Patient Engagement in the GAPP Study: Approach and Planned Activities

RAISING AWARENESS THE TEDDY KIDS' WAY – Biotech Week 2026

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TEDDY - European Network of Excellence for Paediatric Clinical Research

Background & Objective

TEDDY Network plays a strategic role in advancing paediatric research.
Through dedicated engagement and advocacy initiatives, it **fosters the active involvement of children and young people**, while promoting children's rights in healthcare and in research participation.

Working Group on Engagement & Advocacy

Coordinates engagement activities and Provides methodological guidance, ensuring structured and inclusive participation.



Empowering young individuals by incorporating their perspectives in health-related decision-making is a fundamental right
(Art. 24, Charter of Fundamental Rights of the European Union)

Paediatric patients' engagement and empowerment TEDDY Model

Aim

- Promote children's empowerment as a priority in clinical research.
- Encourage young patients to actively participate in decisions affecting their lives.
- Reinforce children's specific knowledge and experience in health research.

Principles

- **Right to Involvement**: Children/young people participate in decisions impacting health and wellbeing.
- **Insight Contribution**: Young participants provide ideas and innovative solutions for pediatric needs.
- **Collaboration with Sponsors:** Sponsors review trial materials (protocols, summaries) and integrate meaningful input from children.

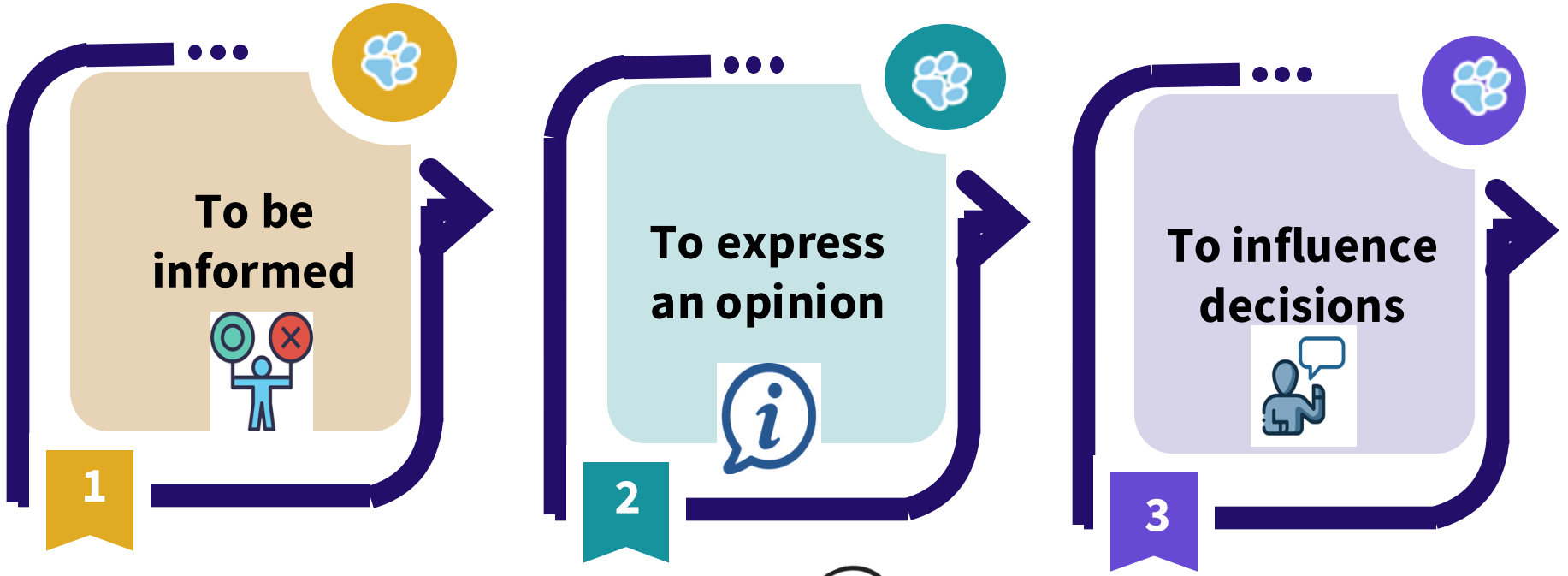


The model adopted by TEDDY NETWORK

Objectives

• Promote a shift in perspective that places the empowerment of children and adolescents at the center, recognizing their active role in decisions that affect them, and valuing their experiences and specific knowledge.

• The involvement of children in health and biomedical research is a progressive process, aligned with the development of their capacities, and involves different levels of participation:



TEDDY Charter

TEDDY Model: KIDS-YPAG Groups to Promote Children's Participation in Decision-Making Processes

Strong motivation **01**

Scientific contribution on par with experts **02**

Appropriate educational tools (cartoons, videos) **03**

Engagement with institutions and external stakeholders **04**

Our Statutes provide for an **ADVISORY GROUP – TEDDY KIDS**, one member of which is part of the **TEDDY Board of Directors**.



The first **YPAG** from **TEDDY** was established in 2017. To date, 10 groups are members of the **TEDDY KIDS Network** and are also part of **iCAN** (international Children Advisory Network).



TEDDY KIDS Network

The TEDDY KIDS Network includes the following YPAG groups:



- **POLPEDNET Warsaw**
- **KIDS Bari**
- **Eye YPAG London**
- **KIDS rare Hellas**
- **KIDS Albania**
- **KIDS Umbria**
- **ANDO Portugal**
- **RAiN Ireland**
- **KIDS Kosova**
- **KIDS Munich**

[TEDDY KIDS Network]



GAPP (GAbapentin in Paediatric Pain) Multinational Trial sponsored by TEDDY Network

Multi-center, non-profit Phase III, single-arm, adaptive, prospective cohort study to evaluate the pharmacokinetics, efficacy and safety of gabapentin liquid formulation in children from 3 months to less than 18 years of age experiencing moderate to severe chronic neuropathic, nociplastic or mixed pain.

Study Objectives

The primary objective of the study is to evaluate the effectiveness of gabapentin in reducing chronic pain intensity in paediatric patients.

Secondary objectives include:



Assessing the safety and tolerability of gabapentin in children and adolescents.



Characterising the pharmacokinetic profile of gabapentin across different



Evaluating the impact of treatment on quality of life, sleep and daily functioning.



Assessing treatment acceptability and overall patient and caregiver satisfaction.

FAST-EU Submission: 11th September 2026

GAPP Patient Advisory Board (PAB)

The Patient Advisory Board (PAB) is a dedicated advisory group of young people with lived experience, caregivers, and patient representatives. It provides patient-centred advice across all phases of the GAPP Study with representation on the Study Steering Committee (SSC) to ensure patient perspectives inform study oversight.

Why it matters

- Improve the relevance and acceptability of peadiatric research
- Address key challenges, including limited recruitment and the off-label use of medicines
- Strengthen participant-centred study design
- Support recruitment and retention

Applying the TEDDY Model: The GAPP Study Experience

Strong motivation **01**

To drive high engagement from the start in the creation of the **Patient Advisory Board** (PAB), TEDDY launched a targeted **Call for Interest** across TEDDY social media platforms and official website, alongside direct outreach to the **TEDDY KIDS Network**.

Expression of interest to join the Patient Advisory Board (PAB)— Gabapentin in Paediatric Chronic Pain study (GAPP Study)

May 30 2026



Applying the TEDDY Model: The GAPP Study Experience

Scientific contribution on par with experts **02**

TEDDY organised four **dedicated PAB workshops** during the study preparatory phase, bringing PAB members together with clinical experts to contribute to study design, clinical protocol review, consent/assent forms, patient diaries, and communication materials.



Applying the TEDDY Model: The GAPP Study Experience

Appropriate educational tools (cartoons, videos) **03**

Original scientific content: authentic clinical protocols, aligned with SPIRIT-C guidelines, were used to assess clarity and patient burden.

Empowerment: tailored visual tools and a technical glossary supported informed participation.

Interactive feedback: Mentimeter enabled real-time participant input, combining scientific rigour with patient empowerment.

Applying the TEDDY Model: The GAPP Study Experience

04 Engagement with institutions and external stakeholders

- Patient representation is embedded in the **PAB and SSC (Study Steering Committee)**, with a young patient representative joining **SSC meetings** and contributing to trial decisions.

- A **GAPP Roundtable** at the **TEDDY General Assembly & Scientific Meeting** brings together young PAB members, the **SSC and DSMB** to discuss the study and patient involvement.



The Patient Advisory Board: patient voices inside GAPP

The GAPP Study represents a concrete example of how the principles of the TEDDY Charter can be put into practice, transforming the involvement of children, adolescents, and families from simple consultation into active participation throughout the research process.