EPTRI

European Paediatric Translational Research Infrastructure

The Belgian EPTRI node as an example for an integrated approach to paediatric research

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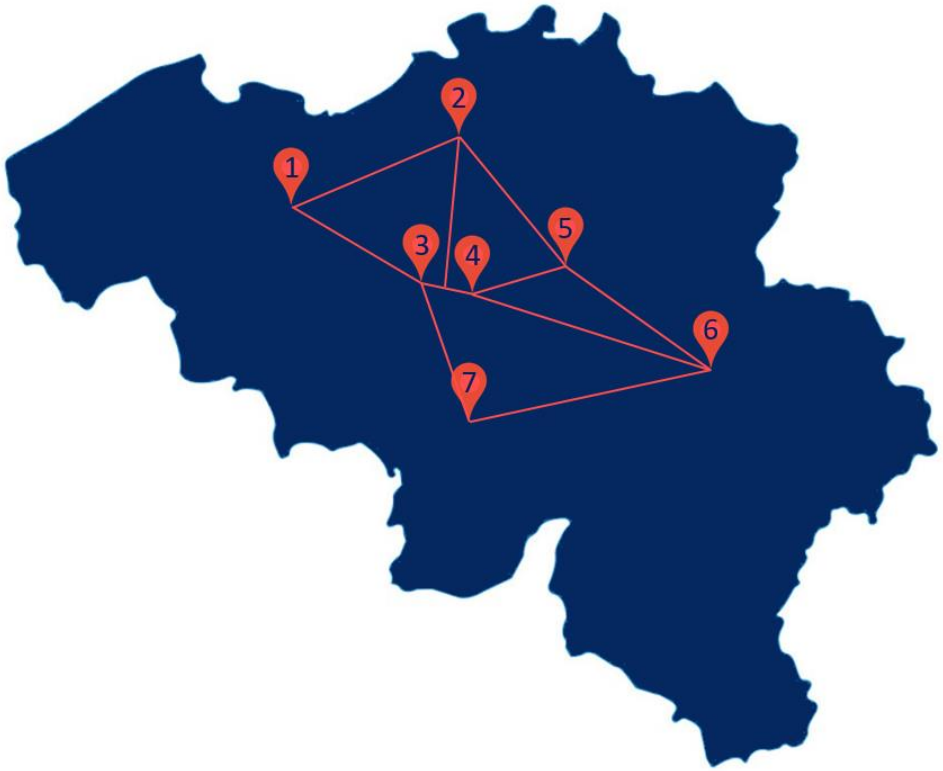
BELGIAN EPTRI JRU



1. UZ Gent & UGent
2. UZA & UAntwerpen
3. HUDERF & ULB
4. Cliniques Universitaires Saint-Luc & UCLouvain
5. UZ Leuven & KU Leuven
6. CHU Liège & ULiège
7. Institut de Pathologie et de Génétique (IPG)

The **Belgian national EPTRI Joint Research Unit (JRU)** involves paediatric research organisations and hospitals from Flanders, Brussels and Wallonia

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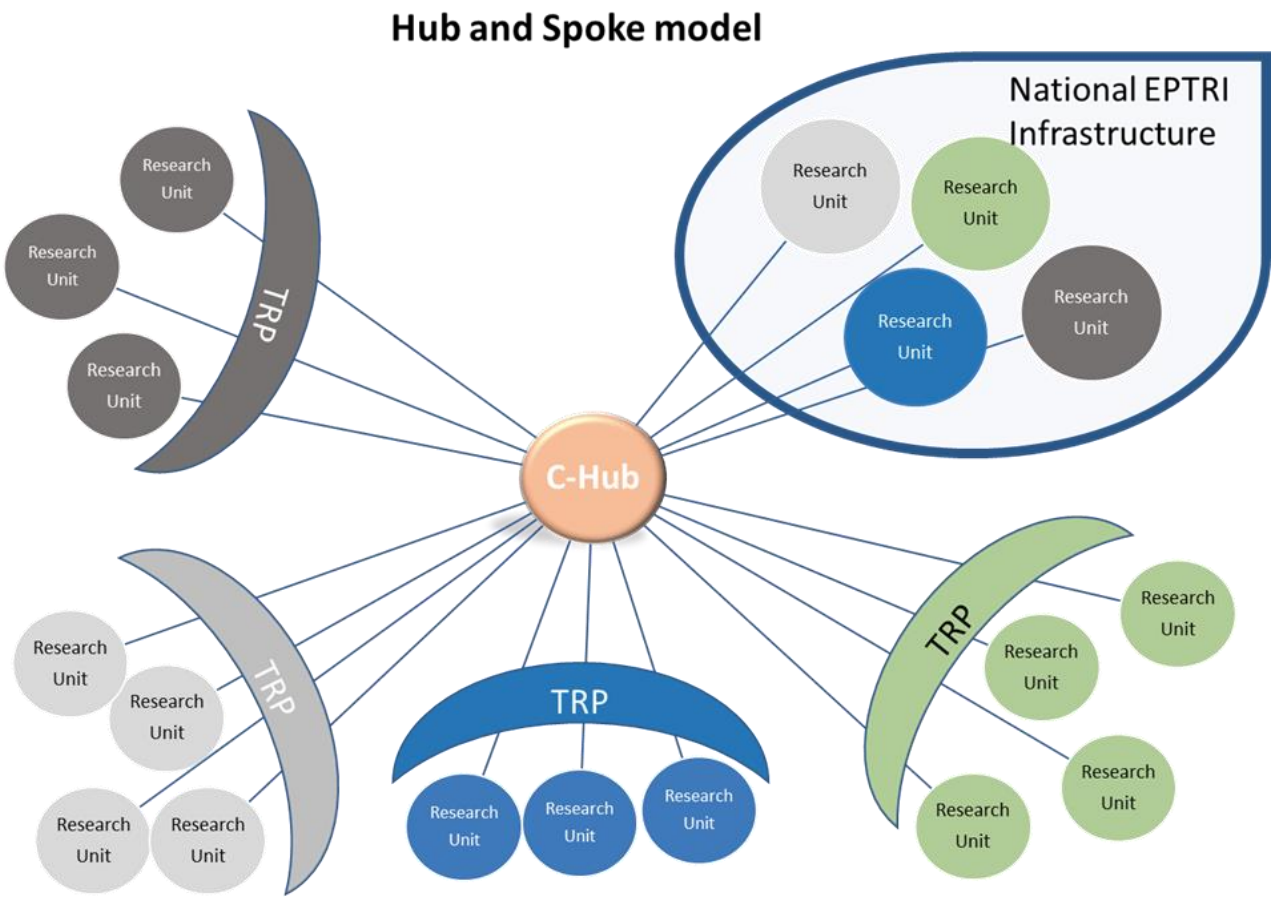
EPTRI.BE in the EPTRI Model



The national node represents a stable association between all the EPTRI participant research institutions within a country.
It will have a crucial role in interconnecting research units from the EPTRI TRPs, involved in different field of paediatric medicine research and having different level of expertise and organisation.
It communicates and interplays with EPTRI C-HUB to share projects and funds

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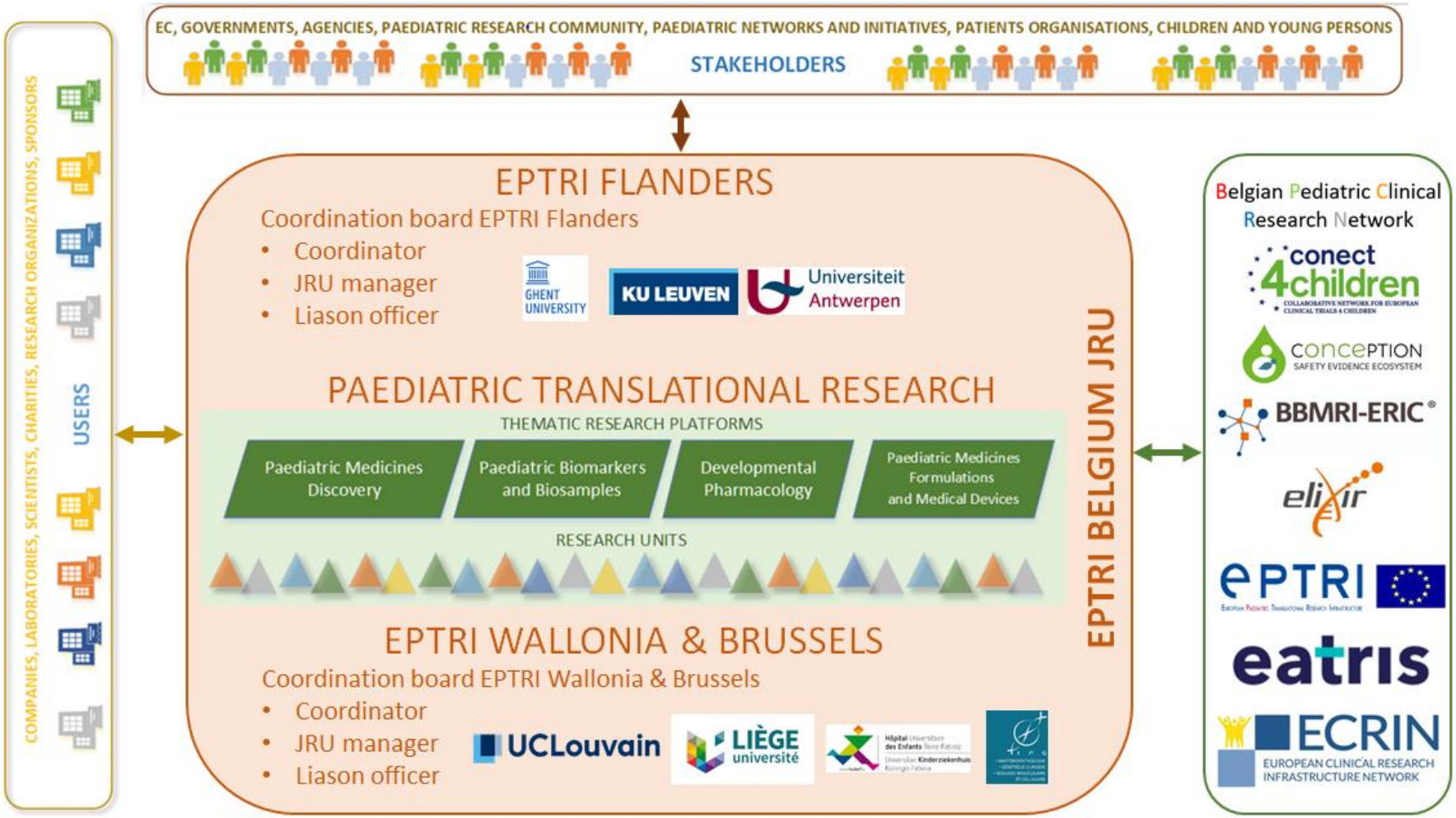
EPTRI National nodes

National nodes will be committed to support the **integration of efforts** of paediatric research organisations at national or regional level, by **connecting and facilitating** activities not specific for a single TRP.

To avoid duplication and overlapping or competing activities in the country, the integration efforts will involve not only the **RUs**, but also the already existing national paediatric research initiatives, such as **paediatric clinical networks** already developed in many EU countries as well as with national nodes of existing biomedical infrastructures with demonstrated paediatric interest

EPTRI.BE will be in contact with the **C-Hub** allowing the national community of researchers to participate in **international initiatives**, define a **national research policy** that is favourable to paediatric research.

EPTRI-BE Organisation



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EPTRI-BE participation to TRPs

The Belgian JRU partners will gather complementary scientific and technological competencies in the different EPTRI **thematic research platforms**:

1. **Paediatric medicines discovery**: several preclinical models have been developed within this consortium: placental and umbilical cord and 3D organoid cell cultures from paediatric samples, preclinical model of juvenile cirrhosis, biliary atresia, models of juvenile liver failure , and models of rare diseases such as peroxysomal diseases and Crigler Najjar; juvenile animal models such as the rabbit BPD model, juvenile Göttingen minipig, juvenile conventional pig model and developmental zebrafish model
2. **Paediatric biomarkers and biosamples**: identification, characterisation and validation of biomarkers used as prognostic tools, safety markers and diagnostic tools in paediatric diseases
3. **Developmental pharmacology**: including PK bioavailability/ bioequivalence studies, population PK/PD analysis and PK/PD modelling
4. **Paediatric medicines formulations and medical devices**: including regulatory knowledge

The partners will ensure a strong liaison with other RIs and networks such as the **BBMRI-ERIC** for paediatric biobanking, the IMI **conect4children** network for paediatric clinical trials and the Belgian Paediatric Clinical Research Network (**BPCRN**)

EPTRI-BE participation to TRPs

Fields	Insitutions	Reference person	Details on research activities
Paediatric Medicines Discovery	KU Leuven	Karel Allegaert	The research group works on rabbit BPD model, placental transfer model and stem cell research.
	UCLouvain , Cliniques St Luc	Etienne Sokal	His research study is focused on liver derived stem cells and its possible use in regenerative medicine, advanced therapy medicinal products to treat immuno inflammatory liver diseases, pre clinical model of juvenile cirrhosis, biliary atresia, models of juvenile liver failure , and also models of rare diseases such as peroxysomal diseases and Crigler Najjar; He is the founder of Laboratory of Promethera Biosciences.
	Ghent University	Mathias Devreese	His research is focused on the development of a piglet model for preclinical paediatric drug research.
	University of Antwerp	Steven Van Cruchten	His research group explore the juvenile Göttingen minipig as a preclinical model for paediatric drug research and development of a juvenile Göttingen minipig PBPK model.
Paediatric Biomarkers and Biosamples	KU Leuven	Karel Allegaert	His work is focused on bioanalysis (CDG syndrome) and bedside research tools (like neuromuscular assessment, maturational EEG, ECG or imaging)
	Antwerp University Hospital	Annelies Van Eyck	The research group works on adipokine secretions (leptin, adiponectine, TNF, IL6) examined in the context of obstructive sleep apnea and obesity. They also study the prognostic role of Volatile Organic Compounds in BPD.

EPTRI-BE participation to TRPs

Fields	Insitutions	Reference person	Details on research activities
Developmental Pharmacology	KU Leuven	Pieter Annaert	His research group works on the development and application of in vitro models for determining the functional ontogeny of hepatic transporters and enzymes. Also, they study the integration of ontogeny data into PBPK models.
	KU Leuven	Karel Allegaert	His research group works on basic in vivo and in vitro studies, first in child studies and model development to facilitate such studies (PBPK, popPK, PD markers).
	Ghent University/ Ghent University Hospital	Pieter De Cock	His team develops PK/PD models in neonatal and paediatric intensive care children, and they also perform research on renal function estimation methods in ICU children.
	Ghent University	An Vermeulen	They use modelling and simulation (popPKPD, PBPK,) to optimise dose/and dose regimen selection in paediatric subjects across the age range 0-18 years. They also perform in vitro metabolism studies, IVIVE and bio-analysis.

GOALS

- We propose an **integrated paediatric research system** that links together EPTRI Belgium with landmark RIs, conect4children, the BPCRN and institutions that provide services to paediatric research
- This integrated system can provide: **expertise, experienced facilities and practical support** for pre-clinical and clinical paediatric research in Belgium and Europe. To share the understanding of patients' needs and concerted efforts in paediatric research will further enhance the health of children
- The overarching goal of EPTRI Belgian JRU is to create **a framework** for basic and **translational paediatric research** to **facilitate** the **development of new innovative medicines for children**
- EPTRI Belgian JRU has the goal to move to a new approach characterized by medicines **specifically designed to address the needs of children** and to reduce the existing gap on **medicines availability** for babies, children and adolescents

Objectives and Key Performance Indicators

- ✓ **KPI1**: inventory of dedicated research infrastructure for paediatric translational research in Belgium
- ✓ **KPI2**: implementation centralized governance structure for EPTRI Belgian JRU
- ✓ **KPI3**: implementation of a quality manual for study data standardization concerning paediatric translation research
- ✓ **KPI4**: master collaboration agreement for academic and commercial use
- ✓ **KPI5**: Min 10 projects with a total value of more than 20 M€, with a minimum of 2 partners involved during the first 4 years.
- ✓ **KPI6**: A minimum of 30,000 paediatric patient samples stored for research to create an paediatric Biobank directory in collaboration with BBMRI.BE.
- ✓ **KPI7**: Stakeholder meetings, events or workshops on an annual basis for networking and dissemination of project results

ESFRI roadmap & cost model

- Belgian submissions for **ESFRI roadmap 2021**: parallel submissions to regional governments
  - ✓ **Flanders**: submission on FWO international research infrastructue call in April 2020 to get goverment support
  - ✓ **Wallonia & Brussels** : meeting with regional contact points
- All Belgian partners have signed EPTRI-EU Memorandum of Understanding
- Partners will provide **in-kind contributions** to EPTRI-EU