

ePTRI

EUROPEAN PAEDIATRIC TRANSLATIONAL RESEARCH INFRASTRUCTURE



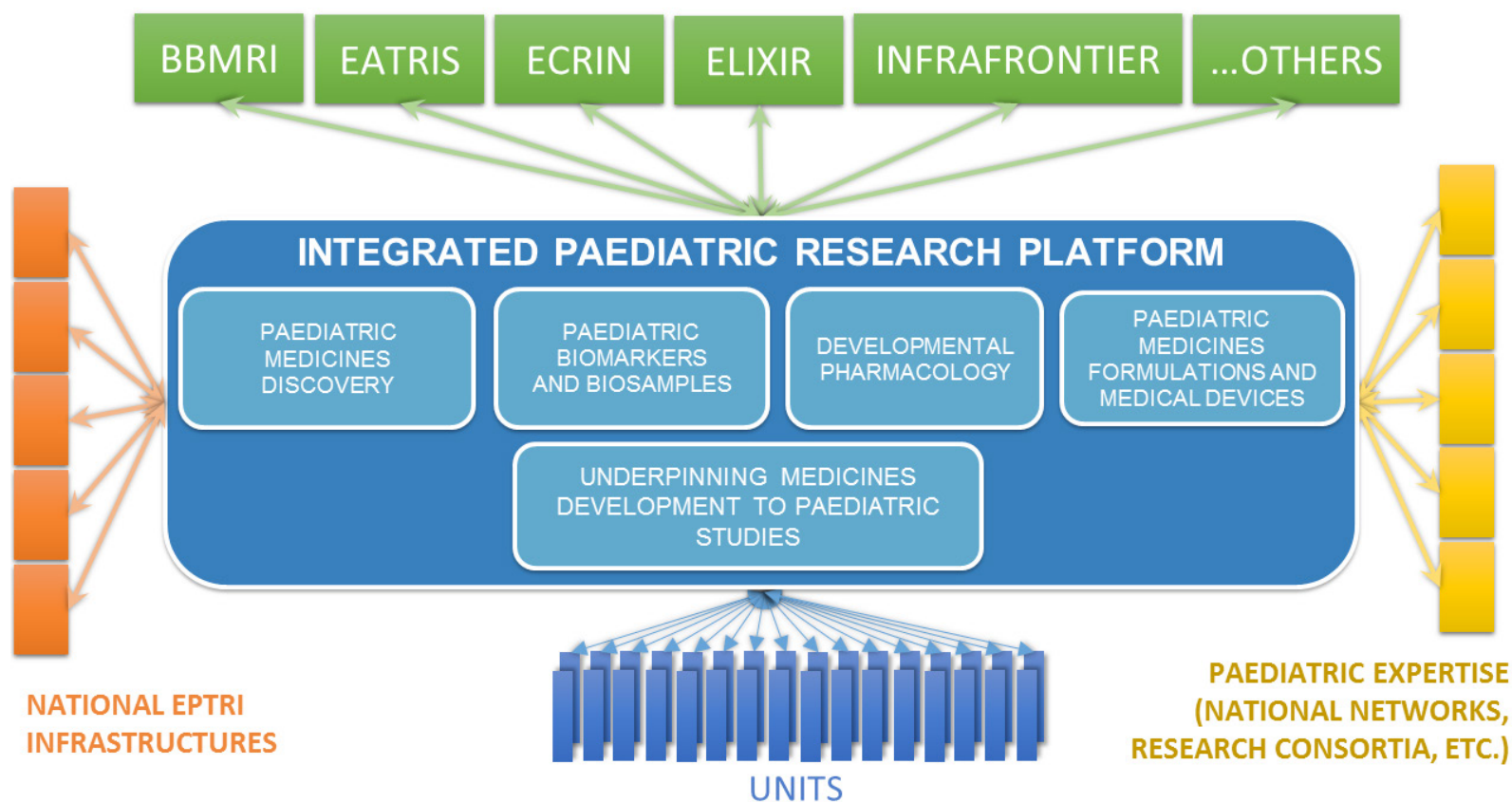
THE BRIDGE TOWARDS THE FUTURE OF PAEDIATRIC RESEARCH

The European Paediatric Translational Research Infrastructure, **ePTRI**, a **new complementary Research Infrastructure (RI)** in the context of the existing RIs is intended to putting together and networking all the available competences and technologies useful to enhance paediatric research in paediatric medicines development from drug discovery and early phases to be translated into clinical phases and medicines use.

The infrastructure will be composed of five technical and scientific domains including:

- 4 thematic platforms
 - » Paediatric Medicines Discovery
 - » Paediatric Biomarkers and Biosamples
 - » Developmental Pharmacology
 - » Paediatric Medicines Formulations and Medical Devices
- the scientific domain
“Underpinning medicines development to paediatric studies” integrating key technologies into paediatric medicines development process and acting as a bridge between ePTRI and other paediatric initiatives and clinical trials networks.





In order to set up the new RI within the European landscape, the following three phases have been planned:

- a **Context Analysis phase**, aimed to identify the potential service providers to be included in the future European Paediatric Translational Research Infrastructure and the possible gaps to be covered;
- an **Operational phase**, aimed to design the different components of the new RI, including the governance model, the strategies for interaction with national Authorities and the existing RIs, the IT-architecture model, the services to be provided and a business plan;
- a **Feasibility phase**, in which selected pilot experiences will be proposed simulating the operations of EPTRI to work as a “one-stop-shop” for advice in paediatric drug development.

To harness efficiency in delivery of paediatric research activities and services, EPTRI plans to create “**paediatric common services**” with already established RIs.

Moreover, EPTRI will be an **open science space allowing researchers to work together without geographical, institutional or financial barriers** and a system of many interconnected areas, each of them led by a top-edge group focused on a specific topic/research area.





Innovation potential and expected impacts

EPTRI will bring a **positive impact on the scientific community**, as it is expected that, following the rising integration of the different research units within the new establishing RI, the scientific relevance of the paediatric research at national and international level will increase. EPTRI is also expected to positively impact on the social and ethical aspects, since it will address the theme of research for a vulnerable and neglected population.

Despite EPTRI will not deliver new medicinal products on the market, it will bring benefits also on children's health as it will establish the right framework to speed-up the drug development process in paediatrics and to include the top-level research innovations in research for children's health. This will end in an increased offer of appropriate efficacious and safe medicines for children in all the paediatric ages (from neonates to adolescents).

This will lead to a **reduced fragmentation of the paediatric research landscape** through **harmonisation of procedures, implementation of common standards and the promotion of scientific excellence** in research collaborations, so to maintain EPTRI to a high competitiveness at European level.

The innovation potential of EPTRI is particularly linked to the enhancement and the wider implementation of the **Key Enabling Technologies (KET)** for drug development that have been poorly used in the paediatric field and are able to drive Europe's innovation. The infrastructure will bring together clinicians, researchers and industry (both SME and large Pharma) to support smarter paediatric medicines development in an atmosphere of innovation and collaboration for the benefit of health sciences, academic research, economic development and ultimately patients.

In particular, EPTRI will have the following expected impacts:

- help academic and non-academic organisations to strengthen their base of knowledge and technological know-how;
- increase the value of the human capital enhancing the quality of life, so to generate healthy and productive life years;
- facilitate access to progresses and results in health care and diseases' prevention for children;
- bringing together the expertise provided by the paediatric scientific community including users' communities and patients' associations,
- include into the activities and services already developed in the framework of the biomedical ESFRI Research Infrastructures a specific paediatric competence that is still underrepresented there;
- preparing the ground to increase paediatric research and reduce the serious delay to provide children with new, innovative and advanced therapies as resulting from the advancement of biological and medical sciences;
- link advancements in paediatric research to the rapid development of regulatory provisions, to favour the development of more demonstrative projects based on innovative study design.



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