

# Biomarkers and Biobanking platform

Marios Phylactides/ Marina Kleanthous

The Cyprus Institute of Neurology and Genetics

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# List of deliverables

Deliverable Number	Deliverable Title	Lead beneficiary	Type	Dissemination level	Due Date (in months)
D6.1	Report on the existing <b>needs</b> in paediatric research for biomarker development and use	BBMRI-ERIC	Report	Confidential	6
D6.2	Report on the <b>opportunities and threats</b> to address paediatric biomarker platform	CING	Report	Confidential	9
D6.3	Description of the <b>research activities</b> to be provided within the platform supporting biomarkers use in paediatric medicines development	BBMRI-ERIC	Report	Confidential	13
D6.4	Report on <b>feasibility study</b> "Identification of biomarkers for the segregation of paediatric beta thalassaemia patients responding to drug Hydroxyurea"	CING	Report	Confidential	27
D6.5	<b>Summary Report</b> on the WP6 platform activities as part of the final CDR	BBMRI-ERIC	Report	Confidential	26

# Surveys of service users and providers

## Two rounds of surveys

### Round 1: General survey

- Service users and providers
- Collaborators, Institutional databases (BBMRI, EATRIS, CVBF)
- Sent out twice
- Scientific fields of interest
- Use of /research in biomarkers
- Research needs
- Platform components
- Capabilities
- Interest in becoming service providers (areas)

# Surveys of service users and providers

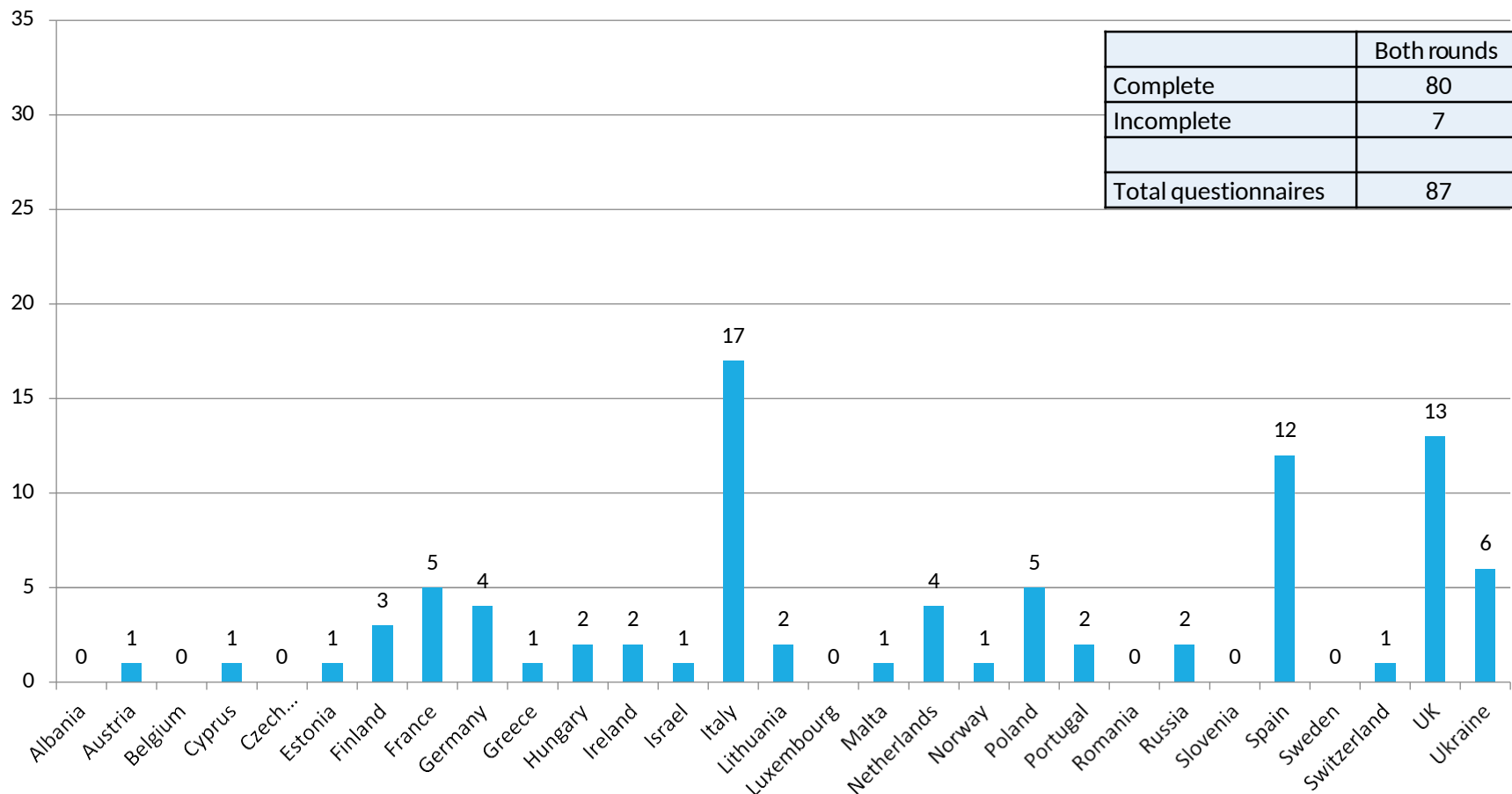
## Round 2: Focus on services and facilities

Focused on Service providers

- Biobanks
- Omics services
- Bioinformatics services
- Biomarker identification/validation activities
- Lab capabilities

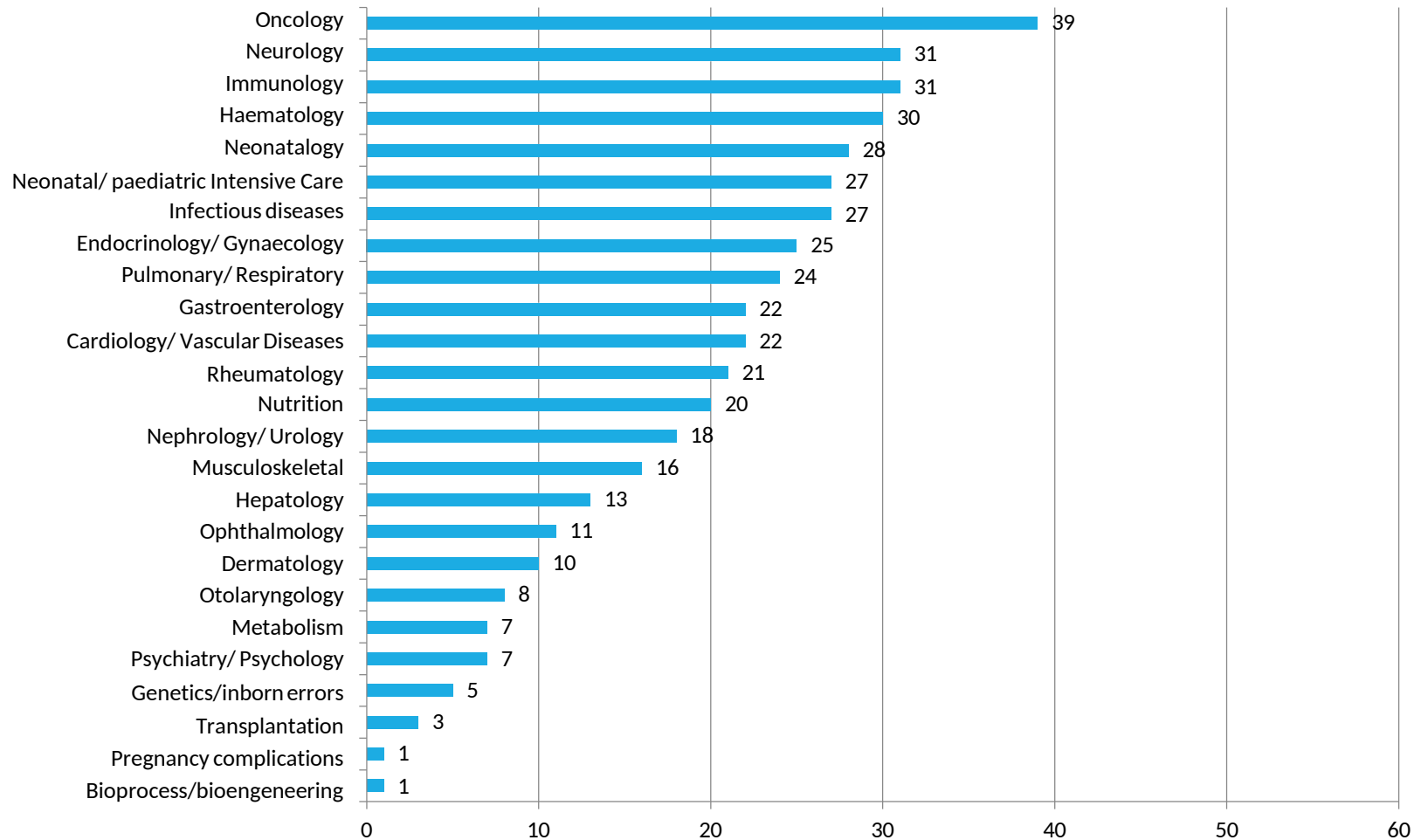
# Surveys of service users and providers

Responder units per country



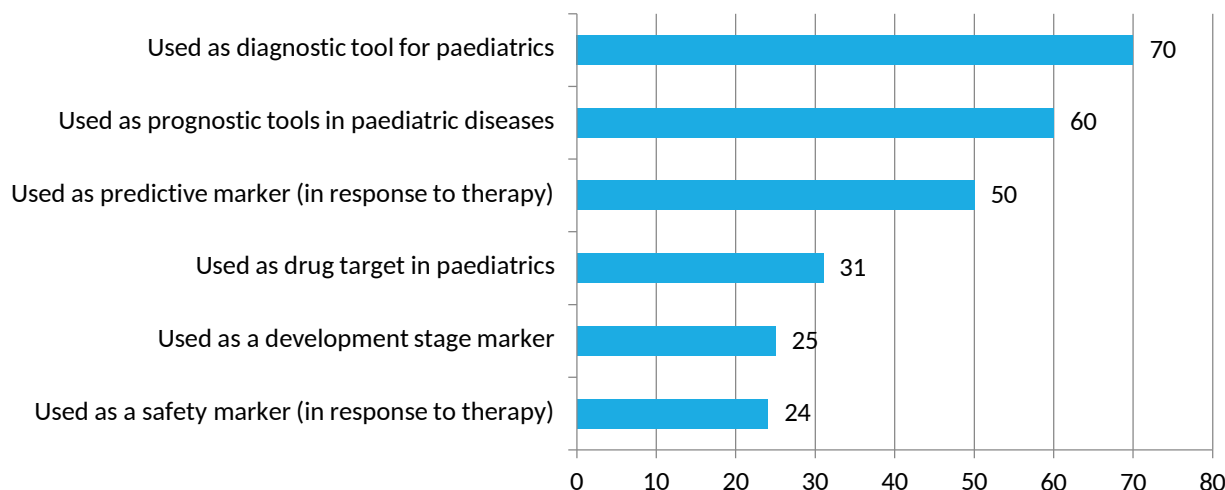
# Surveys of service users and providers

## Main therapeutic fields of interest

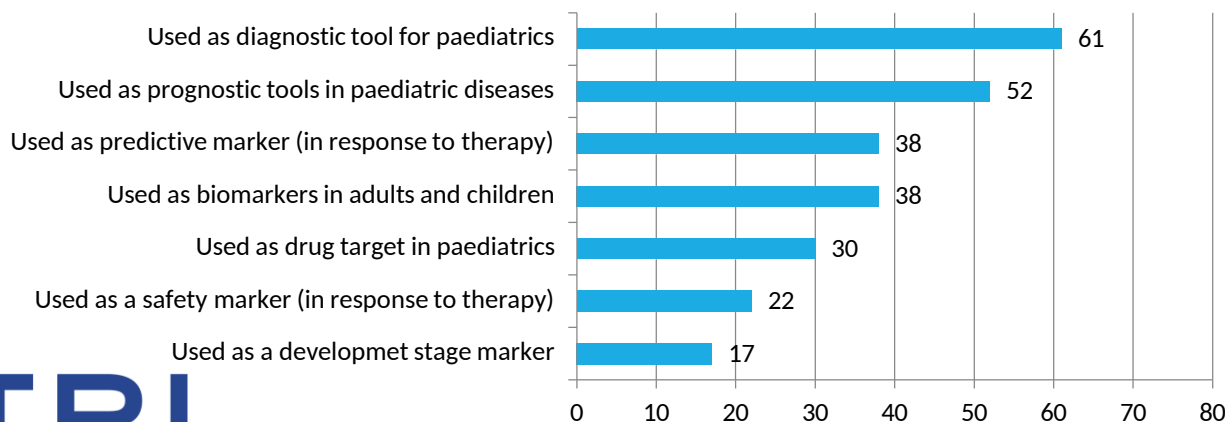


# Surveys of service users and providers

## Identification/characterisation of the biomarkers



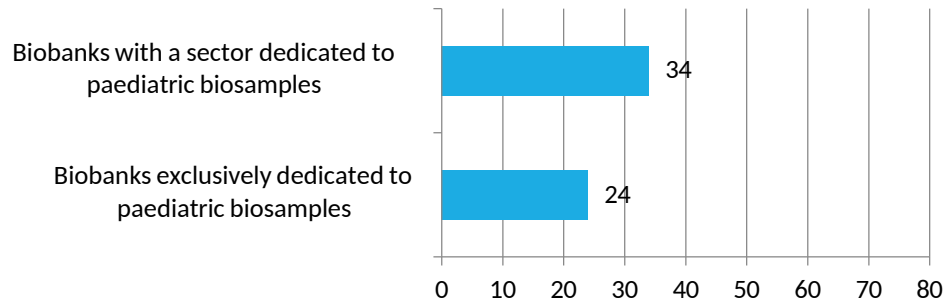
## Validation process of the biomarkers



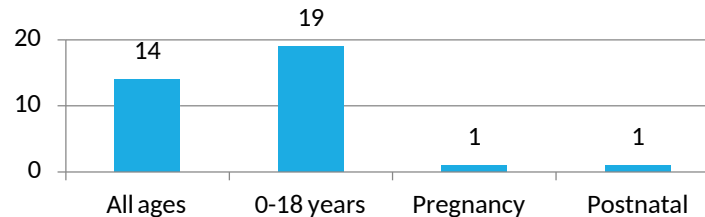


# Surveys of service users and providers

## Biobank organisation



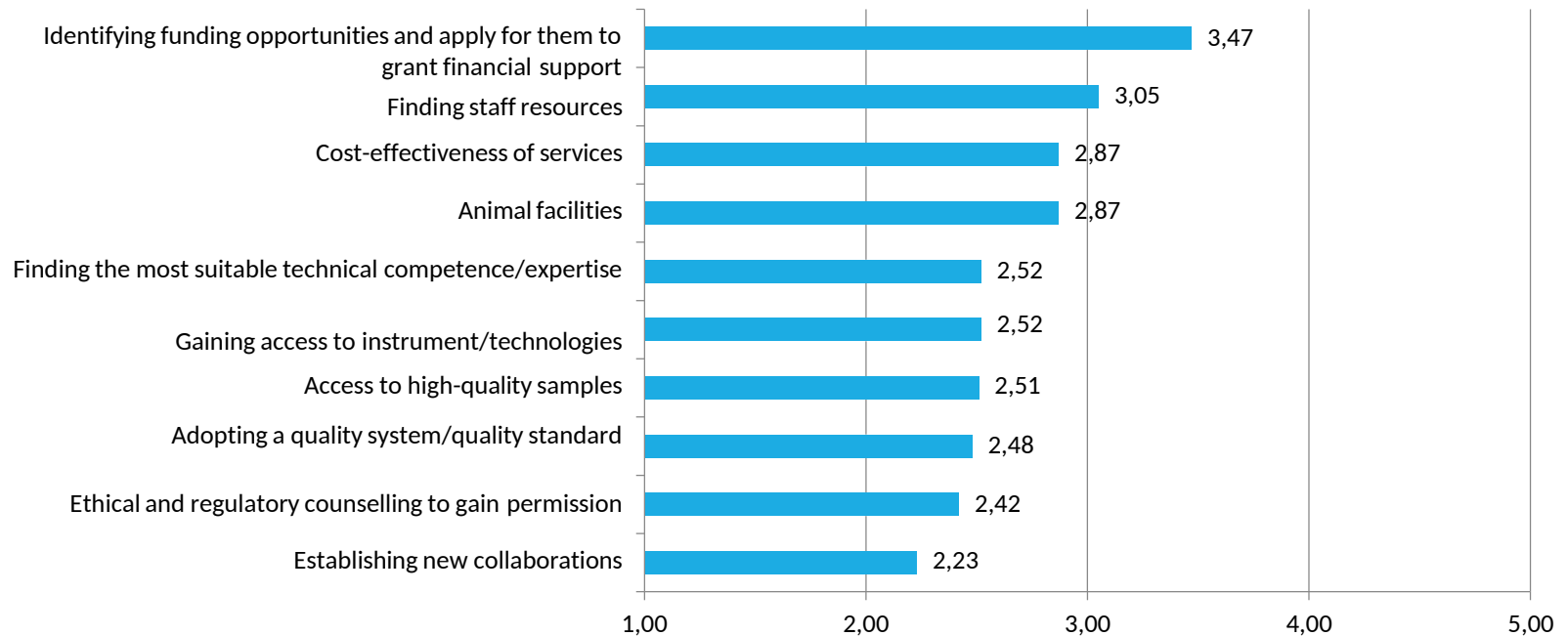
## Range of human development stage covered





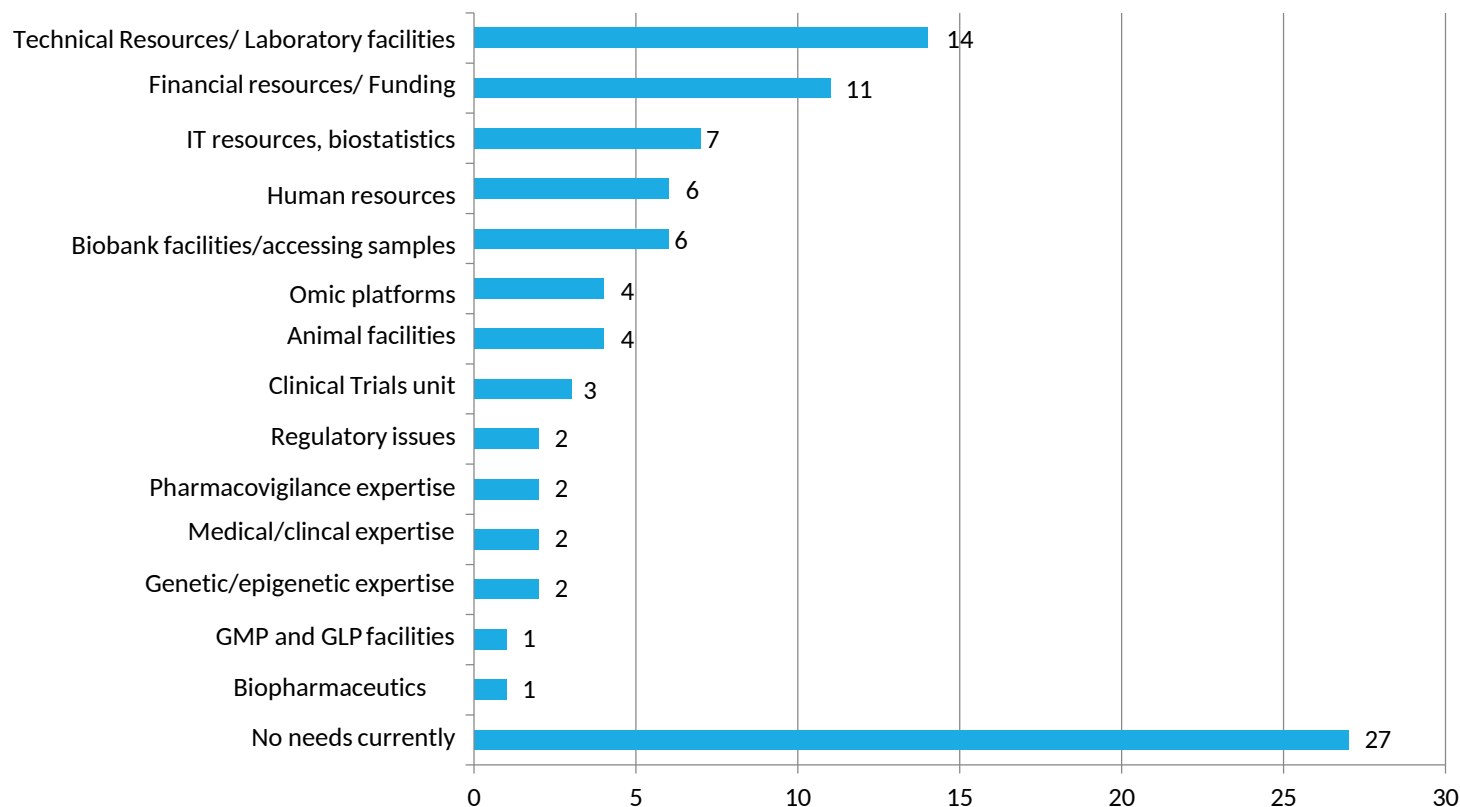
# Surveys of service users and providers

## Most relevant difficulties



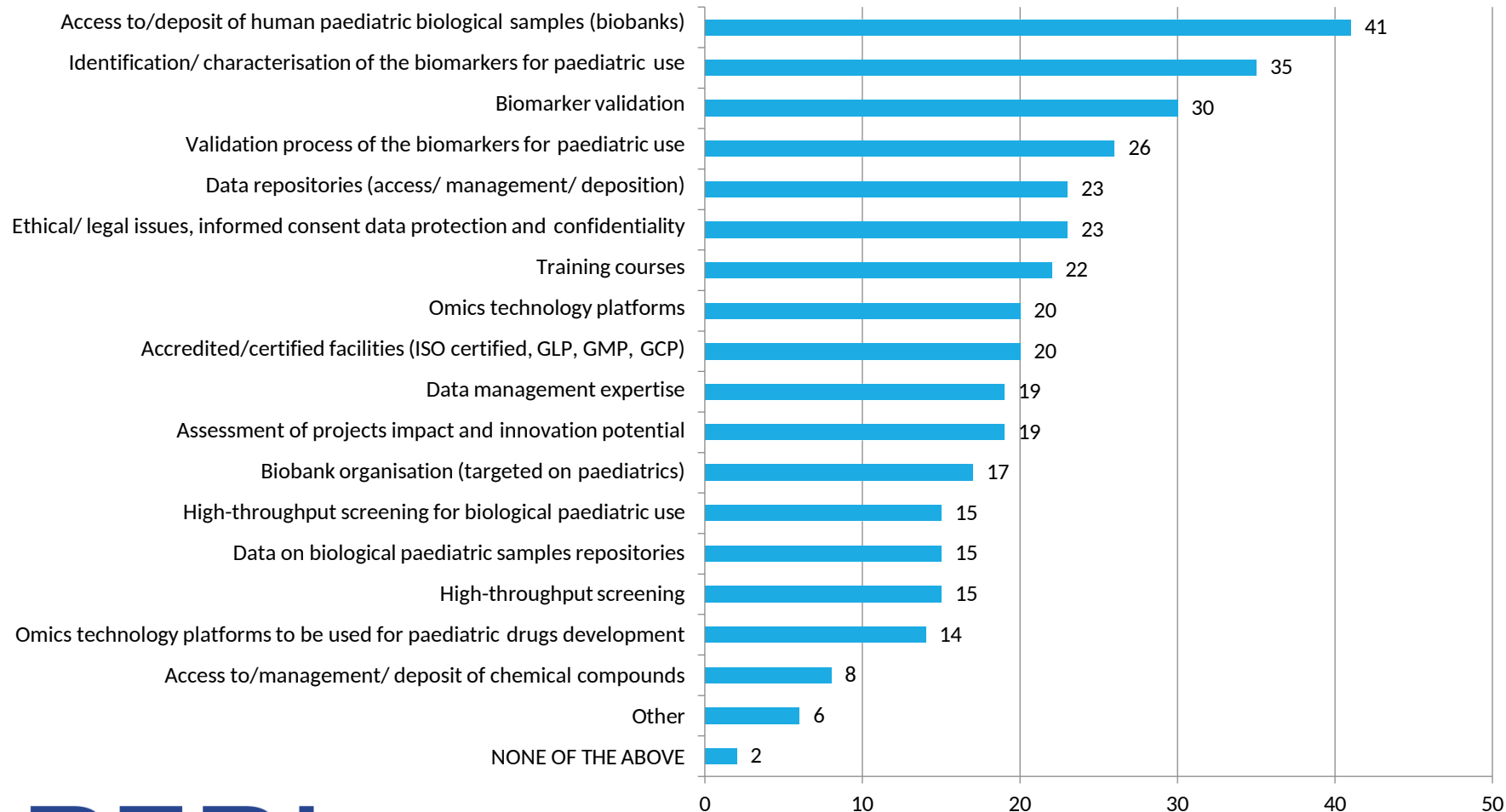
# Surveys of service users and providers

## Currently unavailable expertise/resources/facilities



# Surveys of service users and providers

## Research services that responder could provide within a R.I.



# Analysis of survey results

## **Research services of interest to users in the framework of a research infrastructure**

- Biomarker identification and validation
- Access to high quality samples (biomaterials that are linked with accurate clinical data)
- Help on ethical issues
- Presence of data repositories
- Training courses

## **Specific expertise, resources and facilities currently not available/accessible in paediatric research activity**

- 'Omics' platforms and IT and biostatistical support
- Technical resources. Ranged from very specific to very general

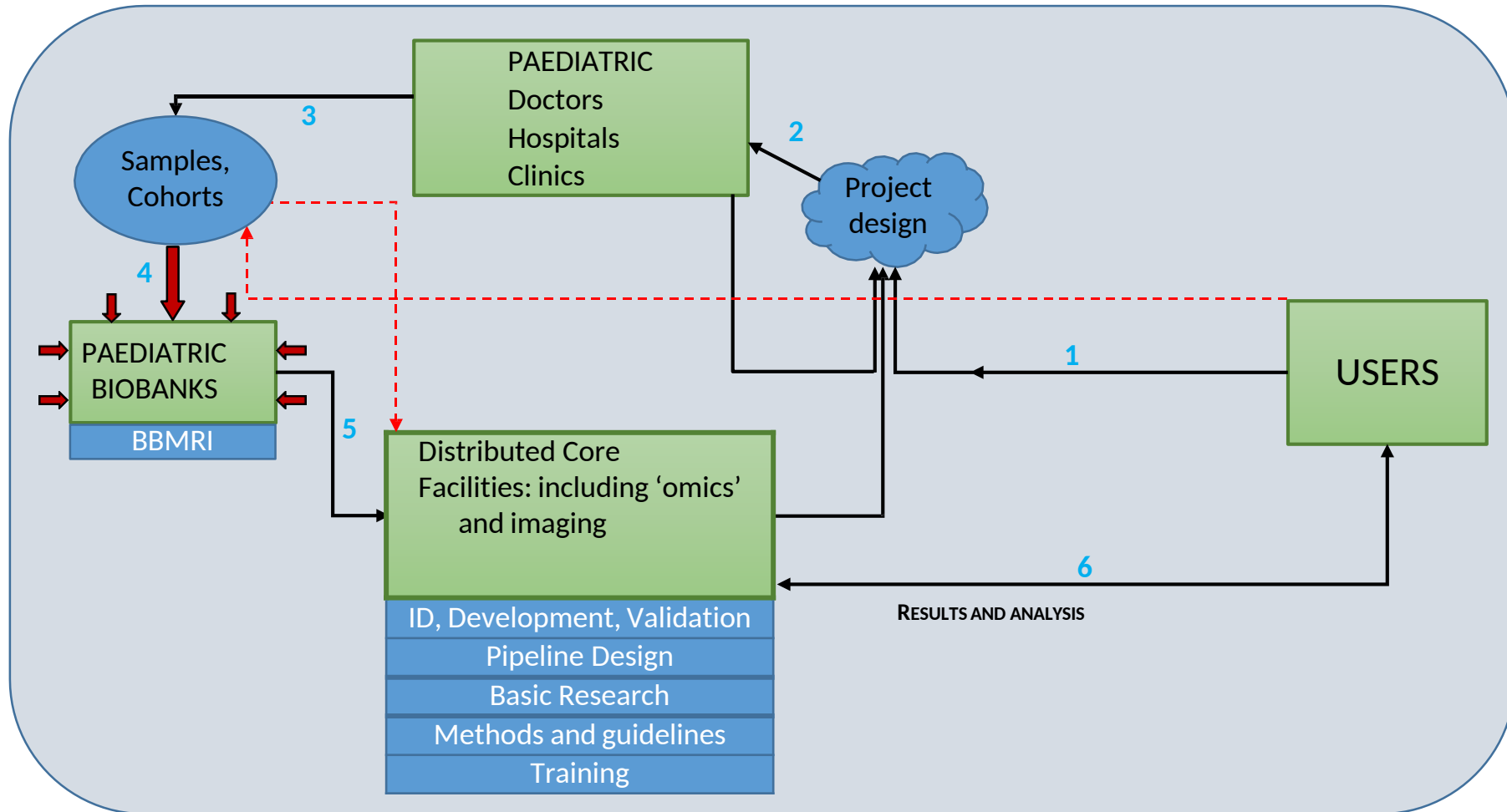
## **Other issues raised by the responders**

- Lack of funding opportunities
- Staff resources

## **Issues raised by BBMRI**

- Standardized and harmonized protocols are still lacking within the omics field.
- ID-EPTRI should participate in the development of best practices for omics studies and of defined pre-analytical conditions that are a prerequisite for reproducible results.

# Proposed biomarker platform



# Services to be provided by the Paediatric Biomarkers

1. Access to paediatric biosamples and related data
2. (Access) to collection of animal biosamples for paediatric studies
3. *In vitro* Omics technologies application for paediatric biomarkers identification
4. Bioinformatics (analysis of omics data)
5. *Ex vivo* experimental models for paediatric biomarkers identification
6. *In vivo* experimental models for paediatric biomarkers identification
7. Support to qualification procedure



# SWOT analysis

## HELPFUL (for our objective)

## HARMFUL (for our objective)

### STRENGTHS

1. First large platform dedicated to paediatric biomarkers discovery and validation
2. Size
3. Expertise of participating institutions
4. A specialist RI covering most of the EU, crosslinking with existing RIs
5. Providing 'Local service'
6. Minimal set-up costs
7. Flexibility in the cost structure

### WEAKNESSES

1. Novel platform with an unknown business model and related cost/revenue structure
2. Variable service by RI members, not dedicated service providers
3. Lack of experience in managing access procedures and regulations
4. Overlapping expertise by existing RI in the EU
5. Lack of personal touch
6. Lack of a defined cost structure based on prospective or extended collection models
7. Increased cost to link with hospitals and to establish industry collaborations

### THREATS

1. Low levels of adoption within the EU supporting countries
2. Competition from commercial entities
3. Low interest by pharma companies
4. Lack of funding opportunities to sustain users and for upgrading the research infrastructures.
5. Covering all normal and pathological human development leads to ineffective coverage and services

### OPPORTUNITIES

1. EU's strategic plan for RIs
2. Creation of a non-profit pathway for novel biomarker identification and development specific for paediatric pathologies
3. Specialization on a specific field (paediatric)

INTERNAL  
(within organisation)

EXTERNAL  
(outside organisation)



# Feasibility study

**Objective:** the discovery & development of predictive biomarkers for the stratification of  $\beta$ -thal paediatric patients relative to response to the drug Hydroxyurea

**EPTRI contribution:**

**WP 6** Identification of collection of biological samples and data for patient stratification

**WP 6** proteomics, transcriptomics and metabolomics analysis of samples and bioinformatic analysis of data

**CMO-Underpin clinical studies/trials-** connection to existing paediatric initiatives/National Network for the performance of clinical studies

**CMO-EAB** Advice on bioethical issues and legislation

**CMO- Patients Involvement**-advice on patient involvement

# Feasibility study-Conclusions

- EPTRI cannot be a universal sample provider
- Expect good coverage of omics and bioinformatic services
- Strong support from the EPTRI central office services

Thank you for your attention