



## **TEDDY** EUROPEAN NETWORK OF EXCELLENCE FOR PAEDIATRIC CLINICAL RESEARCH

*Scientific Meeting and General Assembly*

The paediatric theme in the  
forthcoming clinical research scenario

19th December, 2016

Padiglione Salviati, III Floor  
Ospedale Pediatrico Bambino Gesù  
Piazza Sant'Onofrio 4 - Rome



# GRIP/PENTA

Carlo Giaquinto  
University of Padova



# HISTORY and MISSION

## Paediatric European Network for Treatment of AIDS (PENTA)

([www.penta-id.org](http://www.penta-id.org))

- Established in 1991 as collaboration between paediatric HIV centres in Europe. Aim: to undertake independent clinical trials to address questions about antiretroviral therapy (ART) in HIV infected children where answers cannot be extrapolated from trials in adults
- Activities: not just clinical trials, but cohort studies collaboration, pregnancy studies and training/ educational programmes.
- Funding comes from:
  - EC (10 projects coordinated by PENTA since Biomed 1, involvement in more than 20 EU funded projects)
  - MRC
  - INSERM/ANRS
  - US-NIH (project-based), UNICEF etc
  - Italian National Institute of Health (project-based)
  - Pharmaceutical companies



# From the initial focus on HIV to the broader area of Paediatric Infectious Diseases

- 2010: from PENTA to PENTA-ID
- **Focus on neglected and complex diseases**

## *EU funding:*

- **NeoMero** (neonates)
  - **NeoVanc** (neonates)
  - **GRiP** (“medicine for children”)
  - **PREPARE** (prevention of epidemics)
  - **EMIF** (creation of a European epidemiology/ICT platform)
  - **COMBACTE-MAGNET** (molecules against Gram Negative infections)
  - **GAPP** (clinical trials on “off-patent” drugs)
  - **RESCEU** (RSV)
  - **ZIKAction** (ZIKA)
- 
- **Specific contracts and agreements with major International Paediatric Hospitals** not following up HIV positive children
  - 2011: **PENTAid recognised by the EnprEMA as a level 1 Paediatric Clinical Trial Network in Europe** to conduct clinical trials in pediatric HIV, antimicrobials and vaccinology. **PENTA as PDCO member 2008 - 2014**

# HISTORY and MISSION

## The Foundation



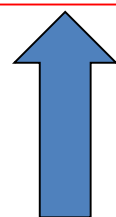
- set up in 2004
- represents **the ideal legal and financially viable framework to run research and educational activities in different countries** in the field of Paediatric Infectious Diseases and Paediatrics in general
- a centre for **project development** and **project management**
- involved in 12 proposals (4 as Coordinator) to the European Commission (FP7 and IMI) in 2011 and 2012. All applications were “2 stage” and 6 out of 12 proposals went to the second stage. 4 of them have been funded in 2013. In one of them PENTA is the coordinator and in the other three is one of the main partners
- **unique expertise in running international research projects**
- **In 2015 a spin off company (PENTA-ID Innovation was set up to provide services to commercial**



# PENTA-ID Activities and main projects and fundings

## HIV

- Trials
- Cohorts
- EPIICAL
- Pregnancy



EU (5%)  
Pharma (75%)  
PENTA F (20%)

## Antimicrobials/virals

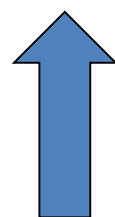
- NEOmero/vanc
- COMBACTE
- PREPARE
- (G)ARPEC
- EPeMyn
- RESCEU



EU (80%)  
Pharma (?)  
PENTA F (20%)

## Hepatitis

- Cohorts
- Trials
- Pathogen



EU 0  
Pharma (10%)  
PENTA F (90%)

## Ped medicine/others

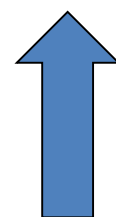
- GRIP
- TEDDY
- ENPREMA
- EUPTCRI
- GAPP
- EMIF
- ZIKa action



EU (90%)  
PENTA F (10%)

## Education

- HIV
- Other ID
- GRIP Mast



EU (30%)  
Pharma (30%)  
PENTA F (20%)  
UNICEF (20%)



# PENTA-ID Network Organization



**PENTA  
Foundation**  
Non-profit legal  
entity

**PENTA-ID  
Innovation**  
For-profit spin  
off

Executive  
Committee

Trials/studies  
Steering  
Committees

Clinical Trial  
Units/CROs

Non profit  
funders

Regulators

Patient  
Organizations

Pharma

## PENTA-ID Network

50+ clinical sites and > 100 partners in  
Europe, Latin America, Asia & Africa



# GRiP – from birth to 6 year old

Born in 2010



Now walking in 2017



A consortium financed by the European Union 7<sup>th</sup> Framework Programme (€10 million)

Partners from 7 Member States:

Finland, France, Italy, Poland, Spain, The Netherlands, UK

Includes regulators at the EMA

International partners:

Sickkids-Toronto (Canada), WHO, NIH (USA), NCCHD (Japan),

Brighton Collaboration, Basel (Switzerland)

Led by University of Padova



# GRiP Partnership

PARTICIPANT ORGANISATION NAME	ACRONYM	COUNTRY	LEAD SCIENTIST
AZIENDA OSPEDALIERA DI PADOVA	AOPD	Italy	C. Giaquinto
NATIONAL INSTITUTES OF HEALTH	NICHD-NIH	USA	S. Hirschfeld
EUROPEAN MEDICINES AGENCY	EMA	UK	A. Saint-Raymond
ERASMUS UNIVERSITAIR MEDISCH CENTRUM	EMC	The Netherlands	M. Sturkenboom
UNIVERSITY OF LIVERPOOL	ULIV-NIHR	UK	M. Turner
BAMBINO GESÙ PAEDIATRIC HOSPITAL	OPBG	Italy	P. Rossi
INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE	INSERM	France	E. Jacqz Aigrain
NATIONAL CENTER FOR CHILD HEALTH AND DEVELOPMENT	NCCHD	Japan	H. Nakamura
ST GEORGE'S HOSPITAL	SGUL	UK	M. Sharland
CONSORZIO PER VALUTAZIONI BIOLOGICHE E FARMACOLOGICHE, TEDDY	CVBF-TEDDY	Italy	A. Ceci
UNIVERSITY OF LEIDEN	UL	The Netherlands	O. Della Pasqua
ACADEMIC MEDICAL CENTER	AMC	The Netherlands	H. Van der Lee
BASQUE FOUNDATION FOR HEALTH RESEARCH AND INNOVATION	BIOEF	Spain	MC Lopez Herrera
CHILDREN'S MEMORIAL HEALTH INSTITUTE	PCZD	Poland	M. Migdal
WORLD HEALTH ORGANIZATION	WHO	Switzerland	G. Forte
UNIVERSITY COLLEGE LONDON	UCL	UK	C. Tuleu
JOINT AUTHORITY FOR THE HOSPITAL DISTRICT OF HELSINKI AND UUSIMAA	HUS	Finland	K. Hoppu
BRIGHTON FOUNDATION	BF	Switzerland	J. Bonhoeffer
PENTA FOUNDATION	PENTA	Italy	S. Faggion
DUTCH GENETIC ALLIANCE	VSOP-EGAN	The Netherlands	C. Oosterwijk
THE HOSPITAL FOR SICK CHILDREN	SICKKIDS	Canada	M. Offirnga/S. Ito





# GRiP – Vision

- GRiP will provide a collaborative sustainable framework for the development and utilisation of medicines for children by facilitating consistent development and evaluation of medicines and promoting and providing integrated training in relevant areas.



# The objectives

- **Aim:** to facilitate the development, and promote the availability, of medicines for children.
- **Work Packages:**

WP1: Training Programme	WP4: new methods for CTs
WP2: Pharmacoepidemiology platform	WP5: paediatric forms and formulations
WP3: Research tools for interoperability	WP6: neonatology

# Pilot Master in

## *“Paediatric Medicines Development and Evaluation”*

*Nov 2014 – Sept 2016*

Module nr and abbreviation	Module title	Responsible GRiP Partner/Faculty Member	Affiliation	ECTS
	<b>Start of the Master: Fresher's meeting (19-21 Nov 2014)</b>	<b>Paolo Rossi</b>	<b>University of Rome Tor Vergata Conference site: Villa Mondragone</b>	<b>1</b>
Module 1 MED	Introduction to Paediatric Medicines	Paolo Rossi Viviana Moschese	University of Rome Tor Vergata	4
Module 2 DEV	Developmental Pharmacology Pharmacokinetics	Evelyne Jacq Aigrain John Van Den Anker	INSERM/Université Paris Diderot-Paris 7 University Children's Hospital Basel	4
Module 3 RET	Regulatory and Ethical Issues Regarding Paediatric Medicines Research	Agnes Saint Raymond	European Medicines Agency (EMA), London	4
Module 4 EXP	Experimental Drug Evaluation in Paediatrics	Adriana Ceci Paola Balardi Gerard Pons	Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF), Pavia University Paris Descartes PRES Sorbonne Paris Cité	4
Module 5 FOR	Paediatric Drug Formulations	Tony Nunn Catherine Tuleu	University of Liverpool University College London (UCL) School of Pharmacy, London	4
Module 6 TRI	Paediatric Clinical Trial Management	Mark Turner John Van Den Anker	University of Liverpool University Children's Hospital Basel	4
Module 7 PPP	Post-Licensure Paediatric Drug Evaluation: Pharmacovigilance & Pharmacoepidemiology	Miriam Sturkenboom Katta Verhamme Sabine Straus Agnes Saint Raymond	Erasmus University, Rotterdam European Medicines Agency (EMA)	4
Module 8 PREG	Pharmacology in Pregnancy and Neonates	Evelyne Jacq-Aigrain	INSERM/Université Paris Diderot-Paris 7	4
Module 9 BIO	Biomarkers and Innovative Tools in Paediatric Clinical Pharmacology	Oscar Della Pasqua Adriana Ceci Paola Balardi	University College London (UCL) School of Pharmacy, London, Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF)	4
Module 10 VAC	Paediatric Vaccines	Jan Bonhoeffer John van den Anker Miriam Sturkenboom	University Children's Hospital Basel; Erasmus University, Rotterdam	4
<b>Work placement and/or training stages and Thesis</b>				<b>19</b>
				<b>60</b>



