**RESPECT Summary Report:** The RESPECT consortium responded to a call from the EU 7th Framework programme for a coordination study concerning Identifying patients' needs in the clinical trials context (HEALTH-2007-4.1-4). This call requested that three questions be answered: 1) How can patients be better mobilised and empowered? 2) How can patients get the clinical outcomes that really matter to them? 3) How can the patients' needs be integrated into clinical trials?

Methods: A mixture of qualitative methods was used. Case study interviews were conducted with the children; focus groups with parents and clinical staff were undertaken; interviews with pharmaceutical company staff were made; online surveys and a series of workshops were held in five European states. An action research method was used in the workshops where data collection and dissemination was carried out.

**Results**: The RESPECT project found that the reasons for participation reflected the needs of the participants and although these reasons varied there were a number of recurring themes. The first theme was that most respondents believed that they would get better medication by participating in a trial and hence were disappointed if they were allocated into the control arm. Although clinical trial research is based on the principle of equipoise, clinical trial researchers saw paediatric trials as a special case where many new medications have been previously tested on adult populations. The second theme to emerge was that families appreciated the opportunity for additional monitoring and specialist care for their child. The third theme was the social obligation which the participant's families felt; this was referred to by many who expressed a wish to either 'pay back' the health care system for providing health care for their child previously or helping other children with the same condition illustrating a sense of group membership. A fourth theme was that parents included their child in order to learn more about the condition themselves or to help the child learn more. Many of the reflections of the families could be characterised as concerning a need to be actively involved in the care of their child. These needs were modified by several factors related primarily to the risks involved in participation, i.e. greater risk was balanced by greater personal need, but also to their trust in the doctor or medical profession and the concern of a good parent that they must do what is best for the child. Another factor which related to need and risk was the inconvenience of participation, i.e. the greater the need the more inconvenience was tolerated.

**Conclusion**: The project concluded that participation issues are resolved where the family including the child has more say in the clinical trials process. In order to achieve this a partnership model emerges in terms of empowerment based on five elements: 1) a mutual respect which encourages cooperation; 2) access to information and the opportunity to acquire knowledge; 3) active involvement through self-determination; 4) independent monitoring of the patients' reported outcomes and 5) accountability of the clinical trial team to the patient. Thus, although information provision about a particular trial is a necessary precondition for making an informed decision about participation, it is also necessary to ensure that research and ethical review practices are transparent and accessible so that the child's representatives, including their patient organisation, can be included in the process and hold accountable these practices when meeting the needs of the child. The challenge is to empower parents to make truly informed decisions on behalf of their children. This can be achieved by going beyond informed consent to the education process that is needed to prepare people for participation and making practices transparent. By moving towards the realisation of this empowerment model the child's needs are met.