Mutual Respect and Shared Goals for Clinical Trials on Children

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Background
As a result of the European Paediatric Regulation, there is a need for increased participation of children in clinical trials of medicines.

Objective
The European RESPECT project aims to achieve consensus among all stakeholders in the clinical trials process, including the families, on how to create an environment in which children are empowered to participate in clinical trials.

Methods
Interviews, surveys and workshops with clinical staff, families participating in trials, patient organisations and pharmaceutical companies, were conducted in order to identify good practice examples and insights into the needs of children and parents concerning their participation in trials.

Results
Paediatricians reported that parents did not always understand the difference between clinical trials and regular treatment. They did not see the importance of medical research and did not always have an altruistic attitude. Other families saw themselves as research partners in the trial and wanted to feel that their input was valued, although they did not always feel that their contribution was appreciated sufficiently. This reflected the statements of physicians who reported that they rarely inform parents about the trial results. Several patient organisations reported that they were ill-equipped to give input on which trials and which outcomes have the highest priority for their members. However, we found good examples of trials where patients felt empowered to make valuable contributions. We also found patient organisations giving input into trial design and protocols, helping to define outcome measures and to recruit trial

participants. Children themselves have given feedback on the design of informed consent materials.

Conclusion

There is a need to create an environment in which children, parents and patient organisations understand the value of clinical trials for all children who share the same medical condition. Our concrete proposals encourage closer cooperation and mutual respect among sponsors, clinical trial centres, paediatricians, families and patient organisations, each contributing their unique perspectives as active research partners. Public health in Europe can benefit from such consensus on the rationale, design and conduct of clinical trials. Within this environment, industry will have a greater responsibility to ensure that trials are not only safe, but also relevant and meaningful to the patients.