OrphaDev4Kids PROJECT

TEDDY General Assembly and Scientific Meeting
Saturday 19 September 2026 – Afternoon

OrphaDev4Kids Patient Expert Committee Parallel Session
Evaluation of paediatric and orphan Medical Devices innovative projects

Emanuela Crea

Co-funded by the European Union

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OrphaDev4Kids Project

Advancing Medical Device Paediatric Research for Rare Conditions

Co-funded by the European Union

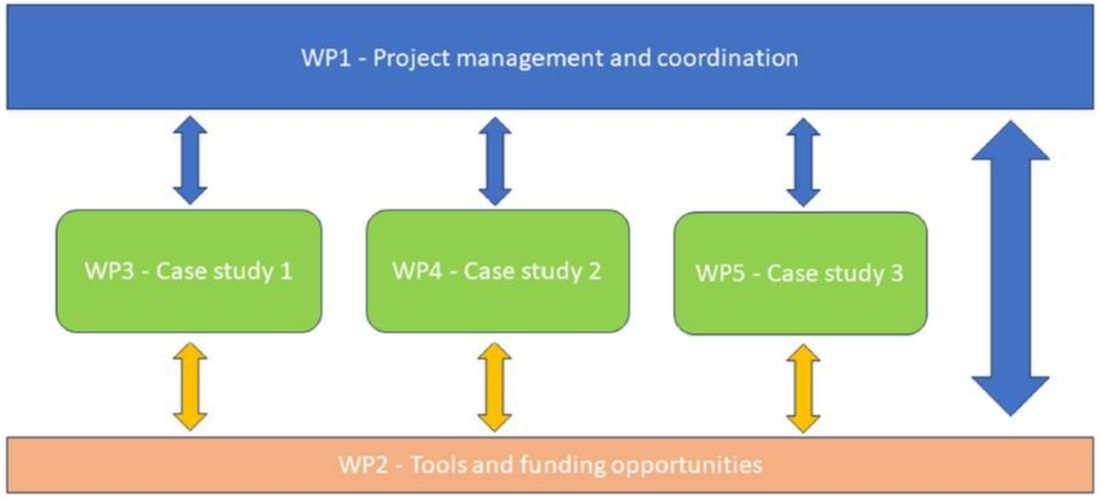
About us

OrphaDev4Kids Project is a consortium of researchers and clinicians aiming to address the issue of Orphan medical devices (MDs) to be used in the paediatric population.

Goals

To implement an innovation ecosystem in the orphan and paediatric MDs field to maximise the value-for-patients of the research and development projects supported by the Consortium.

Project's Work Plan



EPTRI
European Paediatric Translational Research Infrastructure

OrphaDev4Kids PROJECT

WP2: OrphaDev4Kids offers tools, facilities, and support to advance paediatric medical device development, maximising impact in pediatric MD research.

Services provided by OrphaDev4Kids Project

- Advice on all the development phases, from the plan to the completion of a paediatric development process, including:
  - prototype design
  - design of non-clinical specific studies and safety risks evaluation
  - design of paediatric clinical studies and performance tests
  - tests and measures necessary to perform relative studies
  - health technology assessment (HTA) studies
  - advice on ethic, regulatory and social issues
  - business plan development and IPR management
- Support in accessing funding and matching opportunities

Case study 1: Wearable multiplexed biosensor for cyanotic congenital heart disease

Support the development of a wearable multiplexed biosensor for the prevention of lactic acidosis in children with unrepaired congenital heart defects

Case study 2: Medical device for non-invasive cardiac assessment in patients with Tetralogy of Fallot

Support the development of a non-invasive medical device (Videocardiograph – VCG) for the assessment of the mechanical function of the heart in real time during open-chest surgery

Case study 3: Medical device for Bone Fragility

Support the development of an absorbable biocompatible implant with a paediatric indication for the treatment of bone fractures in children

ePTRI®
European Paediatric Transnational Research Infrastructure

TEDDY NETWORK

European Network of Excellence for Paediatric Research

Patients Expert Committee (PEC) and engagement of young patients in Orphan Medical Devices development

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TEDDY'S Involvement in OrphaDev4kids Project

In the OrphaDev4kids project, WP1 – Task 1.1 we have created the Patients Expert Committee (PEC), and we contribute to the engagement of children and young people through collaboration with several YPAGs which are members of the TEDDY KIDS Network.

TEDDY play a central role in the OrphaDev4Kids project by leading young patients engagement in Orphan Medical Devices development.

TEDDY supports the formation of the Patients Expert Committee (PEC) and ensures young patients' perspectives inform all project phases—from identifying unmet needs to guiding research and device feedback.

The Patients Expert Committee (PEC) will be engaged in the following activities:



Organization of Education and Training Modules

intended to shape the knowledge of the PEC on Medical Devices.

Incorporation of PEC's Opinion

Advice on the overall unmet needs on paediatric MDs and on the work plan for the development of three MDs-related case-studies.



How the Patients Expert Committee can support the project OprhaDev4kids?

The PEC plays a central role in ensuring that the voices and needs of paediatric patients are integrated into the development and evaluation of medical devices.

Providing Feedback from PEC Perspective:
The PEC reviews and gives input on medical devices, highlighting specific needs, concerns, and priorities relevant to children and young people.

Identifying Unmet Needs:
The PEC helps identify gaps in current medical device solutions for paediatric care, contributing to the definition of priority areas for innovation.

Shaping Research and Development Plans:
The PEC contributes to the design of research activities and the development plans of medical devices by offering insights based on real-life experiences of young patients and their caregivers.



Promoting Patient-Centred Approaches:
Through its work, the PEC fosters a patient-centred mindset in the development of paediatric medical devices, ensuring that usability, comfort, and acceptability are taken into account.

Collaborating with Researchers and Developers:
The PEC acts as a bridge between young patients and the scientific/clinical community, facilitating dialogue and improving the relevance and effectiveness of medical solutions.

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Patients Expert Committee (PEC) MEMBERS

TEDDY NETWORK
European Network of Excellence for Paediatric Research

Commitment of **TEDDY KIDS Network** to acts as Orphadev4kids Expert committee



YPAG	Name & Surname
KIDS ANDO PORTUGAL	Clara Sim-Sim
KIDS ALBANIA	Fiona Rako Enio Ibrahimi Niki Struga Steisi Prenga
KIDS BARI	Alberto Giandomenico Bartolomeo Sciancalepore Daniele Sciacqua Giorgia De Santis Leonardo Fiore Sara Cupertino
KIDS KOSOVA	Lir Salihu Riga Basholli
KIDS RARE HELLAS	Eirini Daskalopoulou
KIDS UMBRIA	Francesca Migno Francesco Barbetta
KIDS WARSAW	Karol Slowik

10 members are minors.

7 members are adults.



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PEC's Involvement in WP3 – Task 3.2 Advice on MD design and manufacturing

On 15 March 2025, the **kick-off meeting of the PEC** of the European project **OrphaDev4kids** was held at the University of Bologna, **organized by TEDDY** as part of **Work Package 3 (WP3)** of the OrphaDev4kids project.









The meeting opened with a presentation by Emilia Biffi, titled “Development of Paediatric Medical Devices: Identifying and Gathering User Needs”.

This was followed by a presentation from Roberta Nossa, who introduced the Survey on Cyanotic Congenital Heart Disease (CCHD) for patients. The survey aims to support the design of a wearable biosensor that will improve the quality of life for children living with CCHD.

The KIDS presentation session was opened by Aleksander Wiśniewski, who discussed “Enhancing Clinical Studies through Young Patients’ Involvement” in Poland.

The TEDDY KIDS then showcased their ongoing activities in the field of rare pediatric diseases.

The PEC of the OrphaDev4kids project played an active role in reviewing the CCHD patient survey

SURVEY FOR PATIENTS WITH CCHD



The Patient survey has been implemented on **REDCap** and it is **ready for dissemination**

🔗 Patient Survey – Medea REDCap

Thanks to the invaluable input and active involvement of the Patient Expert Committee (PEC), the survey has been thoroughly reviewed, refined, and successfully finalized to better reflect the needs and perspectives of the patients.



TEDDY Network's Contribution to WP3 Survey Dissemination through Its Stakeholder Network



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Patient Expert Committee (PEC) Workplan for Today

WP2 – T2.2 Access to matching services – Involvement in the evaluation process of research idea proposal on MDs for potential funding.

Objectives

1. Review the proposed medical device projects.
2. Share your opinion on their usefulness and relevance for young patients.
3. Identify strengths, concerns, and possible improvements.
4. Help ensure that future solutions meet the real needs of children, young people, and families.

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Thanks