

## Public consultation on "Summary of Clinical Trial Results for Laypersons"

### Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use

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Organisation: TEDDY - European Network of Excellence for Paediatric Clinical Research

Category: Network of Excellence

TEDDY - European Network of Excellence for Paediatric Clinical Research, is pleased to respond to the public consultation on "Summary of Clinical Trial Results for Laypersons".

TEDDY is an independent multidisciplinary and multinational network composed by partners from 15 EU and non-EU countries, where researchers, scientists and health experts work together to identify the most appropriate common rules that reflect the specificity of the patient population. TEDDY is a member of Enpr-EMA (the European Network of Paediatric Research at the European Medicines Agency) and of ENCePP (the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) at EMA and is aimed to implement good clinical trials (CTs) practices and tools as well as to develop studies and research on medicinal products in children in compliance with EU legislation and guidelines. Among others, TEDDY is experienced in developing communication and educational tools tailored for children in order to facilitate their participation in all the relevant experimental procedures including assent and consent forms preparation.

Considering the relevance of the theme of empowerment of paediatric patients in the healthcare field, **we propose to include the paediatric aspect** in the consultation document by adding a paediatric paragraph and a paediatric section in the annex 1.

#### Justification

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. In the last years, the idea that children's preferences should always be taken into consideration is agreed upon also among parents. For this reason, healthcare professionals have to consider children and families' active participation as a fundamental step to reach consensus and compliance to treatments.

Furthermore, in 2012, following a large consultation phase, the Paediatric Committee (PDCO) issued a [Concept Paper](#) on the involvement of children and young people in its activities, with the children's best interests as primary consideration. It has to be also highlighted that the setup of a child-friendly approach

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implies a collaborative and continuous action involving paediatricians and healthcare professionals, psychologists, families, children.

It is universally established that written communication, combined with verbal interaction, may enhance children's understanding of their participation in a clinical research (Ungar et al 2006) as well as the contents and styles of documents addressed to children are elements that largely influence their understanding of written documents. As an example It has been demonstrated that the use of pictures, following appropriate recommendations, improves the quality of communication, especially for patients with very low literacy skills (Houts et al 2006). However, available data and publications show that ad hoc informative strategies for empowering minors in clinical trials are rarely produced. In addition the difficulty increases in multicentre trials, involving countries with different cultural and educational backgrounds.

Children have the right to know and get access to the resulting evidence based medicinal products and should be involved in the process as much as possible, using age appropriate information.

Children and parents should be involved not only in the revision of clinical study protocols but also during the whole study development. Furthermore, it is necessary to recognize that a standard model of information is not valid for all age groups above all for extreme groups. In particular, in addition to parents, children (6-10 years), adolescent and mature minor if older than 16 year).

These concepts are clearly underlined also in the consultation document "Ethical considerations for clinical trials on medicinal products conducted with minors" stating that: "the investigator and protocol writer should ensure that there is involvement of children (suffering from the relevant condition) and of families in the development of information material, and where feasible also in the design, analysis and conduct of the trial."

Consequently, even if the paediatric population is not specifically cited by the EU Clinical Trials Regulation 536/2014 (Article 37) requiring sponsors to provide summary results of clinical trials in a format understandable to laypersons, children cannot be excluded by the advantages of this obligation.

### **TEDDY proposal**

**In the light of the above considerations, we claim for the inclusion in the proposed Recommendations and Templates for authors of laypersons summary, of specific reference to the paediatric population. In case of studies involving children, the laypersons summary should be written in age appropriate, simple and understandable language to ensure ease of reading by parents and by children.**

**Categorization of the information should be provided corresponding to the different minor ages needs and capacities to understand the message.**

To this aim, **the existing "Young Persons Advisory Groups (YPAGs)"**, or similar groups including both patients and non patients may be involved in the preparation of the final documents.

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The document has been promoted by the TEDDY Network Boards (Scientific Coordinating Committee and Strategic Planning Board) on behalf of the TEDDY Network.

If you have any questions, please contact the TEDDY Scientific Secretariat at [teddynetwork@cvbf.net](mailto:teddynetwork@cvbf.net).

## References

Houts P, Doakb C, Doakb L, Loscalzoc M (2006) The role of pictures in improving health communication: A review of research on attention, comprehension, recall, and adherence Patient Education and Counseling 61:173–190

Ungar D, Joffe S, Kodish E (2006) Children are not small adults: documentation of assent for research involving children J pediatr 2006;149:s31-s3

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