

# Empowering children in clinical trials

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There is evidence that over 50 percent of medicinal products developed for children have not been tested or authorised for use by this age group. The research project RESPECT ('Relating Expectations and Needs to Participation and Empowerment of Children in Clinical Trials') has sought to change this.

Led by the Institute of [Clinical Sciences](#) at the Sahlgrenska Academy at

Gothenburg University, Sweden, the project set out to identify the needs and motivations of children and their families who have participated or might participate in clinical trials in Europe.

Previously, [healthcare professionals](#) had no alternative but to use medicines 'off-label', judging the suitability and the correct dose of these medicines themselves in the absence of paediatric labeling information. This posed significant risks of inefficacy and potentially [adverse reactions](#) for children. The project also sought to identify how to translate this information into messages which empower and motivate people to participate in future clinical trials research.

To do this, interviews, surveys and workshops were carried out across Europe involving children who have participated in clinical trials. The aim was to collect answers to the following questions: How can paediatric patients be better mobilised and empowered? How can they get the [clinical outcomes](#) that really matter to them? And, how can their needs be integrated into clinical trials?

By incorporating the child's participation and outcome needs into the planning process of a clinical trial, a partnership model of [empowerment](#) emerged, based on four elements: self-determination through active involvement; accountability and transparency; cooperation and [mutual respect](#); and lastly knowledge and access to information.

Professor John Chaplin, a senior researcher at the Institute of Clinical Sciences at Sahlgrenska Academy, Gothenburg University, says: 'We explored the issues raised by children's participation in [medical research](#) by speaking with paediatric patients and their parents, patient support organisations, paediatricians, ethical committees, and representatives of the pharmaceutical industry to gather their experience, insights and suggestions. This enabled us to make recommendations on how to empower children so that medical researchers respect their interests and

can motivate their participation in future clinical trials.'

The major impact of this project has been the promotion of clinical trials for the development of innovative medicines to improve child health and treat paediatric diseases. Increased cooperation between different partners in the clinical trials landscape will help to make them more effective and thus encourage greater innovation and industry development.

Overall the RESPECT project advanced understanding of how to efficiently promote good practice in paediatric clinical trials research. It also revealed that [clinical trials](#) were discussed with more confidence when families had greater involvement and control over their participation. Furthermore, case studies demonstrated that people want to feel their participation will make a meaningful contribution to medical research.

**More information:** Sahlgrenska Academy at Gothenburg University  
[www.gu.se/english/](http://www.gu.se/english/)  
RESPECT project factsheet  
[cordis.europa.eu/projects/rcn/86771\\_en.html](http://cordis.europa.eu/projects/rcn/86771_en.html)

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