



Working Group

**Active engagement of children and adolescents in
the themes of clinical research**

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PATIENT EMPOWERMENT

WHO (World Health Organization) defines empowerment as “a process through which people gain greater control over decisions and actions affecting their health” and should be seen as both an individual and a community process.

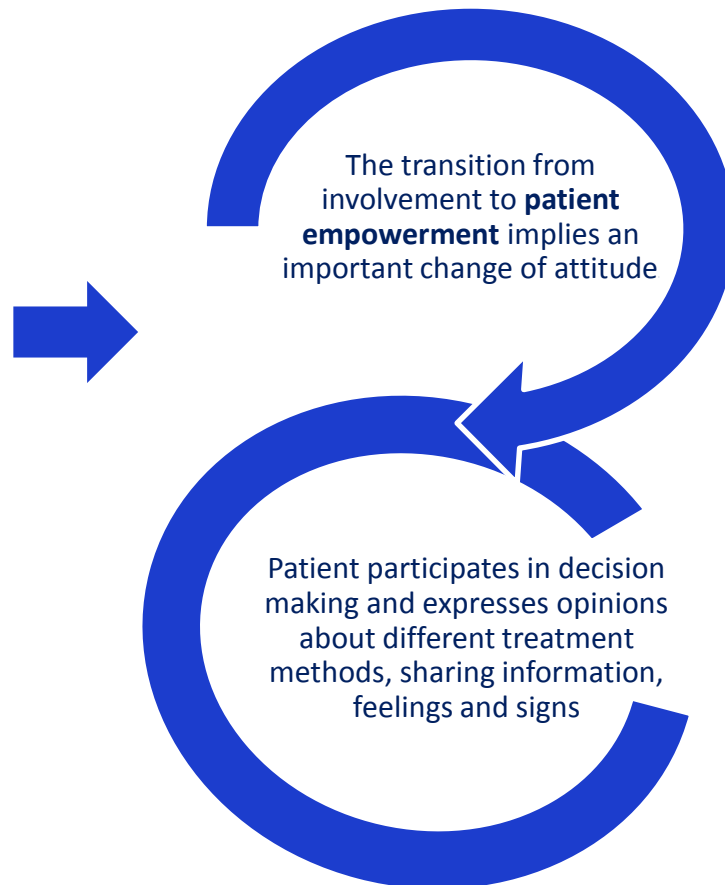
Health promotion glossary. Geneva: World Health Organization; 1998.



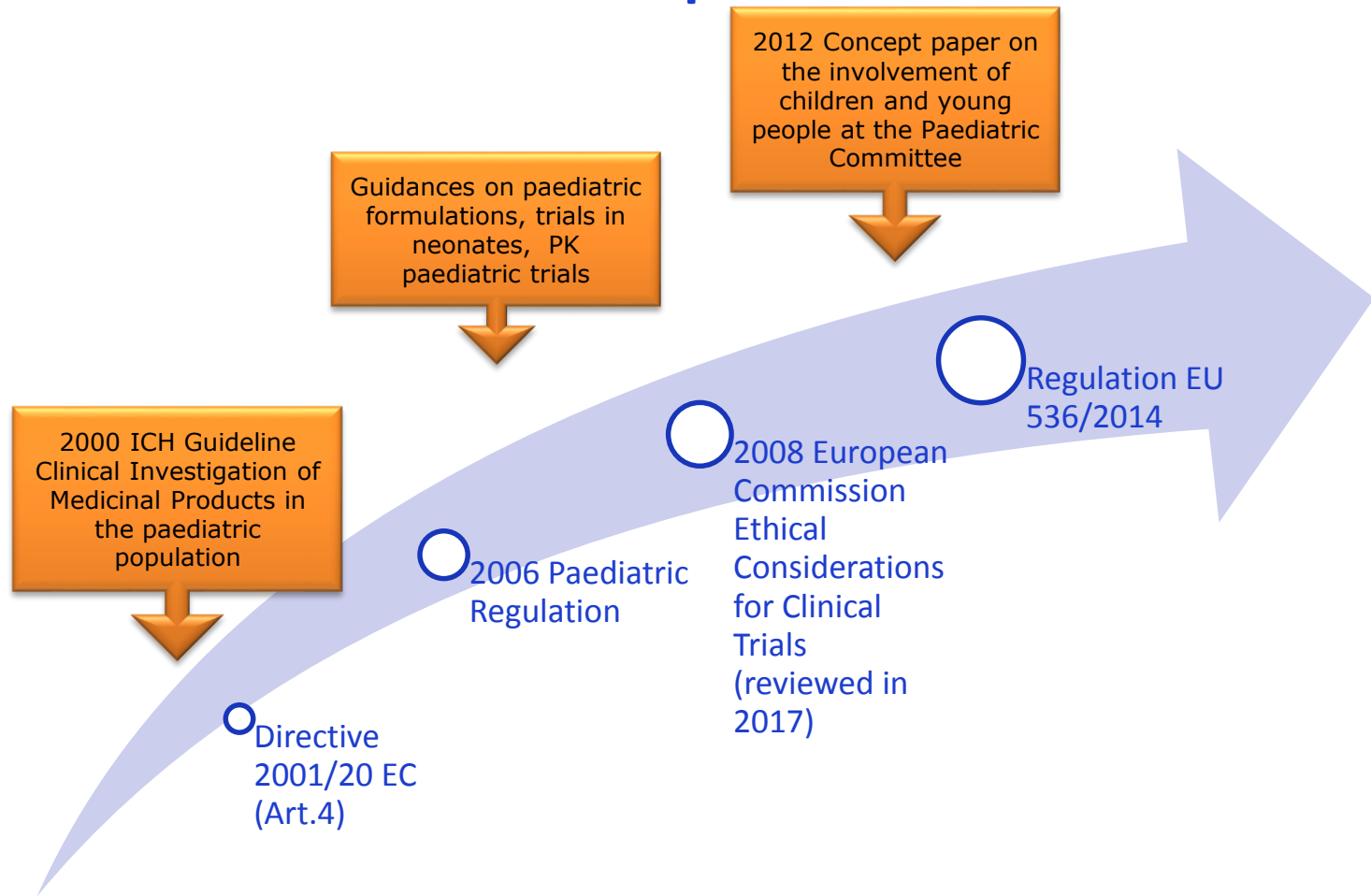
It is an approach encouraging the active participation and self-determination of the patients in the caring procedure. An empowered patient acquires the critical tools to make decisions regarding his/her health and interact with healthcare professionals.

Paediatric patients' participation in medicines research and development

1. understanding by the patient of his/her role
2. acquisition by patients of sufficient knowledge to be able to engage with their healthcare provider
3. patient skills
4. presence of a facilitating environment



Children in medicines research and development



Patient Engagement

- **Children's active participation in the decision-making process** is needed not only in the daily clinical practice, but also and especially in all the activities related to the development and use of drugs.
- **Children and parents should be involved** not only in the revision of clinical study protocols but also during the whole research development process!



Why this Working Group?

- TEDDY is particularly committed in the **development of age-appropriate informative materials** to duly inform children and families.



- TEDDY has been working for several years to **raise social awareness on the importance of patients engagement**, in particular children involvement, in all the phases of clinical research. The first two YPAGs in Italy and Albania have been developed in collaboration with CVBF.



Mandate

The aim of this working group is to promote a change in attitudes in order to make the patients empowerment a priority in the clinical research field.

Considering that patients have to take an active role in activities or decisions that will have consequences for the patient community, because of their specific knowledge and relevant experience as patients.

Minor shall take part in the informed consent procedure in a way adapted to his/her age and mental maturity.



Objectives

- Promoting dialogue among different actors (patients, carers/family representatives, expert patient advocates, etc.), to increase the active engagement of children and adolescents in the themes of clinical research.
- Encouraging the active participation and self-determination of the patients and their parents in the caring procedure, promoting their involvement not only in the revision of clinical study protocols but also during the whole study development.
- Providing patients with all the critical tools and expertise to make decisions regarding his/her health and interact with healthcare professionals, with a particular focus on rare diseases.

Objectives

- Developing a clear guidance on Patient and Public Involvement (PPI) in different areas of the medicines development process in order to enhance quality and relevance of the research itself.
- Promoting the development and dissemination of age-tailored information materials, summaries of the results and awareness campaigns through the direct involvement of patients.
- Encouraging the sharing of information and best practises among the different Young Persons Advisory Groups at European level and worldwide.

Action points

Action point 1:

Contribute to the “EMA action plan related to the European Commission's recommendations on product information” by sending an overview of initiatives on electronic/digital formats for the product information that we are aware of or working on. More information are available here:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/11/news_detail_002853.jsp&mid=WC0b01ac058004d5c1

- ❖ **Deliverable:** Survey completion available at: <https://ec.europa.eu/eusurvey/runner/EPI>
- ❖ **Timeline:** By end of February 2018. This input will be considered for the organisation and participation in the 2018 workshop.

Action point 2:

Organise a reasoned reading of the current product information sheet with the children of the YPAGs to highlight what should be changed to make it more understandable.

- ❖ **Deliverable:** Kids proposal of improvements
- ❖ **Timeline:** By 31 May 2018

Action point 3:

Promote the development of the paediatric page of the product information sheet for EU medicines, that can be easily understood also by the children.

- ❖ **Deliverable:** Proposal to be presented at the 2018 multi-stakeholder workshop organized by EMA together with the European Commission in the third quarter of 2018 to develop key principles for the use of electronic formats.
- ❖ **Timeline:** By June 2018

Action points

Action point 4:

Develop the summaries of the results of some projects in which TEDDY is directly involved.

- ❖ **Deliverable:** Development of the summaries of the results of the DEEP project
- ❖ **Timeline:** By end of August 2018

Action point 5:

Developing a clear guidance on Patient and public involvement (PPI) in different areas of the medicines development process to enhance quality and relevance of the research itself (starting from the Eupati guidances models)

- ❖ **Deliverable:** Guidance on PPI
- ❖ **Timeline:** By December 2018.

Action point 6:

Involve patients and their parents in the revision of assent forms of selected clinical trials in which TEDDY is involved

Deliverable: ?

Timeline: June 2019

Action point 7:

Organise a communication campaign and event to raise awareness on the active engagement of children and adolescents in the themes of clinical research

- ❖ **Deliverable: ?**
- ❖ **Timeline:** By December 2019

Thank
You



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