ePTRI
EUROPEAN PAEDIATRIC TRANSLATIONAL RESEARCH INFRASTRUCTURE

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Consorzio per Valutazioni Biologiche e Farmacologiche

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Fundació Privada per a la Recerca Sant Joan de Déu (FSJD)

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1. List of authors

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2. Executive Summary

First press release launched to the means of communication with the general of the project and about the development of the Kick-off-meeting.

3. Contents

3.1. Press Release

CVBF
Consorzio per Valutazioni Biologiche e Farmacologiche

EPTRI
European Paediatric Translational Research Infrastructure

ID-EPTRI a new research infrastructure that will facilitate the future development of better paediatric medicines

Roma, January 2018 - **ID-EPTRI** (European Paediatric Translational Research Infrastructure) is a project coordinated by the Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF-TEDDY) that granted with 3 million of Euros from funding of the European Commission. The main objective of the project lasting 24 months, is to **design the framework for a new European Paediatric Research Infrastructure (RI)**.

Minors represent 20% of the European population and their care is one of the most important priorities and challenges for Europe. It's essential the development of evidence-based paediatric medicines and treatment strategies. Nowadays around the 50% of the medicines addressed to children and young patients have not been tested specifically for them. For this reason, it's strategic the development of the suitable research infrastructure that can solve this problem, studying the paediatric research from the early phases to the paediatric formulation. Children and young patients cannot be never compared with adults as they are growing up and their metabolism is different. For this reason, the only way to develop better medicines for children and young patients is studying them specifically for this type of "special" population. A dedicated infrastructure integrating the different basic research networks addressed to paediatric population will help in the process to reduce time and increase the number of projects. On the other hand, it also can help to a fast translation into the clinical practice.

This new research infrastructure, EPTRI is complementary to the other existing Biomed Research Infrastructures acting as a 'Paediatric Common Service' in the ESFRI (European Strategy Forum on Research Infrastructures) Scenario. The project involves 26 partners (listed in the **Appendix 1**) from EU and non-EU countries including consolidated research infrastructures, top-level universities, scientific and clinical centers of excellence in Europe and aims to create a Conceptual Design Report (CDR) to set-up the European Paediatric RI.

In order to set up the new RI within the European landscape, there will be three different phases:

1) a context analysis, aiming to acquire the information needed to complete a consistent CDR;

2) an operational phase focused more specifically on the design of the whole RI;

3) a feasibility phase in which selected pilot experiences will allow testing a limited number of services and tools delivered by EPTRI.

The involvement of children and young people is included in the development of the project, with the aim to ensure that their needs are addressed in the conceptual design report for the development of the new infrastructure, that will join and cover all the different domains previous to the clinical research in drug development: 1. Pediatric Medicines Discovery and Preclinical Studies; 2. Biomarkers; 3. Paediatric Pharmacology, 4. Formulation Science, 5. Underpinning Paediatric Studies.

EPTRI will allow to

- Cover the current existing gaps connecting the different steps in research from early stage.
- Enable and prepare researchers in many methodological areas to conduct research that effectively underpins the development of paediatric medicines.
- Increase the global competitiveness of the European RI also in favor of children, young people and their families.

To test this new RI, in the second year a feasibility phase is proposed to develop virtual exercises simulating the operation of the RI. In this phase four types of experiments will be developed: 1. Feasibility studies with scientists; 2. Feasibility studies with governments; 3. To test the interest of patients' associations and YPAGs and 4. Commons services with RI feasibility studies.

The Kick-off Meeting of the project will be held in Rome next 15th and 16th of January, with the involvement of all the partners. The agenda of the event is included in the Appendix 2. All the means of communication are welcome to attend to the meeting. In case of interest to plan a meeting with the coordinators of the project, please contact in advance with us. The venue is going to be:

Ministry of Education, Universities and Research
Sala della Comunicazione
Viale Trastevere, 76/a
Rome, Italy

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About Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF)

Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF) is a not-for-profit organisation, founded in 2000 with the mission to perform research and provide scientific, economic and regulatory consultancy for innovation in the health sector at European level. The main fields of interest are life sciences and biotechnologies, drug development for small populations (pediatric and rare diseases), research management and methodology, monitoring, statistics, regulatory, ethics and pharmacovigilance.

Learn more: https://www.cvbf.net

4. Annexes

4.1. Annex 1: List of Participants

Participant No	Participant organisation name	Acronym	Country
1 Coordinator	CONSORZIO PER VALUTAZIONI BIOLOGICHE E FARMACOLOGICHE	CVBF	Italy
2	FONDAZIONE PENTA-FOR THE TREATMENT AND CARE OF CHILDREN WITH HIV-ONLUS	PENTA	Italy
3	EUROPEAN INFRASTRUCTURE FOR TRANSLATIONAL MEDICINE	EATRIS-ERIC	Netherlands
4	UNIVERSITY COLLEGE LONDON	UCL	UK
5	ATHINA-EREVNITIKO KENTRO KAINOTOMIAS STIS TECHNOLOGIES TIS PLIFOFORIAS, TON EPIKOLNONION KAI TIS GNOSIS	ATHENA	Greece
6	BIOBANKS AND BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURE CONSORTIUMN (BBMRI-ERIC)	BBMRI-ERIC	Austria
7	THE CYPRUS FOUNDATION FOR MUSCULAR DYSTROPHY RESEARCH	CING	Cyprus
8	ASSISTANCE PUBLIQUE - HOPITAUX DE PARIS	AP-HP	France
9	STICHTING KATHOLIEKE UNIVERSITEIT	RUMC	Netherlands
10	THE UNIVERSITY OF LIVERPOOL	ULIV	UK
11	ROMANIAN ANGEL APPEAL	RAA	Romania
12	INSTYTUT POMNIK CENTRUM ZDROWIA DZIECKA	IPCZD	Poland
13	OSPEDALE PEDIATRICO BAMBINO GESU	OPBG	Italy
14	FYZIOLOGICKY USTAV AKADEMIE VED CESKE REPUBLIKY VEREJNA VYZKUMNA INSTITUCE (VVI)	IPHYS	Czech Republic
15	FUNDACIO SANT JOAN DE DEU	FSJD	Spain
16	NIZHEGORODSKIY GOSUDARSTVENNIY UNIVERSITET IM N.I. LOBACHEVSKOGO	UNN	Russia
17	SERVICIO MADRILENO DE SALUD	SERMAS-HULP	Spain

18	ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK	ECRIN	France
19	QENDRA SPITALORE UNIVERSITARE NENE TEREZA TIRANE	UHCT	Albania
20	TECHNION - ISRAEL INSTITUTE OF TECHNOLOGY	TECHNION	Israel
21	TARTU ULIKOOL	UTARTU	Estonia
22	UNIVERSITATSKLINIKUM ERLANGEN	UKER	Germany
23	SWISS CLINICAL TRIAL ORGANISATION VEREIN	SCTO	Switzerland
24	STATE "INSTITUTE OF PEDIATRICS OBSTETRICS AND GYNECOLOGY NATIONAL ACADEMY OF MEDICAL SCIENCES OF UKRAINE"	UKR	Ukraine
25	VASTRA GOTALAND LANS LANDSTING	VGR	Sweden
26	UNIVERSITAIR MEDISCH CENTRUM UTRECHT	UMCU	Netherlands

4.2. Annex 2: Agenda Kick off meeting

AGENDA DAY 1 Jan 15th, 2018

8:30 • REGISTRATION

8:45 • OPENING SESSION

Welcome address from the supporting Italian Institutions

Ministry of Education, University and Research (MIUR)	S. La Rosa
Italian Medicines Agency (AIFA)	S. Vella
Apulia Region - Director of University Paediatric Hospital	A. Del Vecchio
University of Bari "Aldo Moro"	L. Margari
Regional Agency for Technology and Innovation (ARTI)	A. Monterisi
OPENING REMARKS	D. Bonifazi

9:15 • SESSION 1

The role of RIs to strengthening research outcomes and to improve patients' health — Chairs: A. Ceci, I. Lutsar

How to implement a new RI: lessons from the Executive Master in Management of Research Infrastructures	M. Lavitrano
BBMRI ERIC: Biobanking and BioMolecular resources Research Infrastructure	E. Steinfelder
EATRIS ERIC: European infrastructure for translational medicine	G. Migliaccio
ECRIN ERIC: European clinical research infrastructure network	C. Kubiak
The role of ERNs in the European scenario and interactions with RIs	L. Sangiorgi

Agenda DAY 1 Jan 15th, 2018

11:00 • Coffee Break

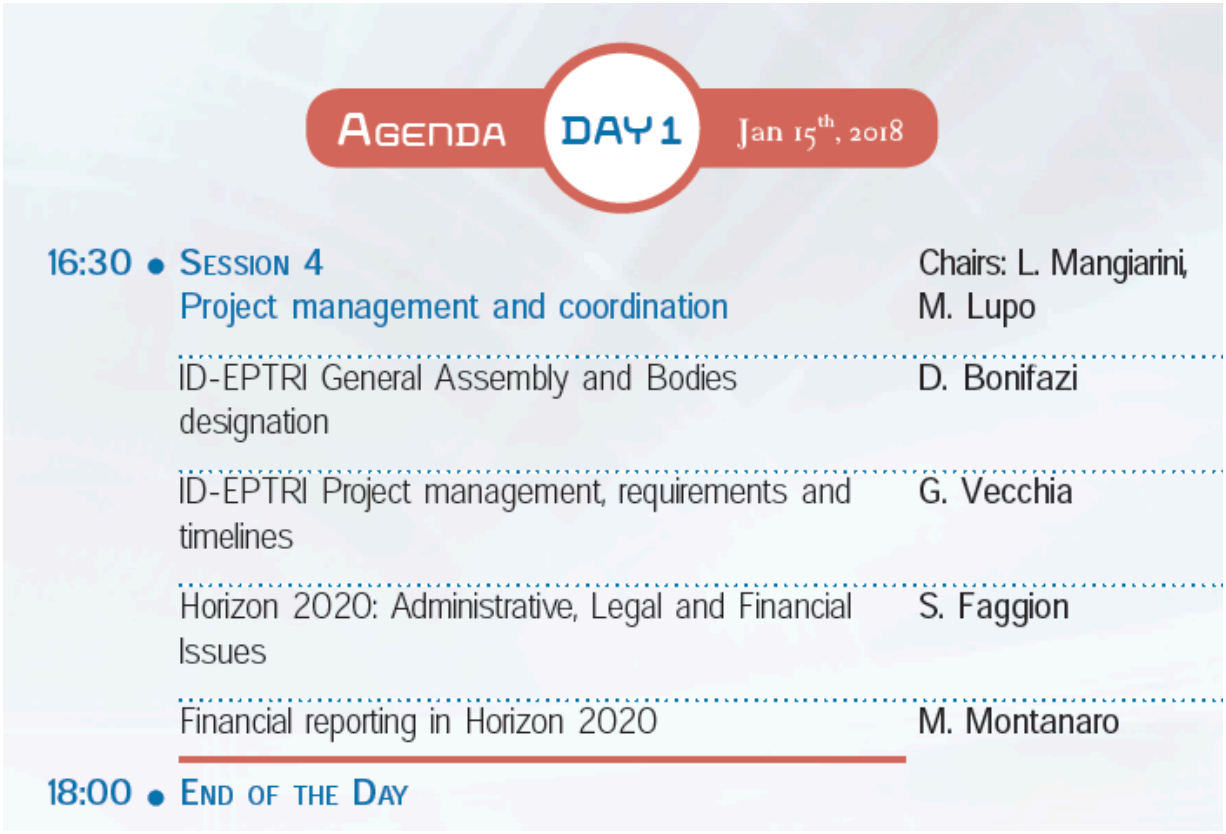
11:30 • Session 2
The EPTRI project and the involved Partners
Chairs: P. Macheras, C. Altomare

ID-EPTRI: overview of the project (planned activities, expected results and impact, timelines)	D. Bonifazi
Introduction round and presentation of Project Partners and involved staff (5 min. for each representative of the EPTRI General Assembly member) • Introduction of each Beneficiary and team members • Information on the organisation • Competences related to the project • Expectations of the project	All the Partners

13:30 • Lunch

14:30 • Session 3
The Global Scenario for EPTRI
Chairs: M. Turner, C. Giaquinto

How European Biological and Medical Sciences Research Infrastructures boost Innovation	J. Demotes
Relationship with the existing RIs and other organization groups	A. Ceci
Map of units and context analysis	S. Wimmer
Ethical issues and set up of the Project Ethical Advisory Board	M. Migdal
Governance and sustainability: key strategies to design, establish and govern a sustainable European research infrastructure	F. De Man


AGENDA
DAY 1
Jan 15th, 2018
16:30 • SESSION 4
Project management and coordination
Chairs: L. Mangiarini, M. Lupo
ID-EPTRI General Assembly and Bodies designation
D. Bonifazi
ID-EPTRI Project management, requirements and timelines
G. Vecchia
Horizon 2020: Administrative, Legal and Financial Issues
S. Faggion
Financial reporting in Horizon 2020
M. Montanaro
18:00 • END OF THE DAY

Agenda DAY 2 Jan 16th, 2018

8:30 •	**Session 5** Paediatric Medicines Discovery (WP5) and Biomarkers (WP6)	Chairs: O. Mukvich, J. Kindblom
	Design of the thematic platform supporting paediatric medicines discovery and early drug development	E. Mikros
	Run in a Proof-of-concept study simulation	H. Kubova
	Design of the thematic platform supporting biomarkers in paediatric medicines development	M. Lavitrano
	Feasibility study for the development of biomarkers in paediatrics	M. Kleanthous
10:00 •	**Coffee Break**	
10:30 •	**Session 6** Paediatric Pharmacology (WP7) and Formulation Science (WP8)	Chairs: V. Kazantsev, M. Turner
	Design of the thematic platform on paediatric pharmacology	E. Jacqz Aigrain
	Physiologically based PK/PD and modelling	S. de Wildt
	Design of the thematic platform on formulation science. Feasibility study on use of in vitro / in vivo tools for Taste Assessment	C. Tuleu
	Techniques employed for taste masking of pharmaceuticals	N. De Nora
12:00 •	**Session 7** Underpinning Paediatric Studies (WP9)	Chairs: D. Nika, P. Wenger
	Design of the thematic platform to relate work that underpins medicines development to paediatric clinical studies	M. Turner
	Certification of paediatric clinical research centres	A. Simonetti

Agenda DAY 2 Jan 16th, 2018

	The PedCRIN project to integrate paediatric tools in an existing RI	S. Malik
13:00 •	**Lunch**	
14:00 •	**Session 8** Concept design, IT structure and feasibility assessment of the infrastructure	Chairs: M. Mellado, S. Marini
	Paediatric clinical pharmacology data use and re-use	O. Della Pasqua
	Common data models for re-use of health care data	M. Sturkenboom
	Organisation and technical design (model) of the infrastructure	M. Felisi
	Information Technologies (IT) supporting EPTRI activities	F. Bonifazi
	Design model for collaboration with the existing RIs in Biomed field	G. Migliaccio
15:30 •	**Session 9** Communication, networking and patients involvement	Chair: F. Kalambayi, D. Bonifazi
	Communication and dissemination plan in the project	M. Lupo
	Communication and dissemination materials in the project	J. Claverol
	Project website	L. Mangiarini
	Plan for patients participation	B. Nafria
	The patients' perspective and the European RIs landscape	Patients Association Representatives
17:00 •	**Goodbye Cocktail**	
18:00 •	**End of the Day**	

5. Document History

Date	Author	Changes
09/01/2018	Begonya Nafria / Joana Calverol	Initial proposal of the document
12/01/2018	Mariangela Lupo	Inclusion of the final version the kick-off-meeting agenda