



European network of paediatric research
at the European Medicines Agency



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quality criteria for paediatric clinical trial sites – an Enpr-EMA initiative

Ricardo Fernandes, Lead, STAND4KIDS – Supporting Trials Portugal; CMO, conect4children Stichting

Pernille Skovby, National Coordinator, DanPedMed-Supporting Trials Denmark, c4c-s National Hub Coordinator

Solange Corriol-Rohou

Kirsten Sherman Cervati

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Why are we here



To establish a shared understanding of what constitutes quality of paediatric sites reflecting the perspectives of the sites themselves as well as those of stakeholders involved in the conduct of a clinical trial, including children and their parents/caregivers

To identify and map existing criteria and standards for sites performing both investigator-initiated and industry sponsored paediatric clinical trials



Results

- A document focusing on 4 questions:
 - What is a paediatric site?
 - Why do we need paediatric site standards?
 - What do we mean by quality of a paediatric site?
 - How to identify a fit-for-purpose paediatric site?



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EMA:

Quality criteria for paediatric clinical trial sites – an Enpr-EMA initiative
Recommendations by the Enpr-EMA working group on criteria for paediatric clinical trial site standards.

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Key findings 1: What is a paediatric site?

A core definition of a **paediatric clinical trial site** is a specific location where drugs, medical devices, and other therapeutic interventions are evaluated in paediatric participants, that may include a specific or a broader age spectrum from neonates up to less than 18 years of age in the EU

Paediatric sites are composed of a team led by a principal investigator, usually a paediatrician (including experts in a specific therapeutic area in paediatrics) with appropriate location(s)/facility(ies) to execute the trial according to the protocol



Key findings 2: Why do we need paediatric site standards?



Because:

We need to identify sites that are most likely to conduct a trial on time, on budget and according to the specifications outlined by the sponsor, regulators, and GCP

Key findings 3: What do we mean by quality of a paediatric site?



- Quality of a site relates to different concepts and approaches: trial protocol/goals, GCP, capacity, preparedness, performance, quality domains and measures
- Factors that may influence and are interconnected with quality requirements

Key findings 4: How to identify a fit-for-purpose paediatric site?

All sites that set out to enrol children and young people, whether they are paediatric-only or also (or mainly) recruit adults, should meet the same specific site requirements; there should be no opportunity to downgrade those requirements in case of "adult"- mainly sites

There are examples of sponsor or network-driven assessments of known and recognised paediatric sites of excellence (with existing frameworks to identify these sites)

Conclusion

The establishment and adoption of a core set of site preparedness practices and quality assessment criteria that are applicable across sites, irrespective of size and geography or clinical specialty, should help streamline the process of site assessment for organizations, research teams, sponsors, and participants

Well established paediatric research networks could play a key role in this regard