



Face to face meeting of the Paediatric Patient Expert Group (PEG) on innovative methodologies based on in silico models and on the secondary use of health data

TRAINING PLAN

Under the framework of the European Invents project (HORIZON-RIA, N°101136365), a PEG will be created to educate and empower children and adolescents about the progress of biomedical research, including the latest advancements in health data and in clinical research methodologies and their relevance to certain paediatric rare diseases. The purpose of this PEG is to ensure the proper collection of patients' health data, including methodological considerations for data collection, reporting, management, and analysis, along with meaningful patient input.

Following an online introductory meeting, a **face-to-face training meeting** will be held in early November (2-3 November 2024).

The training will foresee case studies, practical activities and discussions to ease your understanding of the topics.

The meeting will be performed in English and the lessons will be prepared and delivered by a team of professionals, such as paediatricians, investigators, psychologists, representatives of patient' associations, Young Persons Advisory Group (YPAG) facilitators, legal, ethical, and regulatory experts.

The INVENTS face-to-face training meeting is composed of 3 educational modules. Each module has a 3-hour duration and 4 lessons. Facilitators will be in charge of ensuring that the topics dealt by teachers will be well-understood by participants: Yanis Mimouni/Sarah Zohar (France), Alessandra Natale (Italy), Kit Roes/Joanna in 't Hout (The Netherlands) (to note: so far, participants from Italy, France, UK and the Netherlands declared their availability to join the PEG).

Each lesson will be introduced by a 10-minute presentation and then followed by questions, games, and practical exercises. The lesson format is a graphic presentation commented by teachers.

An introduction will be held by INSERM/ WP6 representative at day 1 before the delivery of the educational modules to explain the roles of the PEG in the next two years of the project. Educational modules:

1. General training

This module will introduce general information about rare and paediatric diseases, unmet needs, ethical aspects, like children's rights in health and research, paediatric assent, ethical and regulatory implications of data collection and data reuse, GDPR, management of incidental findings. These concepts will be provided by the following lessons.

Lesson 1: What is paediatric research, children's rights in health and research - *Mariagrazia Felisi*
Lesson 2: Data collection and reuse - *Markus Elze*

Lesson 3: How innovation can improve paediatric clinical research, children's health and wellbeing - *Maria Panagiotopoulou*,

2. Disease/product-specific training

This module will provide insights on the relevant diseases and update on the medicinal products development (e.g. tocilizumab and secukinumab products indicated for patients with rare juvenile idiopathic arthritis, polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis and giant cell arteritis; fingolimod product indicated for paediatric patients with multiple sclerosis).

Lesson 1: Rare paediatric arthritis in a nutshell, old, new and upcoming medicines to treat paediatric arthritis – *Roche representative*

Lesson 2: – Paediatric multiple sclerosis in a nutshell, old, new and upcoming medicines to treat paediatric multiple sclerosis - *Marina Savelieva*

3. Training on the research methodology foreseen in INVENTS

This module will provide insights, relevance and advantages on traditional clinical trials and innovative approaches e.g. innovative trial designs, in silico trials, virtual cohorts, real world data (RWD) use.

Lesson 1: New methods for prospective studies involving children - *Maria Panagiotopoulou*

Lesson 2: New methods invented with a scientist laptop - *Tim Friede*

Lesson 3: Could data from real-world provide insightful inspiration for biomedical research?
- *Kit Roes*

All the modules will be complemented with practical activities and will be conducted with several educational tools, including serious games, videogames, videos, infographics, presentations, and comics books to provide scientific and legal concept in a fun and comprehensible way. After the classroom-taught engaging lessons and practical activities,

short assessment questionnaires will be distributed to participants to test their acquired knowledge.

Here below, a list of some interactive tools foreseen in the training programme is:

- *My Clinical Trials Center (MY CTC game)*, a videogame developed by TEDDY on the basis of the 'play to learn' principle. It's an educational tool aimed at explaining in a fun way what clinical trials are and why they are so important for the research process.
- *Clinical trial explained for kids*, an animated video developed by the Sant Joan de Déu Children's Hospital, used during the third course. The video targets paediatric patients involved in clinical trials and has been developed with the collaboration of the Scientific Council of teenagers of the Sant Joan de Déu Children's Hospital.
- *The comics book "A journey through clinical trials"* developed by the Children's Memorial Health Institute in Warsaw (Poland) within the c4c project, an IMI funded project. The comics highlights the key issues of clinical trials to help inform and educate broad populations of children and adolescents about the difficult subject of clinical trials.
- *"Have Your Say"* an animated video produced under the Council of Europe initiative focused on children's participation in the decision-making process on matters regarding their health. Developed in collaboration with TEDDY Network, the video employed a participatory methodology involving young people from the TEDDY Kids group, aged between 12 and 18 years.