What is a clinical trial?

It is the study with patients of a drug, diagnosis technique or medical device with the aim of analysing its security and safety.

Statistical data has shown that over 50 % of the drugs that are prescribed for children have only been studied with adults. In this context, and with the challenge of assuring the highest level of security of these drugs, the **EMA** (European Medicines Agency) establishes as a mandatory requirement the submission of a **Paediatric Investigation Plan** (PIP) for the study of their administration in children before their authorization.

Depending on the country, young patients under 18 years old who are going to participate in a clinical trial have to sign the **assent document** to be able to participate in the trial. A similar document has to be signed by the parents.

[1] Conroy S et al. Br Med J. 2000;320:79-82

Resources of interest

Tool-box of Eupati
www.eupati.eu

International Children's Advisory Network (ICAN)
www.icanresearch.org

Spanish Agency of Medicines and Medical Devices
www.aemps.gob.es

Search engine of clinical trials of the European Commission
www.clinicaltrialsregister.eu

Clinical Trials (U.S. National Institutes of Health)
http://clinicaltrials.gov

Health research: making the right decision for me.
(Nuffield Bioethics – YouTube)

Kids Barcelona: young person's advisory group
(YouTube- Hospital Sant Joan de Déu)

EUPATI
European Patients' Academy on Therapeutic Innovation

Informed consent document addressed to paediatric patients: the assent

Guidelines for a design focused on the children

By

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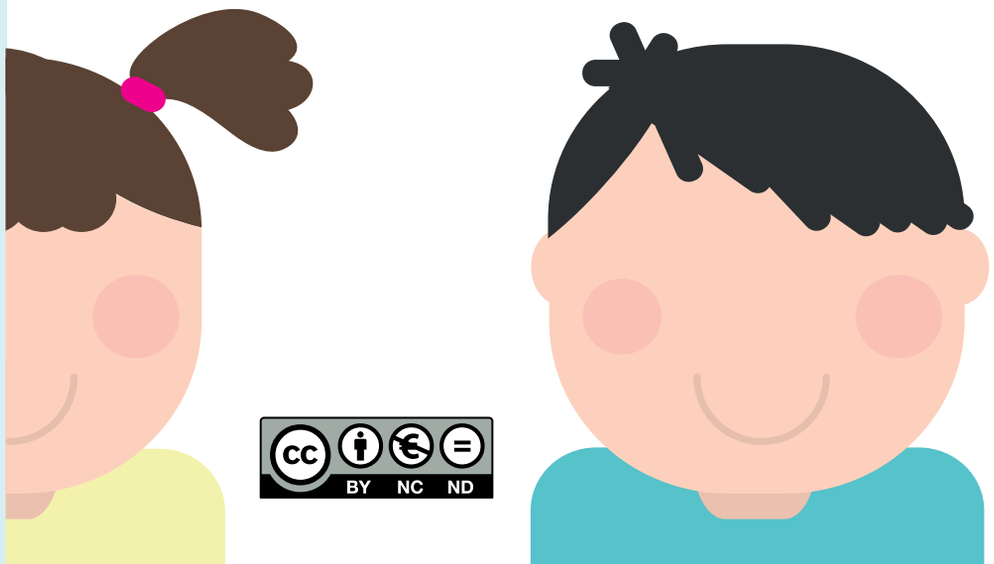

The **Young Person Advisory Group** (YPAG), Kids Barcelona, of Sant Joan de Déu Hospital (Barcelona-Spain) has written some guidelines with a collection of recommendations to be considered by the sponsors of the clinical trials (drug companies, researchers, etc.) and for the ethics committees of the research centres, with the aim that the informed **consent document** (or assent document in the case of paediatric patients) be fully adapted to the children's necessities of information.

The **participation** of a child in a clinical trial must be **voluntary**, and for this reason his/her consent is necessary from a certain age.

This is an altruistic act that contributes to the advancement of science in the treatment of a specific disease.

It must also be ensured that the child or young patient knows his/her rights, what will happen during participation in the study and the important contribution of clinical trials for medical science.

Recommendations on the **content**

- Concise content.
- Use easy to understand vocabulary.
- Include a general explanation of what a clinical trial is.
- Easy understandable explanation of the possible side effects of the drug under study.
- Include a glossary with definitions of the most difficult words to understand.
- Detail the basic contact data of:
  - Principal investigator (PI)
  - Hospital responsible
- Describe what to do in case of emergency, who to connect, how to proceed.
- Audio-visual resources, such as a video or cartoon can make it easier to understand the purpose of the study.

Recommendations on the **format**

- Length from 2 to 5 pages.
- Font size: between 12 and 14 points.
- Always address the child in the second person singular.
- Do not use the term "subject".
- Use the term "patient" or "boy / girl"
- Use colour, drawings, photos or infographics to facilitate the understanding of the information.

CLINICAL TRIAL GUIDE

A CLINICAL TRIAL GUIDE which can be easily used by children, that can be carried, may facilitate their participation:

- Include a calendar
- A space for taking notes
- A glossary with scientific terms
- With more visual than written content

These recommendations have the approval of the Ethics and Research Committee of Hospital Sant Joan de Déu.