FACULTY OF MEDICINE AND HEALTH SCIENCES

GE35 SUBJECT GROUP INTERNAL MEDICINE AND PAEDIATRICS - PAEDIATRIC NEPHROLOGY

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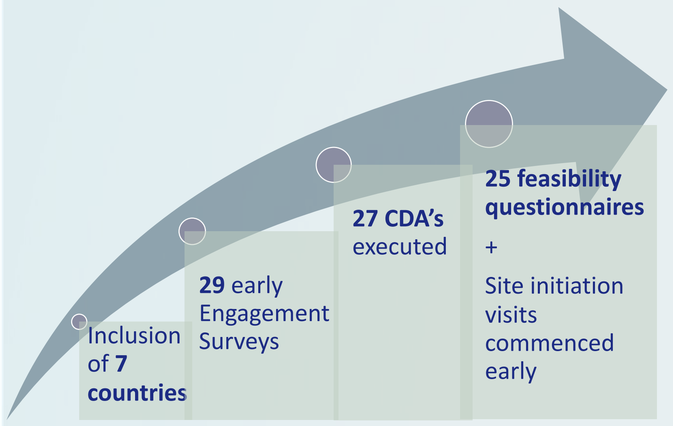
THE EUROPEAN PAEDIATRIC CLINICAL TRIALS NETWORK BEYOND THE ATLANTIC:

THE COLLABORATION BETWEEN I-ACT FOR CHILDREN (US) AND EUROPEAN NETWORK ACTIVITY

Background

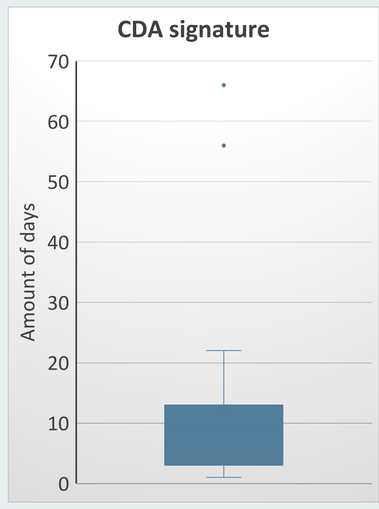
Paediatric clinical trial networks have made many advances over the last few years (1-3). In Europe, **the Innovative Medicines Initiative (IMI2)**-funded **conect4children (c4c)** initiative has promoted innovation and standardization within all levels of paediatric drug development (1,4). Its predecessor in Belgium was the FWO-SBO project **SAFEPEDRUG** (IWT 130033) which started in 2014 to develop and implement new standards for early phase paediatric drug development (3). Across the Atlantic**, I-ACT for Children** (Institute for Advanced Clinical Trials for Children) has progressed vastly in the paediatric clinical network. I-ACT for Children is a **US-based** non-profit organization for the advancement of paediatric clinical trials (5). For the **first** time, a **trans-Atlantic collaboration** was formed between I-ACT for Children and the **Belgian Paediatric Clinical Research Network (BPCRN)** which is one of the 20 countries within **c4c** (6).

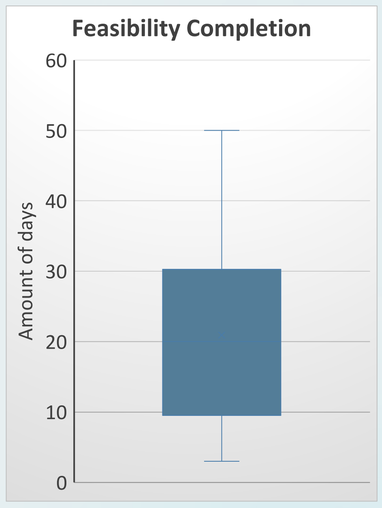
In the elaboration of an **industry** sponsored study, both networks joined hands to perform the international early-engagement, CDA and full feasibility report in 7 countries within the c4c network.



An early engagement survey was conducted, followed by sites signing a Confidentiality Disclosure Agreement (**CDA**), receiving the protocol synopsis, and conducting a full **site feasibility questionnaire**. The **CDA** process was completed in **7 European** countries within **12 days**.

The four-step process until full feasibility report was completed in a total of **over 25 sites** Europe-wide **within a 12-week mark**.





Pan-European network:

- Connection with **national representatives**
- **Personal connection with sites** (weekly close contact due to multitude of studies with national hubs and sites)
- Efficient contact:
  - Problem resolution **speed**
  - **No** language **barrier**

Site inclusion

- **Completed** majority of tasks **before deadline**
- High **response rate** in follow-up questions
- **Summary** completed with **expert review per site**

Study initiation

- **Earlier start** initiation visits
- **Bottlenecks** of the sites identified and **anticipated**
- Option of network follow-up after SFQ

Take Home Message

1. Over the past 5 years, **networks** such as **conect4children (c4c)** and **I-ACT for Children** have made substantial improvements in paediatric clinical trials.
2. By **shortening the timeline** from early engagement to full expert-reviewed feasibility for a pan-European network, paediatric clinical trials become more **attractive** for **industry**.
3. Such platforms and their **collaborations** are **essential** to achieve substantial **improvement** in **medicines** for children in EU, the US and **worldwide**.

Contact

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