29 FIVE-YEAR REPORT ON THE ACTIVITIES OF THE CONNECT4CHILDREN (C4C) EUROPEAN PAEDIATRIC CLINICAL TRIALS NETWORK IN BELGIUM

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Background/Aims Currently, over 60% of clinical trials in children are unsuccessful due to insufficient recruitment, administrative burden, inadequate methodology, among other reasons. Sponsors experience difficulties identifying adequate and developed sites to conduct pediatric trials. To optimize and facilitate clinical trials, (inter)national networks have been developed by (academic) investigators such as the I-ACT for Children network (U.S.A.), Innovative Medicines Initiative 2 conect4children (IMI-c4c) grouped network (Europe), and MICRYN (Canada). For Belgium, the Paediatric Clinical Trial Network within BPCRN Belgian Paediatric Clinical Research Network), was developed in 2009 and included in c4c in 2018, managed by the Ghent University (Hospital).

Method This report describes an update on the progress of c4c over the past 5 years. The Belgian Paediatric Clinical Trial Network has 15 hospitals connected. The network has been involved in 2 academic trials, 10 industry trials and over 35 preliminary feasibility requests.

Results The Belgium national network (BPCRN) was selected in 2/4 academic trials, and 5/5 industry trials within c4c. Constructive communication with the sponsor increased the number of sites from 2 to 8 for the academic studies. The added value of the BPCRN in the academic trials was help by the national hub in regulatory submission and budget plan. For the industry studies, the administrative requests have been centrally buffered, with over 66% of the feasibility questionnaires being pre-filled. Moreover, an additional 32% new sites were identified for the industry sponsors.

The network is also involved in i) data standardization, inclusion of real-world data and rare disease data-dictionary development, ii) expert panels and iii) teaching pan-European courses for site and investigator development. Moreover, the Belgian network has been the liaison for the totality of European national networks with the US-based network I-ACT for Children, for clinical trials running outside of the c4c project scope.

Conclusion Over the past 5 years, substantial developments and progress have been made with the Belgium network activity by BPCRN. Central optimalisation of site identification, site development and trial start-up have been prioritized. To achieve a sustainable network after IMI2 funding, a longitudinal commitment of both sites and sponsors is needed.

30 CZECH NATIONAL CENTRE: POTENTIAL FOR IMPROVING PHARMACOTHERAPY IN THE PAEDIATRIC POPULATION IN THE CZECH REPUBLIC AND SLOVAKIA

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Introduction The Czech National Centre represents new activities in the field of pharmacotherapy in paediatrics and neonatology in CR and Slovakia as well as the successful ongoing involvement of the Czech Charles University scientific team in the conect4children (c4c) consortium within the collaborative pan-European network (CzechNatHub). Currently, this project aims to facilitate CzechNatHub's sustainability and business plans within and beyond the c4c-periods.

Methodology The project is within the Europe-wide Innovative Medicines Initiative2 (IMI2)2 with joint funding from the European Federation of Pharmaceutical Industry and Associations (EFPIA) and the European Commission The coordination centre for the Czech Republic is the Department of Pediatrics and Inherited Metabolic Disorders of the 1st Faculty of Medicine of Charles University and the General Hospital in Prague is involved in the WP 2,6,7 (education, infrastructure, and research) and WP4 (expert group) with a focus on the c4c maturity matrix (strategic feasibility advice, network, data standards, education, patient and public involvement) using nationally based logistic analysis.

Results Key c4c points were identified to support the skills (beneficiaries) in the field of clinical studies of the entire study team (CRO), to define the role of the study coordinator and his responsibilities and practical skills (industry through AIFP), to teach young doctors, research nurses (Enpr-EMA) and non-medical experts and the public (YPAGNET) to work together as a team where everyone has a defined role and responsibilities, and to develop links with academic societies (Czech Paediatric Society, ESDPPP), and to find funding. The spring multi-stakeholder meeting will bring all this together.

Conclusion The Czech National Centre has become a coordinating academic centre established for pharmacotherapy in the paediatric population for the Czech Republic and Slovakia.

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