Securing children's participation in clinical trials

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Background
The EC Paediatric Regulation aims to reduce off-label use of medicines in children, with adverse reactions that may be more severe than in adults. This need for increased participation of children in clinical trials is the background to the European RESPECT project. The project will produce guidelines for how researchers can respect children's interests and motivate their participation in future clinical trials.

Method
Through case study interviews with families participating in clinical trials and interviews with paediatricians and nurses running trials, we explored their needs and expectations from medical research. We also ran surveys and a workshop with patient organisations to gather their insights into the support needs of children and parents and how to turn these needs into good practice for the conduct of clinical trials.

Results
At the macro level, the importance of medical research needs to be conveyed to the public to encourage an altruistic attitude. The pharmaceutical industry must also allow patient organisations to give input on which trials and which outcomes would matter most to them. At the micro level, patients and their parents show a weak understanding of the difference between clinical trials and regular treatment despite nominally giving informed consent to participate in a trial. Paediatricians need to explain the concept of randomisation and be honest about what is involved, to reduce the risk of non-compliance. Families want to feel that their input is valued and that they are a research partner in the trial. It is important to show genuine appreciation of their contribution to the research. This can be significant and we found examples of patient representatives giving input into trial design and structure of the protocol, helping to define outcome measurements and recruiting trial participants. Children themselves can give excellent feedback on the design of informed consent materials and on their experience of the trial.

Summary
Empowering parents and children to understand the issues in clinical trials and to have a say in the design and execution of the trial, will motivate their participation and have a greater benefit for themselves and others in their position. Closer cooperation between the clinical trial researchers and the children (or their representatives) as active research partners enriches the understanding of the medical condition and the outcomes that really matter to all. Together they are co-producers of improved health care.