TRAINING OBJECTIVE:

- ✓ Give an overview of the regulatory landscape for paediatric research, review specifics and most important challenges with corresponding solutions in paediatric drug development and review specifics and most important challenges with corresponding solutions in paediatric drug development.
- ✓ Following the training, the participants will be familiar with the ethical and regulatory issues, specific protocol considerations and age groups, Informed Consent and Assent processes, drug formulations, safety specificities, recruitment, enrollment, and clinical monitoring specificities, as well as site interactions, relationships with paediatric research networks and infrastructures. Participants will be prepared to plan and execute paediatric clinical trials in any of the age groups which will result in obtaining higher quality data.

VENUE

Bambino Gesù Paediatric Hospital,
Viale Ferdinando Badelli, 38
(Sede San Paolo)
Rome, Italy

REGISTRATION FEES

- ✓ **Early Bird Fee until 30 June 2023**
  - 280 €
  - 240 € for EUCROF Members
- ✓ **After 30 June 2023**
  - 330 €
  - 280 € for EUCROF Members

Training Material

- ✓ A copy of the presentations will be provided as PDF version (available to be downloaded following password receipt).

Training Certificate

- ✓ A training Certificate will be delivered.

EUCROF
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OSPEDALE PEDIATRICO Bambino Gesù

"Essentials of Paediatric Clinical Research"

"What you need to know when preparing, conducting and monitoring paediatric clinical trials"

Tuesday, 12 September 2023

Rome, Italy

TARGET ATTENDEES:

- ✓ Clinical Research Associates (CRAs),
- ✓ Central Monitoring Associates (CMAs)
- ✓ Study Start Up and Regulatory Affairs personnel.
- ✓ Clinical Trial Managers (CTMs)
- ✓ Project Managers
- ✓ Project Directors
- ✓ Patient enrollment and retention specialists,
- ✓ Any person involved in paediatric drug development.

SPEAKERS:

- ✓ Paolo Rossi, *Professor of Paediatrics at Bambino Gesù Paediatric Hospital/ University of Rome Tor Vergata & Director of the Hospital Paediatrics Department, Bambino Gesù Paediatric Hospital, Italy*
- ✓ Martine Dehlinger-Kremer, *President, EUCROF & VP Scientific Affairs, Paediatric SME, Center for Paediatric Clinical Development, Drug Development Solutions, ICON Plc, Germany*
- ✓ *Fabio D'Atri, Policy Officer, Deputy Head of Unit B5 Directorate General for Health and Food Safety, European Commission, Belgium*
- ✓ Nira Garty, *CEO, Perfection CRO, Israel*
- ✓ Alex Cvetkovic Mutañola, *Executive Director Clinical Development Syneos Health, Spain*
- ✓ Ian Vasicka, *Clinical Investigator, Charles University, Prague, Czech Republic*
- ✓ Ricardo Fernandez, CMO at conect4children-Stichting, Portugal
- ✓ Claudio Fracasso – *Paediatric Clinical Director, Pfizer, Italy*
- ✓ Donato Bonifazi, *EPTRI (European Paediatric Translational Research Infrastructure) Coordinator and CEO, CVBF, Italy*
- ✓ Viviana Giannuzzi, *Senior Researcher at Fondazione per la Ricerca Farmacologica Gianni Benzi ONLUS, Bari, Italy*
- ✓ Alessandra Simonetti, *Bambino Gesù Paediatric Hospital, Rome, Italy*
- ✓ Jürgen Schäfer, *Managing Director, Conreso GmbH, Germany*
- ✓ Giuseppe Pontrelli, Bambino Gesù Paediatric Hospital, *Rome, Italy*

AGENDA

08:00 – 08:15	Registration	
08:15 – 08:30	Opening Remarks	Paolo Rossi, Bambino Gesù Paediatric Hospital Martine Dehlinger-Kremer, EUCROF & ICON Plc
Session 1:	**Regulatory Paediatric Drug Development**	
08:30 – 09:00	Global Regulatory and Ethical Considerations for Paediatric Drug Development	Martine Dehlinger- Kremer, EUCROF & ICON Plc
09:00 – 09:30	Impact of the proposed new EU Pharmaceutical Legislation on Paediatric Developments	Fabio D'Atri, European Commission
09:30 – 10:00	Medical Devices in Paediatric Research	Nira Garty, Perfection CRO
10:00 - 10:30	**Coffee break**	
Session 2:	**Medical Considerations of paediatric research**	
10:30 – 11:30	Differences between Children and Adults, specifics of the different paediatric Age Groups and impact on Study Protocols & Assessments Drug Formulation specificities and administration	Alex Cvetkovic Muntañola, Syneos Health
11:30 - 12.00	Safety Considerations in Paediatrics including Covid considerations	Ian Vasicka, Clinical Investigator
12:00 – 13:00	**Lunch**	
Session 3:	**Medical sites and Patient recruitment networks**	
13:00-13:30	Conect4children (C4C), Paediatric network	Ricardo Fernandez, CMO at conect4children-Stichting
13:30-14:00	Role of young people advisory organisations in paediatric research	Claudio Fracasso, Pfizer
14:00-14:30	European Paediatric Research Networks and Infrastructures	Donato Bonifazi, EPTRI and CVBF
Session 4:	**Monitoring and Safety**	
14:30 – 15:00	ICF and Assent: Specific process per Age Group	Viviana Giannuzzi, Benzi Foundation Alessandra Simonetti, Bambino Gesù Paediatric Hospital
15:00 – 15:30	Specific Study Monitoring considerations for Paediatric Trials	Jürgen Schäfer, Conreso
15:30 – 15:45	**Coffee break**	
15:45 – 16:15	Important Aspects of Paediatric Trials from the Clinical Site perspective	Giuseppe Pontrelli, Bambino Gesù Paediatric Hospital
16:15 – 16:30	Closing Remarks	Martine Dehlinger-Kremer, EUCROF & ICON Plc