

#### GE35 SUBJECT GROUP INTERNAL MEDICINE AND PAEDIATRICS - PAEDIATRIC NEPHROLOGY

Eva Degraeuwe<sup>1,2</sup>, Leen De Taeye<sup>1</sup>, Mark Turner<sup>3</sup>, Lieve Nuytinck<sup>1</sup>, Daphné Christiaens<sup>2</sup>, Simon Vanderschaeghe<sup>2</sup>, Elke Gasthuys<sup>1</sup>, Sevasti Karamaria<sup>1,2</sup>, Catherine Van Der Straeten<sup>1,2</sup>, Johan Vande Walle<sup>1,2</sup> Affiliations: (1) Ghent University, (2) Ghent University Hospital (3) University of Liverpool (UK)

# THE EUROPEAN PAEDIATRIC CLINICAL TRIALS NETWORK CONECT4CHILDREN: ACTIVITIES OF THE BELGIUM NATIONAL NETWORK AND ITS PROGRESSION

### Background/Aim

Paediatric drug development faces recurrent barriers such as fragmentation of the stakeholders and differences between research conduct between sites and countries (1-3). Paediatric clinical trial networks have made many and unique advances over the last years through the possibility of a pan-European network funded by the Innovative Medicines Initiative (IMI2). In Europe, the IMI2-funded conect4children (c4c) initiative has promoted innovation and standardization within all levels of paediatric drug development (1,4).

The Belgium Paediatric Clinical Research Network (BCPRN) with its headquarters localized in Ghent, plays an essential role in these developments being involved in most of the work packages of this pan-European network (5). Having its **predecessor**, the federal funded (FWO) **SAFEPEDRUG** (IWT-SBO 130033) the groundwork was laid for translational research for paediatric drug development in Belgium (3,6). One of the finalities was the establishment of a paediatric clinical trial center, connected to the adult trial department D.R.U.G. at the **University Hospital Ghent (6).** 

2009

2014-2018

2018

2019

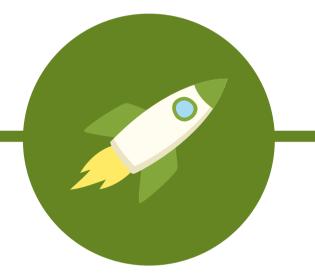
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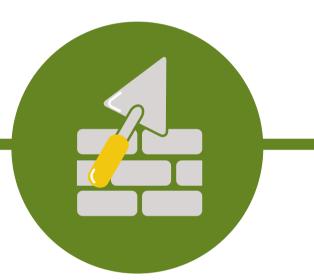
2021











Founded structure of Belgian Paediatric Clinical Research Network (BPCRN)

15 SITES

FWO-SBO supported SAFEPEDRUG. Redefining and improving strategies for drug research in children.

Start of the conect4children (c4c) project. Foundation of structure and standard operation procedures (SOPs).

Roadshow building connection with new sites. **Preparation** for

efficient start of

trias.

Approval of 2 academic clinical trials nationally. Collaboration with I-ACT for children (US). Completion of the Governance Toolkit.

**Legalization** of the BPCRN structure. Finalization of the **Business plan** for sustainability. **Start** of 3 academic **trials** and 4 industry trials.

## DATAMANAGEMENT SUSTAINABLE MODELS \*\* EUROPEAN EXPERT GROUP **PRECLINICAL** FOUNDATION: SAFEPEDRUG LEGALIZATION

#### Results

- Belgium is the second country in Europe to receive national approval for the KD-CAAP study.
  - additional industry Five studies have been included within the c4c network in the coming years.

Health, Innovation and Research Institute of UZ Gent (HIRUZ) and BPCRN are involved in the work package of data management and data coordination.

- Unique data standardization database: CDISC approved
- Approved by a paediatric expert group.
- Completed Governance specific Toolkit: site Management Plan (DMP).

BPCRN is also involved in the workpackage for completing a sustainable business model:

- Updating the European and National Sustainable business model
- A complete SWOT analysis and legal structure for after 2024.

## Take Home Message

11 TRIALS AIM

The SBO-funded SAFEPEDRUG preclinical research has evolved into a clinical setting within the pan-European network of c4c. Over the past 3 years, substantial developments and progress has been made with the Belgium network activity by BPCRN. Platforms such as c4c and I-ACT for Children are essential to achieve substantial improvement in medicines for children in EU, the US and worldwide.

## Contact

Eva.Degraeuwe@ugent.be Johan.VandeWalle@uzgent.be



@c4c\_BPCRN



https://safepedrug.eu/

@c4c\_network











References: 1. Paediatric clinical trials | European Medicines Agency [Internet]. [cited 2021 Mar 12]. Available from