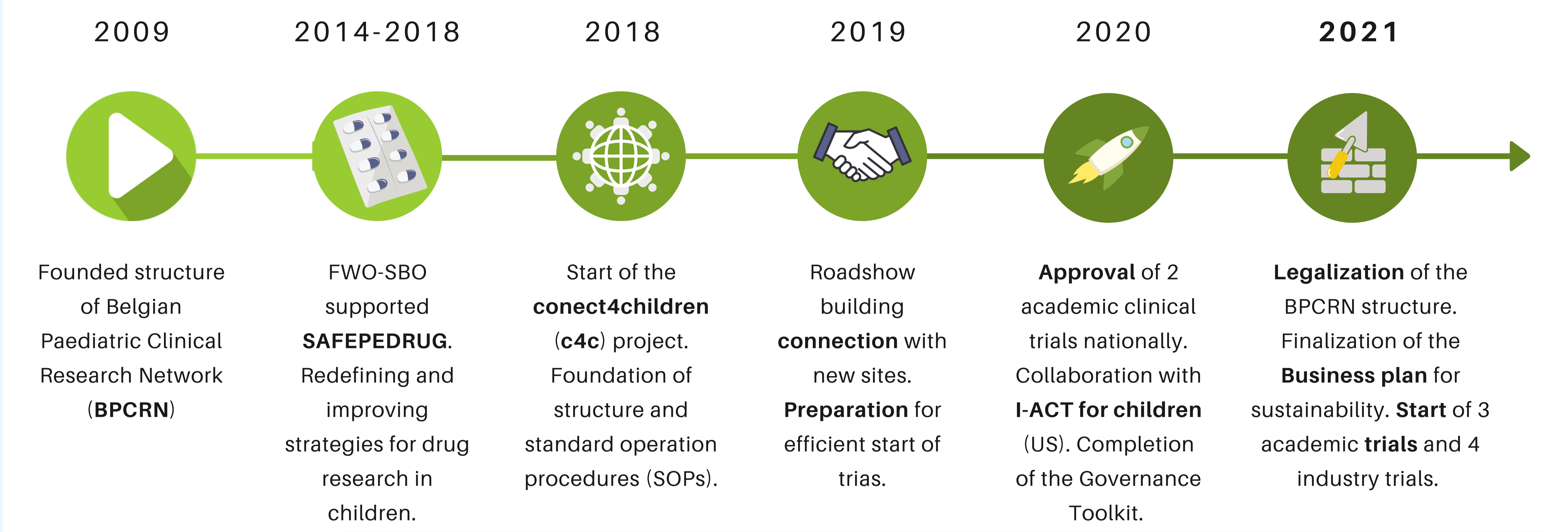


# THE EUROPEAN PAEDIATRIC CLINICAL TRIALS NETWORK CONECT4CHILDREN: ACTIVITIES OF THE BELGIUM NATIONAL NETWORK AND ITS PROGRESSION

## 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 (BPCRN)** 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).



- 15 SITES
- DATAMANAGEMENT
- SUSTAINABLE MODELS
- EUROPEAN EXPERT GROUP
- PRECLINICAL FOUNDATION: SAFEPEDRUG
- LEGALIZATION
- 11 TRIALS AIM

## Results

- Belgium is the **second country** in Europe to receive national **approval** for the KD-CAAP study.
  - Five additional industry 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 Toolkit: site specific Data 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

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**.

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