

## 6<sup>th</sup> European Conference on Clinical Research

7-8 February 2022, Madrid, Spain

**CLINICAL TRIALS IN A NEW ERA** 

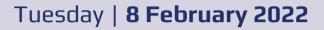






Opening of the Conference and Key Notes				
08:30 - 09:30	Registration & Welcome Coffee			
09:30 - 09:45	Conference Opening	Martine Dehlinger- Kremer, EUCROF & ICON Plc, Germany		
09:45 – 10:15	The New Regulatory Landscape following the COVID-19 Pandemic	Edit Szepessy, European Commission, Belgium Fergus Sweeney, EMA, The Netherlands		
10:15 -10:45	Coffee Break			
Clinical Trial Regulation 536/2014: Regaining Momentum				
10:45 - 11:15	CTR and its Supportive Documents and Tools - Overview	<b>Pieter Van Keerberghen</b> , EMA, The Netherlands		
11:15 - 11:45	CTR - a National Competent Authority Perspective	<b>Maria Antonia Serrano,</b> AEMPS, Spain		
11:45 - 12:15	CTR - an Industry Perspective	<b>Pierre Omnes</b> , Syneos Health, France		
12:15 - 13:15	Lunch break			
Technology Innovations in Clinical Research & the COVID-19 Catalyst of Change				
13:15 - 13:45	Latest trends on Decentralized Clinical Trials enabled by Digital Health Technologies	<b>Isaac Rodriguez Chavez,</b> ICON Plc, USA		
13:45 - 14:15	How in silico methods can help to reduce, refine and (partially) replace clinical trials	<b>Luca Emili</b> , InSilicoTrials, Italy		
14:15 - 14:45	mHealthBelgium: a joint initiative for digital health by government and industry	<b>Steven Vandeput,</b> beMedTech, Belgium		
14:45 - 15:15	Coffee Break			

The New Medical Device Regulation Environment and the Need for Clinical Evidence				
15:15 - 15:45	Clinical investigations for conformity assessment purposes and other clinical investigations: what you need to know	<b>Monique Al</b> , CCMO, The Netherlands		
15:45 - 16:15	Post Market Surveillance and Post Market Clinical Follow Up Plan under EU the MDR	<b>Philippe Auclair</b> , Abbott, Belgium		
16:15 - 16:45	Medical Device Registry as a tool to provide evidence. The experience of Italy in implementing the national registry of implantable prostheses	<b>Marina Torre</b> , Istituto Superiore di Sanità, Italy		
The rise of Big Data				
16:45 - 17:15	Taking the example of covid-19 vaccination	<b>To Be Confirmed</b> , CNAM, France		
Closing Remarks – DAY 1				
17:15-17:30	End of DAY 1 Closing Remarks	Martine Dehlinger- Kremer, EUCROF & ICON Plc, Germany		
18:30 - 22:00 Networking Dinner & Social Event				





An ICH Efficacy Update				
07:45 - 08:00	Registration & Welcome Coffee			
08:00 - 08:30	Modernization of ICH E8 (R1) "General Considerations for Clinical Trials": From 1997 to 2021	<b>Sigrid Balser,</b> Boehringer Ingelheim, Germany		
08:30 - 09:00	Update on ICH E6 (R3) "Good Clinical Practice" and ICH E19 "Optimisation of Safety Data Collection"	<b>Gabriele Schwarz</b> , BfArM, Germany		
09:00 - 09:30	Coffee Break			
Patient Centricity, beyond the Concept				
09:30 - 10:00	Patient generated health data (PGHD)	Rainel Sanchez-de la Rosa, Novartis, Switzerland		
10:00 - 10:30	Freely Given Informed Consent: Challenges	Elmar Doppelfeld, Association of Medical Ethics Committees, Germany		
10:30 - 11:00	Patient Centricity from Theory to Reality	Jorge Mauriño, Roche, Spain Franck Devaux, EC Representative, Belgium Dimitrios Athanasiou, PDCO, EMA; EURORDIS; European Patient Forum, Greece		

Evolving Roles in a New Clinical Research Era				
11:00 - 11:30	Changing role of the CRA - MSL involvement (relational aspects)	<b>José Cabrera</b> , BMS, Spain		
11:30 - 12:00	Consequences of eSourcing site performance	<b>Agustín Gómez de la Cámara,</b> Research Institute Hospital 12 de October in Madrid, Spain		
12:00 - 12:30	Driving the Future Direction of Clinical Operations	<b>Guillermo Badenes</b> , Janssen, Spain		
12:30 - 13:15	Lunch Break			
Breaking News in Clinical Research				
13:15 - 13:35	The GDPR Code of Conduct: Good Data Processing Practice for Service Providers in Clinical Research	<b>Yoani Matsakis</b> , Telemedicine Technologies, EUCROF, France		
13:35 - 13:55	CRO Landscape Benchmarking in Europe	Gert-Jan Dossche, EUCROF, Belgium Benedikt Van Nieuwenhove, EUCROF, Belgium		
13:55 - 14:15	The Distributed TMF and the Decommissioning of Computerised Systems	<b>Alan Yeomans</b> , Viedoc, EUCROF, Sweden		
	The Future of Clinical Re	esearch		
14:15 - 15:00	Panel Discussion, moderated by Karen Taylor	Doug Peddicord, ACRO, USA Gabriele Schwarz, BfArM, Germany Dimitrios Athanasiou, PDCO, EMA; EURORDIS; European Patient Forum, Greece Rainel Sanchez-de la Rosa, Novartis, Switzerland Karen Taylor, Deloitte, UK		
Closing Remarks – DAY 2				
15:00-15:15	End of DAY 2 Closing Remarks	Martine Dehlinger-Kremer, EUCROF & ICON Plc, Germany		