

# Enpr-EMA/c4c workshop on quality criteria / standards of paediatric clinical trial sites

3 October 2022, 13:00- 17:30 (CET)

Presented by Gunter Egger, Enpr-EMA annual meeting, 4 October 2022

# Why discuss quality criteria / standards for paediatric clinical trial sites?

- Gaps and inefficiencies in trial delivery performance and quality, across site identification, setup and execution
- Heterogeneity in site capabilities, activities and development
- Evolving range of trial designs, populations, protocols and operations
- Fragmented sponsor requirements and duplicative approach to their assessment
- Challenges due to paediatric site specificities

# What do we mean by quality criteria / standards?

- A terminology of quality criteria/standards: requirements, specifications, that are harmonised, consistent, and measurable, trackable...ensuring services are fit for their purpose.
- Potential aims: to support paediatric trial site selection by sponsors, to enhance the development of high-quality trial sites
- Examples:
  - Study personnel requirements (e.g. training, qualifications)
  - Study site requirements (e.g. facilities and technical equipment)
  - Contracting requirements (e.g. duration of contract review)
  - Budgeting requirements (e.g. overnight stay for carer)

# c4c site standards questionnaire

- Lead by c4c Task Group with agreement of Project Leadership
- Time period: Aug-2022 to Sept-2022
- To **gather c4c sites data** on c4c site standards
- SurveyMonkey survey that will be followed by a follow-up data collection in the future c4c IS tool

# Enpr-EMA survey among industry

- Lead by Enpr-EMA's international WG with global outreach
- Time period: 2021-22
- To **gather sponsor/CRO requirements**
- Written web-based survey plus follow-up interviews

# Objectives of workshop

1. Start and catalyse discussion around site quality criteria/standards among all stakeholders in smaller break-out groups.
2. Reach a common understanding on the need for such criteria and what they could be used for, how a set of criteria could be reached by sites and recognised by industry.
3. Agree on actions and next steps (e.g. publication of recommendations)

# Questions in break-out sessions

## Session I:

1. Is there a need to identify/develop quality criteria for clinical sites to participate in paediatric clinical trials?
2. To what purpose would quality criteria be used by the different stakeholders (sites/networks/industry/academic sponsors)?

## Session II:

3. How could industry/academic sponsors/networks and sites discuss and agree on quality criteria?
4. How could sites be supported to achieve quality criteria?
5. Is it necessary to have sites accredited, and if so how could/should this be done?

# Outcome – Session I

1. Yes, there is a need for defining quality criteria/standards
  - To **speed up trial set up** and support site selection
  - To ensure **high-quality data (& GDPR compliance) during trial conduct**
  - To enhance **development of sites** (training for research personnel, improved processes, etc)

# Outcome - Session II

- 3. Collaborative approach** needed to agree on criteria: industry/CROs/sites/networks, patients
- 4. Networks** are important to support sites in reaching quality criteria (**training**), standards could serve as a blue-print for sites and motivate funding/resource allocation
- 5. Accreditation/recognition** could have added value for the site selection and speed up selection phase. Perhaps not one-size-fits-all. Danger of disenfranchising some sites, if costly accreditation.

# Action points - Working groups

1. Definitions of quality of paediatric sites
  - Develop common understanding (how can conduct be optimized, what matters to children, young people and their families)
  - That could be applied in different ways by different networks
2. Mapping existing standards
  - E.g. Vaccelerate, Enpr-EMA networks (capability of investigator and sites)
  - Looking for stakeholder buy-in/engagement
3. Implementation
  - High level support
  - Road map / guidance document

Thank you!