PE 25P

Securing children's participation in clinical trials

Catriona Chaplin[1], John Eric Chaplin[1], Carola Pfeiffer-Mosesson[1] and the EU RESPECT project[2]

[1]**Göteborg Pediatric Growth Research Center, Dept of Pediatrics, Institute of Clinical Sciences, Sahlgrenska Academy at University of Gothenburg**

[2]Partners: **University of Gothenburg, University Hospital of Hamburg-Eppendorf, European Patients Forum, University Children's Hospital Ljubljana, Good Clinical Practice Alliance Europe, Azienda Ospedaliera di Padova, CVBF Pavia**

Background

The EC Paediatric Regulation requires increased participation of children in clinical trials in order to reduce off-label use of medicines.

An exploration of the needs of these young patients and their parents is the basis of the European RESPECT project (**R**elating **E**xpectations and need**S** to the **P**articipation and **E**mpowerment of children in **C**linical **T**rials).

Aim

The project aims to identify best practice examples and give recommendations for how researchers can respect children's needs and expectations 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, as well as with trial sponsors, we explored their perspectives on 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.

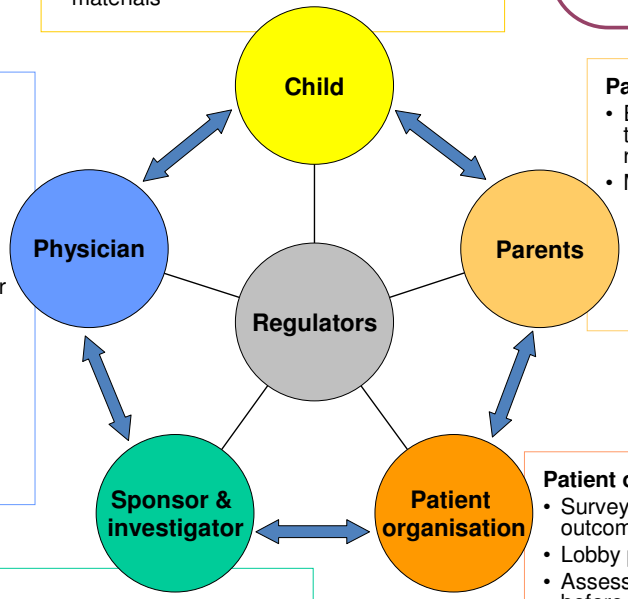
Conclusions

These best practice examples and recommendations should be combined into a single process supported by regulators. Empowering parents and children to have a say in the design and execution of the trial will motivate their participation and increases the likelihood of achieving outcomes that really matter to patients.

Results

We identified different actors in the CT process and found examples of good practice from each of them. They also gave concrete suggestions of what they wanted from each other. Some of these examples are shown in this diagram.

Child
- Should be consulted as the best judge of their own pain and distress
- Even small children can indicate which outcomes really matter to them
- Child panel can review informed consent materials



Physician
- Inform pharma of the unmet needs that families actually report in consultations
- Review the trial protocol for endpoints that matter to young patients
- Give and take feedback from families before, during and after the trial.
- Be honest and gain their trust
- Show appreciation for their contribution
- Report back their comments to the sponsor after the trial

Parents
- Education helps them to distinguish trials from treatment and to see the importance of randomised clinical trials
- Many want to be partners in the trial
  - ➢they research potential trials and details of a particular trial if asked to participate.
  - ➢give detailed observations during the trial
  - ➢expect to get the results of the study

Sponsor
- Consult patient organisations and physicians for unmet medical needs
- Develop patient-reported outcomes
- Minimise invasive procedures
- Reduce inconvenience
- Provide the results of the study to the participating families.

Patient organisation
- Survey members for unmet treatment needs and outcome priorities for young patients
- Lobby pharma companies
- Assess the relevance of a trial for their members before offering recruitment help.
- Give input on the trial design and protocol
- Support families participating in trials

Clinical implications

Physicians are in a unique position to inform trial sponsors about the child's unmet medical needs and to influence which trials are conducted.

It is important to ensure that families understand the need for research and are respected for their valuable contribution to the improved safety of medicines for children.

For additional information, please contact:
John Eric Chaplin, PhD
respect@patientneeds.eu
www.patientneeds.eu

The Sahlgrenska Academy

UNIVERSITY OF GOTHENBURG