

PRESS RELEASE

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IMI2 conect4children Consortium announces the establishment of the conect4children Stichting

A Pan-European Paediatric Clinical Trial Network to Improve Infrastructure and Facilitate Development of Medicines for Children in Europe.

PADOVA – May 2023 – The conect4children (c4c) Consortium today announced the establishment of the conect4children Stichting, a Dutch non-profit organisation, aiming to sustain the work done by the public-private consortium.

The conect4children Stichting is based in Utrecht, the Netherlands.

Establishing the c4c network and creating the conect4children Stichting is the outcome of five years of work of IMI2 conect4children, a public-private partnership co-funded by the Innovative Medicines Initiative 2 and EFPIA.

The partnership successfully co-created a Pan-European Paediatric Clinical Trial Network and related services, effectively tackling the challenges faced by academia and industry in the development of medicines for children.

"We are pleased that the extensive collaboration between industry, academia, and other stakeholders in this IMI2 project has led to this major milestone that will underpin the ecosystem for paediatric drug development". Prof. Carlo Giaquinto, Professor of Paediatrics at the University of Padova, President Fondazione Penta ETS and co-coordinator c4c project.

"This represents significant progress in advancing our collaborative efforts focused on addressing timely access to medicines for children". Jacqueline Phillips MD MBA, Vice President, Johnson & Johnson.

"This is an important milestone for all involved in the development of paediatric medicines in Europe, highlighting the importance of public-private and multi-stakeholder cooperations," said Dr. Thomas Miller, Global Head Acute, Chronic & Pediatric Disease Nucleus, Pharmaceuticals Division, Bayer AG. "For us at Bayer this newly formed, EU-wide paediatric network will become a key tool to support and improve our upcoming paediatric development programes."

"The goal of c4c is to improve the clinical trial infrastructure and to support initiation and conduct of high quality paediatric clinical trials across Europe. The standardization of Clinical Trial sites and the implementation of National Hubs (NHs) and the Single Point of Contact (SPoC) have improved the capabilities to support sponsors, investigators and sites in the conduct of clinical trials." Dr. Gunter Egger, Paediatric Office, European Medicines Agency, member of the c4c External Advsiry Board.

"The generation of processes and standards have reached a high quality which is subject to continuous improvement and learning. Training and education of clinical staff to maintain site quality will be taken up in the foundation." Dr. Birka Lehmann, Lecturer, Friedrich Wilhelm University, Bonn, Chair of the c4c External Advisory Board & former member of PDCO.

"The Stichting is ready to meet the needs of academia and industry during the development of medicines for babies, children, and young people" Prof. Mark Turner, CEO conect4children Stichting.

About services and timelines

The IMI2 c4c consortium will now commence the process of transferring its work into the conect4children Stichting, allowing the new organization to become ready to offer access to the conect4children network and its services to all academic and industry sponsors, including CROs.

Services to be transferred and implemented during 2023:

- Strategic Expert Advice on all aspects of paediatric clinical trial design, including the strategic feasibility of studies, is expected to be available from Q4 2023. The advice includes input from children and young people and more than 400 experts in innovative methodology and clinical trials.
- Support and coordination of clinical trial conduct will be provided by the new organization through National Hubs in 21 countries and are expected to be available from Q1 2024. Services include site identification & feasibility, site set-up, recruitment and site engagement.

Additional services:

Education and Training for sites and researchers about paediatric drug development, and data standards for paediatric research, continue to be developed.

A platform for Paediatric Multistakeholder Meetings (pMSM) will be maintained and further developed.

Further information can be obtained by contacting spoc@conect4children.org.

About Innovative Medicines Initiative and c4c

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking (JU), Europe's biggest Public-Private Partnership, under grant agreement No 777389. The JU receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA (the European Federation of Pharmaceutical Industries and Association).

Under the name c4c, the new research consortium unites pharmaceutical companies, paediatric national networks as well as EU Multinational sub-specialty Networks, large patient advocacy

groups, children's hospitals and other public research organisations from across Europe. The full list of organisations involved in the project can be found at the c4c webpage www.conect4children.org.

Further information

For more info on IMI visit the IHI website: <u>www.ihi.europa.eu</u> and follow on Twitter at @IHIEurope.

Project Office/General Enquires: Email us. communication@conect4children.org

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