

## Project Information

### Full Title

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

### Funded by

European Union Seventh Framework Programme (FP7)



### Research Area

HEALTH-Identifying patients' needs in the clinical trial context

### Total Budget

EUR 500.000

### Duration

36 months  
1 June 2008 - 31 May 2011

### Consortium

#### Project Coordinator

Institute of Clinical Science at the Sahlgrenska Academy at Gothenburg University (Sweden)

#### Associated Partners

European Patients' Forum (EPF)

Consorzio Valuazione Biologiche e Farmacologiche (Pavia, Italy)

University Medical Center Hamburg-Eppendorf Department of Medical Psychology (Germany)

Good Clinical Practice Alliance Europe

University Children's Hospital Ljubljana and the Foundation of Child Neurology (Slovenia)

Azienda Ospedaliera di Padova (Italy)

#### Project website

[www.patientneeds.eu](http://www.patientneeds.eu)



# RESPECT patient needs



How can we empower children participating in future clinical trials research?

What are the needs of the children participating in clinical trials on new drugs in Europe?

## The premise

Studies have shown that over 50% of the medicinal products used in children may not have been tested or authorised for use in this age group. Data concerning medicines are traditionally obtained thanks to clinical trials, however they are conducted predominantly on adults and not on children.

Paediatricians and researchers have been interested for some years in improving the situation. Moreover, recent EU legislation states that all new medicines intended for use with children must be tested in studies including children.

## The objective

The objective of the RESPECT project is to identify the needs of children and their families as related to outcomes in clinical trials. This will include the needs of children who have participated or who might participate in clinical trials in Europe. Secondly, to identify methods by which these needs can be translated into empowering and motivating participants in future clinical trials research.

RESPECT is also exploring the ethical issues involved in children's participation in medical research and are contacting ethical committees, patient support organisations, paediatric patients and their parents to gather their insight and suggestions.

### RESPECT project will achieve:

- a basis for understanding the needs and expectations of children in research
- collection and harmonization of the different approaches and best practices in various fields of medicine and research
- dissemination of this results and the widening of the debates to encourage better informed and more harmonious European patient and research communities.

## Expected outcomes

This project will contribute to the coordination of high quality research by going beyond the current state of knowledge and identifying the needs and motivations of children and their families when participating in clinical trials.

The sharing of the results of the project are expected to facilitate collaboration and information exchange between relevant clinical trials researchers.

Greater participation in clinical trials research will lead in turn to more valid and reliable medicines available for children as envisaged by the Regulation (EC) No 1901/2006 on Medical products for Paediatric Use, the so-called "Paediatric Regulation".



### European Patients' Forum

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The European Patients' Forum (EPF) is a non-profit, independent organisation and umbrella representative body for patients' organisations throughout Europe. Representing the EU patient community we advocate for patient-centred equitable healthcare, and the accessibility and quality of healthcare in Europe. EPF reflects the voice of an estimated 150 million patients affected by various diseases in Europe.