

An innovative Research Infrastructure (RI) to speed-up the paediatric drug development process: the European Paediatric Translational Research Infrastructure (EPTRI)

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BACKGROUND

EPTRI is a project that arises from the need to find answers to the **serious lack of medicines for children** in EU and worldwide.

EPTRI aims to design the framework for a new Research Infrastructure (RI) to cover the technological gap in scientific research affecting the field of paediatric medicinal products.

The proposed RI will give a substantial contribution to many areas:

- “In vitro” models to quantify the impact of ontogeny on the absorption, distribution, metabolism and elimination or excretion (ADME) steps
- Juvenile animal studies
- Optimisation of analytical techniques for drug measurements in biological fluids and in small tissue samples
- Recognised and validated genetic biomarkers relevant in paediatric diseases (for monitoring and as tools to be used in trials)
- Evaluation of pharmacogenetics/genomics/developmental interactions

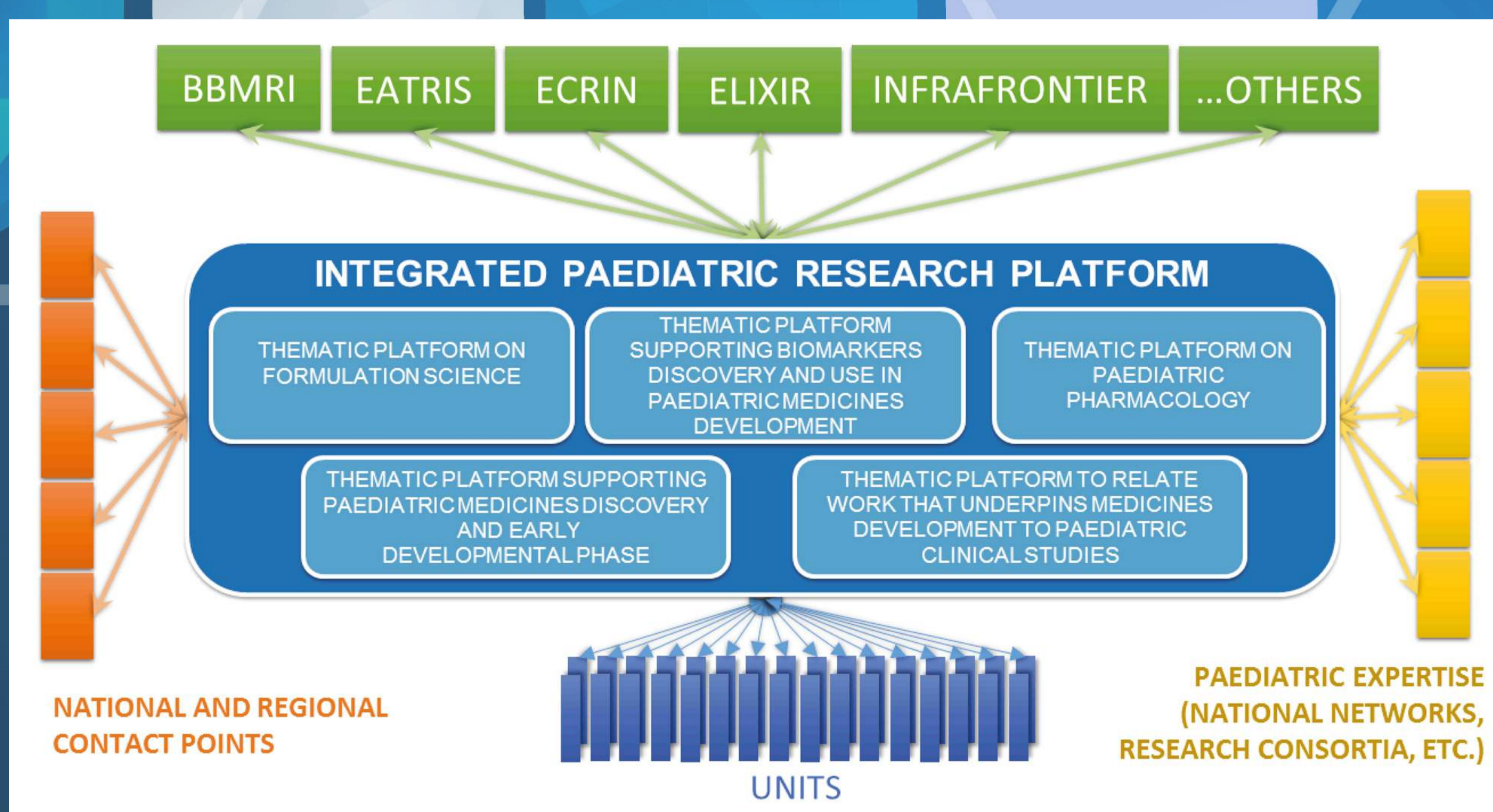
METHODS

In this scenario, the EPTRI project identifies five technical and scientific domains (thematic platforms):

- Human development, early translational discovery and paediatric drug development
- Paediatric biomarkers and biosamples
- Paediatric pharmacology
- Paediatric medicines formulation
- Underpinning paediatric studies.

The last domain will be aimed to specify the needs of the EPTRI users for an integrated approach to technologies that support medicines development in children and will be a bridge between EPTRI and the RIs and networks that support clinical trials.

The first phase of the project is the **Context Analysis** aimed to estimate the possible services providers and the existing gaps. During the **Operational phase**, the different components of the new RI will be organised including governance model strategies for interaction with national Authorities and the existing RIs, the IT-architecture model, services to be provided and a business plan. In the second year, a **Feasibility phase** is proposed to develop virtual exercises simulating the operations of the European Paediatric Translational RI.



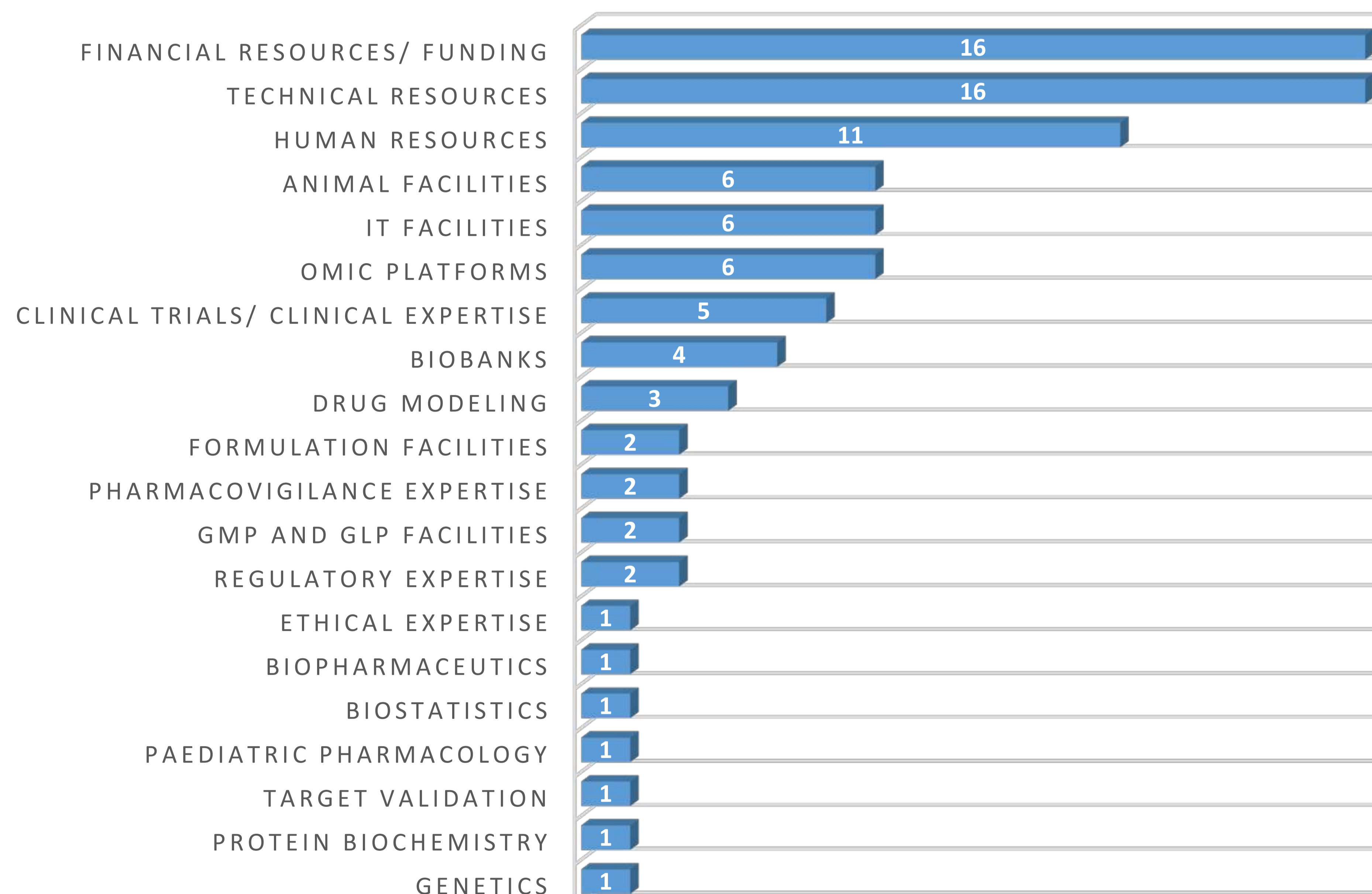
RESULTS

The survey has been delivered to 828 research units in the fields of drug discovery and early development phases, paediatric pharmacology, biomarkers, paediatric formulations. It showed a very interesting scenario with **141 out of 828 research units** providing data on their potential involvement in the future European Paediatric Translational Research Infrastructure.

CONCLUSIONS

EPTRI will built up a new European RI by bridging all the available competences and technologies useful to the paediatric research, creating an open science space, which will allow researchers to work together in order to cover the gap in the development of new drugs for the paediatric population.

PERCEPTION OF THE GAPS IN PAEDIATRIC RESEARCH



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