Enpr-EMA

European Network of Paediatric Research at the European Medicines Agency

EUROPEAN MEDICINES AGENCY

SCIENCE MEDICINES HEALTH

Break out session 3

Proposals on how patients can be involved in networks (trial design etc) and in trials

Chair: Elizabeth Vroom (Duchenne Parent Project) /

Juan Garcia Burgos (EMA)

4th Workshop on European Paediatric Network
European Medicines Agency
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An agency of the European Union

Summary – break out discussion group 3

- 25 participants (patients, CROs, industry, academia, parents, regulators, clinicians, networks, etc)

Summary – break out discussion group 3

Main aspects to be covered:

- Parents involvement: the added value of involving children
- How to facilitate parents/carers/children involvement
- Selecting the best candidate (the ideal profile)

Summary – break out discussion group 3

Patients/carers involvement: the added value of involving children

- Children’s views complements those obtained from parents (e.g. burden and acceptability of intervention) and should be sought
- Quality control for a network – improve outcome
- Early involvement is critical
- Children contribution may vary depending on the disease, cultural differences, age, etc
- Assent forms (template) – ask young people – the need to be understood; need to address specific factors (e.g. age)

Summary – break out discussion group 3

- How to facilitate parents/carers/children involvement
  - Ethics committees: lay people is not enough – patients/carers/parents/children needs to contribute
  - Facilitate training to parents so that they can properly contribute – the role of patients' organisations
  - Need to guide their contribution – explain clearly what is expected from them
  - CT within EnprEMA to include validation by parents.