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SCIENCE MEDICINES HEALTH

Global initiatives progress update:

Multi-Regional Clinical Trials (MRCT) Center and its initiative on promoting global clinical research in children

Promoting Global Clinical Research in Children:
Aligning Ethical, Pragmatic, and Regulatory Approaches

2020 Annual EnprEMA meeting

Presented by Dominik Karres on 28 September 2020
Paediatric Medicines Office

Promoting Global Clinical Research in Children

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Why is this important?

- Children historically excluded from research; practitioners often prescribe based on extrapolation from adult data
- Children deserve access to safe and effective medicines, a goal that is contingent upon conduct of pediatric-specific clinical trials
- Pediatric market is small but important; some diseases specific to neonates, infants and and children
- Persistent ethical issues
- Differing or nonexistent pediatric regulations in different jurisdictions
- Significant challenges in initiation and conduct of multi-site, multi-national pediatric trials

Individuals/organizations involved to date

HRAs and Organizations: 8 health authorities encompassing wide geographic representation

Academic Medical Centers: more than 2 dozen academic/academic medical centers with deep global and US presence

Industry: 10 companies with broad international reach

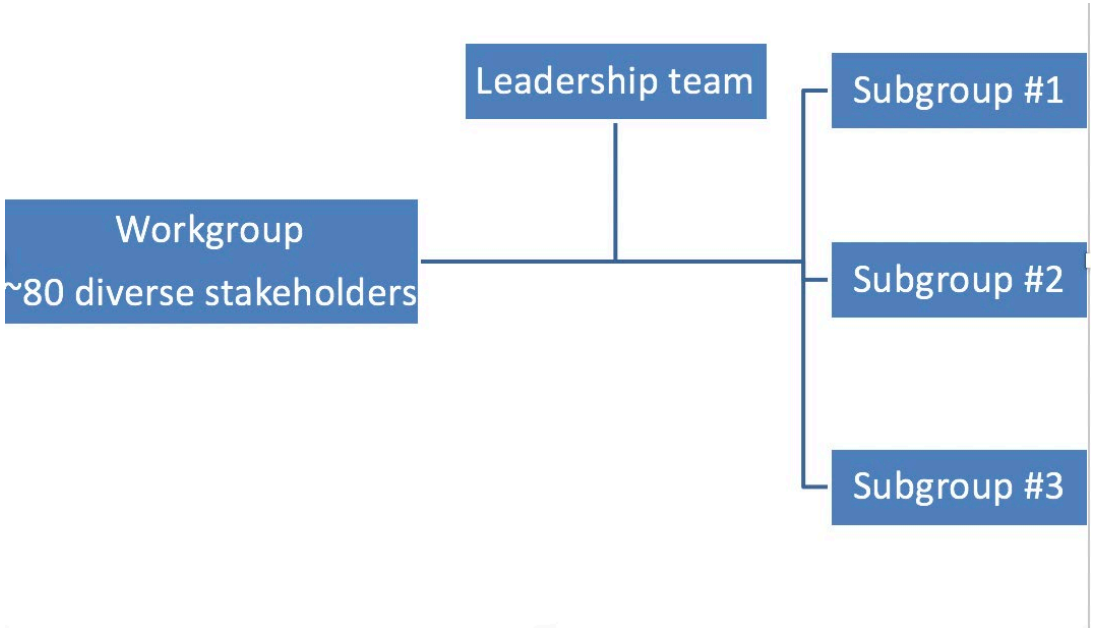
Trade and Professional Associations: 5 associations with broad collaborative networks

Research Institutes & Not-for-Profits: 5 well connected organizations

Patient Advocacy: 5 groups with both US based and international network access

**What other entities or consortia should be included?*

Project Structure



Decision making for children's participation in biomedical research

Benefit/risk considerations for pediatric research

Challenges in Implementation of global pediatric clinical trials

- Each work- and sub-group: Meet by conference call once/month for 60-90 min
- Leadership team: Meet weekly

Subgroups and leadership

Subgroup #1: Decision making for children's participation in biomedical research

- Co-leads: Steve Joffe & Gigi McMillan
  - Backup: Barbara Bierer

Subgroup #2: Benefit/risk considerations for pediatric research

- Co-leads: Sharareh Hosseinzadeh &Dominik Karres
  - Backup: Skip Nelson

Subgroup #3: Challenges in Implementation of Global Pediatric Clinical Trials

- Co-leads: Skip Nelson & tbd
  - Backup: Dominik Karres

Preliminary Project Objectives

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- Current global landscape of pediatric research governance, focusing on legislative, regulatory, and guidance gaps and inconsistencies
- Identify current initiatives to improve pediatric research globally
- Identify challenges related to decision making by and on behalf of children
- Identify meaningful ways to engage patients/families/community members
- Address benefit and risk considerations that create barriers and inefficiencies in transnational research with children.
- Identify and propose solutions to regulatory, ethical, and operational challenges
- Use the COVID-19 pandemic as a lens through which to examine opportunities for innovation in the conduct of pediatric clinical trials.

Deliverable Planning

- All deliverables are created with relevant stakeholders at the table, including involving and respect the centrality of the participants who participate and clinical research.
- By involving patients, families, patient advocates, and patient advisory groups in the development and refinement of project deliverables, we hope to generate relevant resources with a positive global impact.
- Will track with the workgroup foci, and subject to change in discussion with the workgroup and work subgroups.

Any questions?

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Further information

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