

RESPECT project: Why do parents let their children participate in clinical trials?

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Background

During the past seven years, European paediatricians and clinical researchers have shown growing concern regarding the lack of evidence-based prescription and use of medicines on children. Clinical trials must be conducted before the pharmaceutical company is able to obtain a licence to market a product. However, these trials have been almost exclusively conducted in adults until recently.

This results in medicines licensed only for use with adults being prescribed by European paediatricians to children and young people. Without evidence from formal trials with children, they have to rely on clinical judgements about the correct dose and even the applicability of the medicine for paediatric patients. They may also apply the medicines to different indications, that is to say, 'off-label' prescription. In most European countries, more than 50 percent of medicines are unlicensed or used 'off-label' for children.



An EU regulation (EC 1901/2006) now requires paediatric clinical trials before a drug can be licensed for use with children, which means that significantly more children will have to participate in such studies.

Purpose

The RESPECT project has two aims: firstly, to identify the needs of children and their families as related to participation in clinical trials for new drugs in Europe. Secondly, to identify methods by which these needs can be translated into empowering and motivating families who are approached about the child's participation in a clinical trial.

We intend to disseminate these outcomes and widen the debate to encourage a better-informed and more collaborative European patient and research community. The results will be directly implemented by the partners, who represent a cross-section of actors at different levels of the clinical trials area. The results should be applicable to all medications and all medical conditions and also transferable to adult clinical trials as the relevance of patient empowerment will also be applicable to adult patient groups.

Responses from parents and children in clinical trials

- Parents often assume there are no risks involved in a trial. They trust the doctors and rarely refuse to participate.

"It's good that it's the same doctor at the same hospital. It feels safer here."

- No-one wants their child to suffer. Needles are particularly distressing.

"I wouldn't let my son be used as a 'guinea pig' in an experiment that could harm him."

- Parents vary in the degree of autonomy they give the child to make the decision. Most often, the child does not have much say in the decision and trusts that the parents have understood what the research involves.
- For both the parents and the child, it is not clear what the trial will involve. It often comes as a surprise that it is time-consuming or painful or that there may be side-effects.

"It's easy to agree to something if you don't know what it actually involves."

- The child often wants to stop at first but is persuaded to continue. Some of the children say they have now adjusted to the discomfort while others say they would refuse if asked again.
- Parents say it is worth the time and trouble as long as somebody's child stands to benefit (altruism). In practice, they hope for direct benefit to their own child. They don't want their child to get the placebo or miss out on the latest treatment.

"We only participated because there was a 60% chance of getting the vaccine."

- Some parents sought information independently (often reading journal articles) before deciding to participate.

- Parents repeatedly express an interest in receiving feedback on the study findings but rarely get any.

"We would like a website with information about the study: articles, experience, results."

RESPECT project Relating Expectations and needs to the Participation and Empowerment of children in Clinical Trials

Partners:

Sweden	- University of Göteborg
Germany	- University Hospital of Hamburg
Europe	- European Patients' Forum
Slovenia	- Children's Hospital Ljubljana
Europe	- Good Clinical Practice Alliance
Italy	- l'Università degli Studi di Padova
Italy	- Consorzio valutazione Biologiche (Pavia)

We need to empower families to make an informed decision about participation:

Pragmatically, we want most families to be in group **A or B**.
Ethically, we want the majority to be in group **A or C**.
Ideally, we want everyone to be in group **A**.

	EMPOWERED to decide	NOT EMPOWERED to decide
WILLING to participate	A Valid contract	B Blind trust
NOT WILLING to participate	C Demands not met	D Fearful

Trust is a major aspect of willingness to participate in clinical trials research.
If we are to expand children's participation, we need to understand the interdependency of trust, knowledge and empowerment.