

## **Paediatric patients' engagement and empowerment to participate in biomedical research.**

### **The TEDDY Network CHARTER**

#### **Premise**

The active participation of children in decision-making processes, according to their age and maturity, is crucial in routine clinical practice, but also in the experimental process to develop innovative medicines and therapies. Moreover, empowering children and young individuals by incorporating their perspectives in health-related decision making is a fundamental right. When children and young people participate in the processes regarding their health, they develop valuable skills and self-esteem and acquire the ability to manage their condition and treatments more effectively. To promote children empowerment and effective partnerships with health professionals, several Young Person Advisory Groups (YPAG) have been established in several countries of the world within the International Children's Advisory Network (iCAN), and other National or International Networks.

The TEDDY Network has been working on YPAG establishment since 2017 with KIDS Bari (Italy) and KIDS Albania, which are also both members of iCAN.

This Charter describes the TEDDY's model and aligns with the iCAN principles.

#### **Aim of the Charter**

The aim of this Charter is to promote a change in attitudes in order to make the children's empowerment a priority in the clinical research field. This implies that young patients must take an active role in activities or decisions that impact on their life and that their specific knowledge and experience should be reinforced.

The Charter is based on the following Principles:

- (i) Children and young people have the right to be involved in decisions that will impact health and wellbeing through shared goal setting with clinicians and sponsors.
- (ii) Young participants are eager to provide their insights into research ideas and innovative solutions, aiming to address unmet paediatric needs and hasten the development of medicines tailored to children.
- (iii) Sponsors willing to collaborate with TEDDY KIDS/YPAG GROUP, agree to review the trial materials (e.g. protocols, lay summary) and procedures, incorporating any meaningful input and feedback provided by the participants.

#### **TEDDY model**

In the TEDDY model the involvement of children in health and biomedical research, is regarded as a progressive process, made according to their evolving capacities, and implies four levels of participation, also applicable to all the aspects of their life:

1. being informed
2. expressing a view
3. influencing decisions
4. sharing opinion peer to peer.

Moreover, the process funds on the creation of Young Persons Advisory Groups (YPAGs) and KIDS (Knowledge Impacting Diseases through Science) groups.

## **Set up of Young Persons Advisory Group (YPAG or KIDS)**

TEDDY YPAG and KIDS consist of youths actively participating in advising researchers and their teams on a full range of research studies, including clinical trials and other initiatives relating paediatric healthcare. Engaging children early in the research process allows to design studies and trials according with their needs, priorities, and perspectives. Their ability to provide fresh perspectives on a research study can help researchers address research questions and trial designs alongside with the improvement of a communication strategy with the target population and for dissemination of research findings.

Many YPAGs also work on research projects on their own and participate in science conferences where they present their findings and explain the importance of their involvement in research.

Each YPAG is composed of adolescents usually aged from 12 to 17 years old with some younger or older children entering or exiting the group with flexibility and includes both healthy children and patients with a particular health condition or disease. To setup a YPAG, several steps are foreseen as shown below.

### **1- Identification and engagement of YPAG members**

Patients living with specific diseases are identified case by case through specialised Networks, Paediatric clinical trials centres and Paediatric research organisations already collaborating with TEDDY. Suggestions from sponsors and investigators will be collected and implemented. In TEDDY experience, apart from patients living with a disease, healthy adolescents are involved with the aim to engage them in the analysis of the issues related to the disease and advocating for children's right during both research and current therapy.

To engage the members of the group, a multidisciplinary approach is adopted thanks to the collaboration of a team of professionals, such as investigators, child psychologists, pharmacologists, paediatricians and communication experts. Ad hoc tools are employed (e.g., questionnaires) to measure their interest, level of knowledge and motivation.

### **2- Provide education & training**

Several educational modules are proposed and adapted to the project specificities. The modules include:

- General training (education on biomedicine, research and innovation, rare/non rare paediatric diseases, paediatric drug development process, unmet research needs, ethic and legal aspects, children rights in health and research etc...)
- Disease/product-specific training (disease detail, product characteristics and expected effects, etc...)
- Training on the research methodology (traditional clinical trials, innovative in silico trial approaches, role and advantages from RWD use, etc...).

All the modules are complemented with practical activities (visit to laboratories, clinical settings, 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 are distributed to participants to test their knowledge and appreciate their acceptance level.

### **3- Assist Young people participating in health decisions**

To promote children's ability to express their personal view and influencing decisions, a methodology based on an active participation is adopted to directly involve the group in a series of practical activities to ultimately

establish a pair-to-pair dialogue with healthcare professionals, regulators and commercial sponsors. To this end children are supported in leading pair-to pair discussions, i.e. by the participation to setting up a study protocol or by joining an Ethic Committee discussion, and other meetings or Conferences where the voice of children may be relevant.

At the end of this process, expert children demonstrate to be able to identify and defend their interest in research and clinical practices as well as to assess if the expected goals have been achieved.

### **Expected output from patients' participation**

The expected outputs from children engagement and participation in biomedical research and health decision include:

- Young people may be asked to revise assent forms to participate to clinical trials or other studies involving adolescents and younger children, through analysis of the test and use of questionnaires or focus groups to collect feedback on unclear contents and to provide suggestions for further improvement.
- Children will be involved in developing and assessing the appropriateness of several age-specific information materials, summaries of the studies' results and awareness campaigns.
- Interaction with interested stakeholders including companies' representatives and regulators may include:
  - Engage in the process through consultation activities
  - Provide input on research ideas, innovative solutions, unmet paediatric needs identification and priorities
  - Contribute to the design and implementation of clinical and other research studies for children.

### **Collaboration with Sponsors**

When potential sponsors, whether from pharmaceutical companies or academic institutions, express their will to establish a collaborative effort with children's groups, the core principles stated in this charter should be recognised and endorsed as basis of the collaboration. Sponsors should agree on the following principles:

- the voice of people living with a paediatric disease should be represented in any phase of experimental studies and health care organisations involving children;
- the children's interests should be prioritising again any other interests;
- children should receive adequate information on the study or the proposal under evaluation to allowing them to express their informed point of view;
- the children views may influence the sponsors' decisions throughout the entire clinical study process;
- the KIDs and IPAG groups independence and freedom in expressing their opinion should be always guaranteed and respected.