalogues and networks** can be used in a complementary and non-duplicative way*

TEDDY's involvement in ENCePP WGs and SIGs

ENCePP WGs & SIGs



IV. Pragmatism in Clinical Trials

Chair: Maurizio Sessa (Drug Safety Group, University of Copenhagen)

TEDDY MEMBERS INVOLVED



CLAUDIA PANSIERI

OBJECTIVES



- ✓ *Highlight the value of **pragmatic approaches in CT**, and for which context (clinical and regulatory) and research questions this type of approaches is most suitable*
- ✓ *Foster consensus on **terminology, core methodological and design principles, data quality control and assurance measures***
- ✓ *Support **training and capacity building**: enhance expertise among ENCePP partners by providing educational webinars or workshops*
- ✓ *Expand **awareness** and support **collaborative efforts***



Annalisa Landi

Fondazione per la ricerca

farmacologica Gianni Benzi – ETS

al@benzifoundation.org