TRAINING OBJECTIVE:

- ✓ Provide an overview of the regulatory landscape for paediatric research, review specific 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, 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

C.N.I.O.
Centro Nacional de Investigaciones Oncológicas
C/ Melchor Fernández Almagro, Madrid, Spain

REGISTRATION FEES

- ✓ Early Bird Fee until 31 August 2019
  - 280 € (excluding VAT)
  - 240 € (excluding VAT) for EUCROF Members
- ✓ After 31 August 2019
  - 330 € (excluding VAT)
  - 280 € (excluding VAT) 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
European CRO Federation

"Essentials of Paediatric Clinical Research"

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

Thursday, 24 Oct 2019

Madrid, Spain

TARGET ATTENDEES:

- ✓ Contract Research Associates (CRAs)
- ✓ Central Monitoring Associates (CMAs)
- ✓ Study Start Up and Regulatory Affairs personnel
- ✓ Clinical Trial Managers (CTMs)
- ✓ Project Managers
- ✓ Project Directors
- ✓ Feasibility personnel
- ✓ Any person involved in paediatric drug development

PRESENTERS:

- ✓ Carmen Rodriguez, *President AECIC*
- ✓ Martine Dehlinger – Kremer, *President EUCROF & VP Pediatric Development, Synteract*
- ✓ Maria Jesùs Fernandez Cortizo, *Head of Service of Evaluation of Pediatric Medicines Spanish Agency of Medicines and Medical Devices (AEMPS), Paediatric Committee (PDCO) Member at EMA*
- ✓ Donato Bonifazi, *CEO Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF)*
- ✓ Begonya Nafria, *Chair European Young Paerson's Advocacy Group (eYPAGNet) & Patient Engagement in Research Coordinator, Institut de Recerca Sant Joan de Déu*
- ✓ Alex Cvetkovic Mutañola, *Executive Director Clinical Development Syneos Health*
- ✓ Nira Garty, *CEO Perfection CRO*
- ✓ Nuria G Martinez-Alier, *Senior Medical Director, IQVIA*
- ✓ Sophia Romboli, *Country Manager, Zeincro*
- ✓ Jürgen Schäfer, *Managing Director, Conreso GmbH*
- ✓ Ian Vasicka, *Investigator*
- ✓ Pablo Rojo Conejo, *Associate Professor, Complutense University of Madrid and Paediatric Infectious Diseases Specialist of Hospital 12 de Octubre, Madrid*

AGENDA

09:30 – 09:50	Registration	
09:50 – 10:00	Opening Remarks	C. Rodriguez, AECIC M. Dehlinger – Kremer, EUCROF & Synteract
Session 1: Framework for Paediatric Drug Development		
10:00 – 10:30	Global Regulatory and Ethical Considerations for Paediatric Drug Development	M. Dehlinger – Kremer, EUCROF & Synteract
10:30 – 11:00	Impact of EU Paediatric Regulation on Clinical Research	M. J. Fernandez Cortizo, AEMPS & PDCO
11:00 – 11:30	European Paediatric Research Networks and Infrastructures	D. Bonifazi, CVBF
11:30 – 12:00	Role of Children' s Advocacy Groups in paediatric research	B. Nafria, eYPAGNet
12:00 - 13.00	***Lunch***	
Session 2: Medical Considerations		
13:00 – 13:30	Differences between Children and Adults, specifics of the different paediatric Age Groups and impact on Study Protocols & Assessments	A.Cvetkovic Mutañola, Syneos Health
13:30 – 14:00	Medical Devices in Pediatric Research	N. Garty, Perfection CRO
14:00 – 14:30	Drug Formulation specificities and administration	N. Martinez-Alier, IQVIA
14:30 – 15:00	***Coffee break***	
Session 3: Monitoring and Safety		
15:00 – 15:30	ICF and Assent: Specific process per Age Group	S. Romboli, Zeincro
15:30 – 16:00	Specific Study Monitoring considerations for Paediatric Trials	J. Schäfer, Conreso
16:00 – 16:30	Safety Considerations in Paediatrics	I. Vasicka, Investigator
16:30 – 17:00	Excellence in Paediatric Trials from the Clinical Site perspective	P. Rojo Conejo, Hospital 12 de Octubre
17:00 – 17:30	Closing Remarks	M. Dehlinger – Kremer EUCROF & Synteract