Mapping/defining existing quality criteria/standards for sites

Working Group 2

Agenda

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Overview of participants in WG 2

02 **Background**
Why do this work

03 **Objective**
Aim of the WG 2

04 **Methodology**
Literature search, categories

05 **Preliminary Conclusions**

Presenting author

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Stakeholders involved/WG 2

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Pernille Skovby/Co-Chair	Danish Pediatric Research Network
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Background

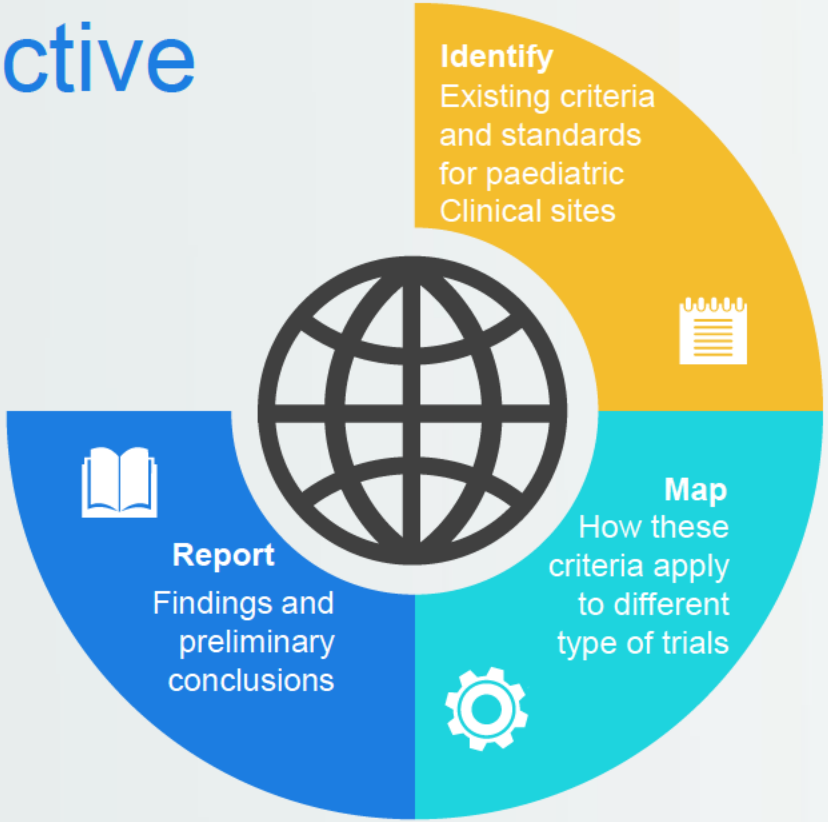
International literature demonstrates that clinical trials in children introduce additional complexities compared to trials in adults

To conduct both academic and industry clinical trials of high quality the demands of sites involved are many

Stakeholders and sites involved in paediatric clinical research must be engaged and meet unique requirements to best achieve the goal of high-quality clinical trials

Defined site standards and collection of metrics to support the development of standards across jurisdictions in an interoperable fashion for paediatric clinical trial sites remains somewhat sparse

Objective


Identify
Existing criteria and standards for paediatric Clinical sites
Map
How these criteria apply to different type of trials
Report
Findings and preliminary conclusions

Methodology

Literature Search

Conducted using agreed upon search terms

Indexing of Literature

Conducted in a shared file documenting publication year, short summary, source, categorization and additional comments

Category Development

Based on literature, c4c experience and the industry/CRO site standard survey

Paediatric Specificities

Adjustments to the needs and priorities of paediatric sites for categorizing, primarily adult literature

Literature Search

Scope

Post-2010 publications, primarily in English

Sources

Pubmed Web of Science, personal database articles, Grey Literature, Organisational websites

Search Keywords

"site standards"
"site quality standards"
"paediatric clinical trials“
“pediatric clinical trials”

Expertise Review and c4c WG

WG reviewed search results for relevance
The c4c WG related to quality sites was consulted and additional relevant literature was included

Category Development

Category Heading	Description & Queries
Staff Experience	Does the staff have the appropriate experience in studies & years? Are they adept at conducting trials or willing to learn?
Requirements (Training)	Is there adequate training? Access and review of relevant guidance documents
Documentation (Quality Management)	Presence of an internal Quality Assurance procedure Are evaluation processes established?
Infrastructure	Is the environment child-friendly? Required equipment and services for study Staff adept at working with children and families
Cycle Times (IRB, Contracts, Budget)	Use of standard templates (agreements, indemnities, etc.) Personnel for budget negotiations with sponsors
Patient Engagement	Conduct of patient orientation Provision of general information to participants Relevant participant material availability

Preliminary Conclusion

The process for initiating paediatric clinical trials is complex and multifaceted

The literature shows that it is possible to identify common areas for performing clinical trials across countries and multiple specialties

Categories have been developed based on those frequently used in literature, input from WG2 members and those previously developed by c4c

Next Steps?

What we propose:

Two main articles relevant for future work:

- “A Trial Assessment of Infrastructure Matrix Tool to Improve the Quality of Research Conduct in the Community”
- “A Framework for Assessing Clinical Trial Site Readiness”

Categories – could we work with sub categorization and bring in more questions?

Next step for this?