



c4c - conect4children (COLlaborative Network for European Clinical Trials For Children)

Paediatric medicines development is embedded in the European policy, legislation and in the work of the pharmaceutical industry but currently the potential of this effort is not realised.

The conect4children (c4c) project will address the critical problems with the design, implementation and operational conduct of paediatric clinical trials, for example the fragmented and redundant efforts between sponsors, sites and countries.

This project will generate a sustainable infrastructure that optimises the delivery of clinical trials in children through: a) a single point of contact for all sponsors, sites and investigators; b) efficient implementation of trials adopting consistent approaches, aligned quality standards and coordination of sites at national and international level; c) collaboration with specialist networks; d) high quality input to study design and preparation through rigorous strategic and operational feasibility assessment and e) the promotion of innovative methodologies.

The project will be managed according to IMI2 best practice with a dedicated communications effort. The clinical trials infrastructure will be setup, implemented and tested by implementing 3-4 industry and at least 1 non-industry proof-of-viability studies. Expert advice groups will promote innovative methodologies and engagement with regulators. The business model for a sustainable infrastructure will be based on the European landscape of paediatric networks and available trial sites, the evaluation of services needs of sponsors of all kinds, and will be informed by the proof-of-viability studies. Supporting activities will include: data management (data about the trials and the network, including performance metrics for network management and promotion; handling trial data for non-industry sponsors; support for common data dictionaries); education and training.

The voices of children, young people and their families will be central to the network.

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Bayer Aktiengesellschaft (Germany)

Sanofi-Aventis Recherche & Développement (France)

Eli Lilly and Company Limited (United Kingdom)

UCB Biopharma SRL (Belgium)

Novartis Pharma AG (Switzerland)

Institut de Recherches Internationales Servier (France)

GlaxoSmithKline Research and Development Ltd. (United Kingdom)

Pfizer Limited (United Kingdom)

F. Hoffmann-La Roche AG (Switzerland)

Azienda sanitaria universitaria Friuli Centrale (Italy)

Università degli Studi di Cagliari (Italy)

Servicio Madrileño de Salud (Spain)

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