Creation of a pan-European Paediatric Clinical Trials Network

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Scope of the proposal

- The overall vision of this proposal is to create a large collaborative paediatric network that will facilitate the development and availability of new drugs and other therapies, and the expansion of knowledge about drugs currently used in the paediatric population.
- This will be accomplished by not only advising on how best to do the necessary research, but by actually building sufficient infrastructure and best practices to support planning, running, and completion of all types of clinical studies (phase I-IV) by all kinds of sponsors (industry and non-industry)

Objectives of the full project (1/2)

- Building a network with a lean central coordinating organisation, arranged around ‘national hub coordinating centres’ cooperating with multiple sites within each EU member state
- Installing scientific advice and trial readiness groups to consult with sponsors on the scientific soundness and feasibility of their proposals and to drive innovation.
- Develop and implement standardised processes, procedures, and performance metrics for initiation and execution of studies and maintenance of high-level performance across the network

Objectives of the full project (2/2)

- Testing viability of the network by measuring performance metrics during the execution and completion of a number of different clinical studies (phase I-IV) from different sponsors (industry, non-industry) and different therapeutic areas, across all age groups
- Develop and implement a business model that provides sustainability of the network after the period of IMI2 funding
- Preparing the network to become a member of the European Network for Paediatric Research at the European Medicines Agency (Enpr-EMA)

Industry consortium, duration & budget

- Janssen (lead)
- Bayer (co-lead)
- Novartis
- Pfizer
- Lilly
- GlaxoSmithKline
- Roche
- Servier
- Sanofi/Genzyme
- UCB

- Indicative duration: 72 months
- The indicative EFPIA in-kind contribution will be in the range of EUR 67MM
- Financial contribution for IMI2 will be also in the range of 67 M EUR

innovative medicines initiative

Suggested architecture of the project

- The suggested work packages for this project would be:
  1. Project Management and Oversight of IMI project
  2. Organisation and Governance of the pan European Paediatric Clinical Trials Network
  3. Business Plan Development, Expansion of the Network, and Sustainability of the Network Sources of Funding post IMI2 support
  4. Scientific Advice, Feasibility and Innovation
  5. Data Coordinating Centre and Data Quality Standards
  6. Network Research Personnel Education and Training
  7. Planning and Execution of Clinical Trials

Expected contributions of the applicants (1/2)

- Experience and know-how in conducting paediatric clinical trials (incl. clinical operations and clinical program management)
- Expertise in paediatric drug development (incl. clinical pharmacology, modelling and simulation, extrapolation, regulatory science, statistical methods, epidemiology and use of clinical databases, study design and ethical considerations)
- Access to a large paediatric population
- Physicians and other health care providers covering a wide array of clinical paediatric subspecialties
- Patient/parent organisations
- Experience in working with the use of standardised procedures and processes in all clinical trials
- Information technology / data management

Expected contributions of the applicants (2/2)

- Expertise in legal and clinical compliance / ICH GCP (International Council for Harmonization - Good Clinical Practice) aspects
- Strong project management and communication expertise
- Office administration and website management

- Organisations in scope:
  - Existing regional or national networks;
  - Pan-EU disease-specialty networks;
  - Large children's hospitals and medical centres;
  - Small-medium sized entities
  - Patient/parent organisations

Key deliverables of the full project

- Establish the structure and governance of the project
- Set up and maintain groups of scientific experts to trigger innovation in the development of paediatric therapies
- Implement standing disease or condition-focused network clinical advisory groups
- Develop and implement standardised processes, procedures, and performance metrics
- Test the readiness of the network for multiple diverse clinical trials
- Build and expand the clinical trials infrastructure across the EU
- Develop a business model and funding mechanism viable after the initial period of IMI2 support
- Build a process to open the network for submission of studies from all kinds of sponsors

Timeline for Next Steps

- Launch of Call Topic 10: 21/12/16
- Short Proposal (SP) submissions from applicant consortia 28/03/17
- Governing Board approval of SP 29/05/17
- Submission deadline for full proposal (FP-stage 2) 14/9/17
- Governing Board approval of FP 10/11/17

Questions?

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