

# EPTRI – European Paediatric Translational Research Infrastructure.

## Bridging the gaps of the paediatric excellence medicine

Bonifazi D.<sup>1</sup>, Lupo M.<sup>1</sup>, Pignataro V.<sup>1</sup>, Toni I.<sup>2</sup>, Kubova H.<sup>3</sup>, Tuleu C.<sup>4</sup>, Lavitrano M.<sup>5</sup>, Ceci A.<sup>6</sup>

### INSTITUTIONS

<sup>1</sup> Consorzio per Valutazioni Biologiche e Farmacologiche, Via Putignani 178, 70122 Bari, Italy

<sup>2</sup> Universitätsklinikum Erlangen, Department of Paediatrics and Adolescent Medicine, Loschgestraße 15, 91054 Erlangen, Germany

<sup>3</sup> Department of Developmental Epileptology Institute of Physiology, The Czech Academy of Sciences, Videňská 1083, Prague 14220, Czech Republic

<sup>4</sup> UCL School of Pharmacy, 29-39 Brunswick Square, WC1N 1AX London, United Kingdom

<sup>5</sup> Department of Medicine and Surgery University Milano Bicocca, Via Cadore 48, 20900 Monza, Italy

<sup>6</sup> Fondazione per la Ricerca Farmacologica Gianni Benzi Onlus, Via Abate Eustasio 30, 70010 Valenzano, Italy

## INTRODUCTION

Development of age appropriate medicines for children is one of the major challenge of our century. Most of the drugs derived by the advancements of the life science have been discovered and developed with adult patients in mind. This has led to off-label and unlicensed use of adult medicines in children. Nevertheless, it has been well established that children are not small adults, rather they represent a very heterogeneous groups for their continuous growth, maturation of body composition and physiologic and cognitive changes.

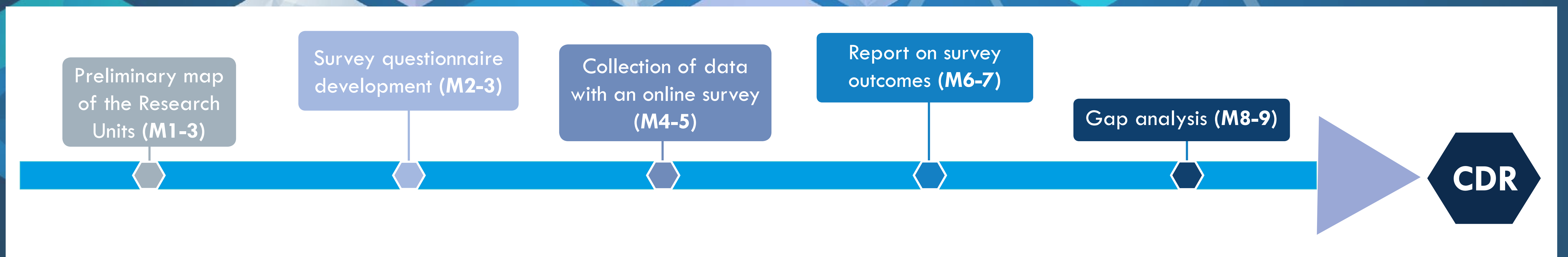
The development of age appropriate medicine for children requires understanding of the physical and biochemical differences between children and adults as pharmacokinetics and pharmacodynamics, potential routes of administration and medicine-related toxicity.

The ID-EPTRI project is aimed to bridge the existing gaps in the paediatric medicine from the early stage drug development phases to be translated into paediatric use of medicines, through a new paediatric Research Infrastructure.

## MATERIALS AND METHODS

The ID-EPTRI project aims to promote and foster paediatric research, to expedite the creation/use of innovative technologies for the development of better and safer drugs for children, and finally to prepare the Conceptual Design Report (CDR) of the future Research Infrastructure (RI). To this purpose, the project will encompass three phases: Context Analysis phase, Operational phase and Feasibility phase.

In this Context Analysis Phase, a survey has been set up to map the competences and expertise in the field of paediatric research in Europe and to identify the possible gaps in the availability of services and facilities to set up the European Paediatric Translational RI.

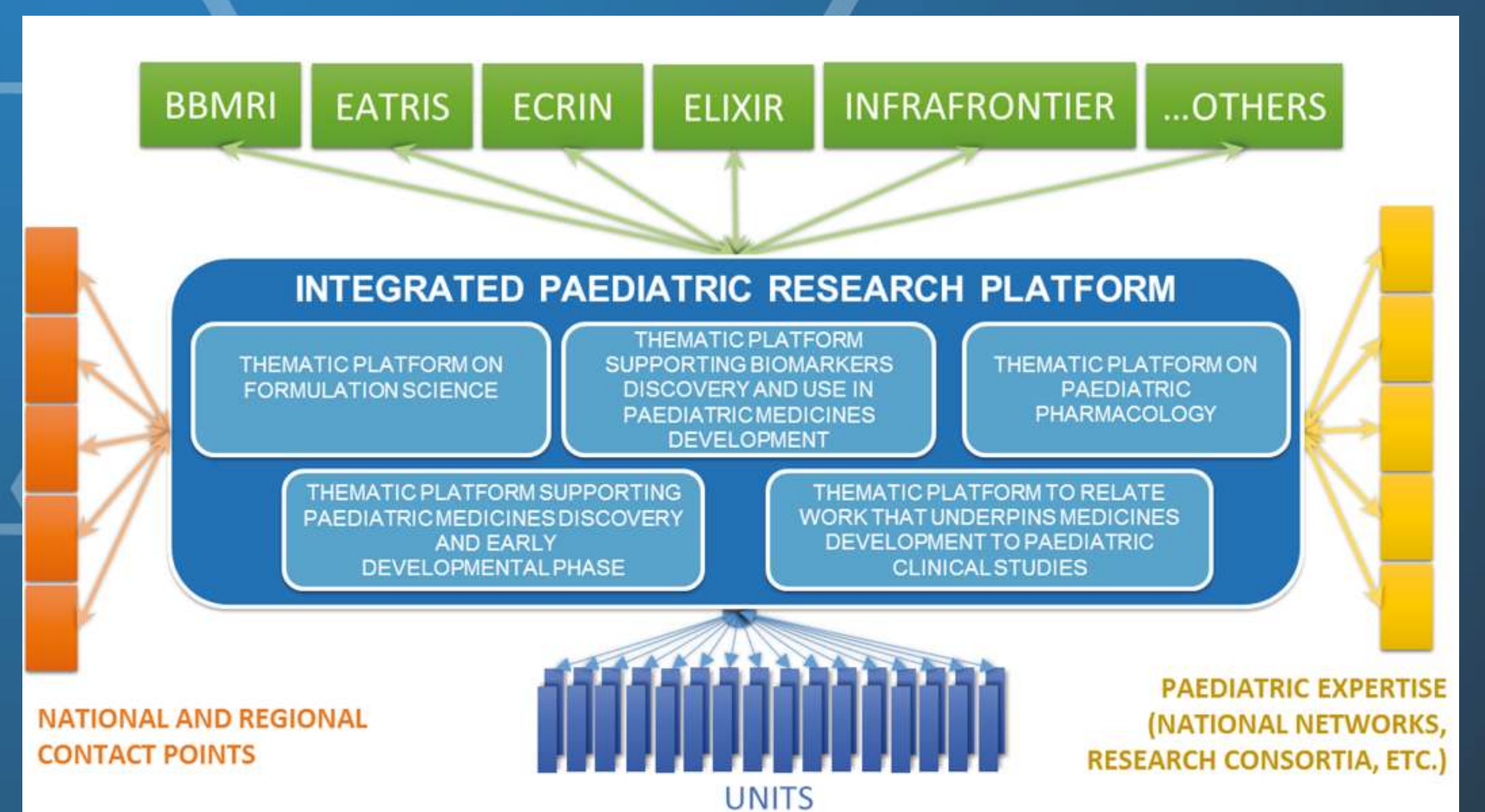


## RESULTS AND DISCUSSION

The survey is focused on five main areas:

1. human development and paediatric basic science;
2. early translational discovery and drug development;
3. paediatric biomarkers and biosamples;
4. paediatric pharmacology;
5. paediatric medicines formulation.

The questionnaire has been delivered to about 955 paediatric leading experts in the five areas, identified through a preliminary map of European research units, the contacts of the Partners involved in the project, bibliographic research, etc. This survey will allow the identification of potential service providers to be included in the future Research Infrastructure and high-end apparatus (resources and research facilities, equipments, platforms, methodologies and experimental settings) which can offer considerable expertise to a paediatric context.



## CONCLUSIONS

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