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6TH EUROPEAN CONFERENCE ON CLINICAL RESEARCH
MADRID, 7-8 FEBRUARY 2022

6th European Conference on Clinical Research

7-8 February 2022, Madrid, Spain

CLINICAL TRIALS IN A NEW ERA

EUCROF
European CRO Federation

Programme

Monday | **7 February 2022**

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	**Pieter Van Keerberghen**, EMA, The Netherlands
11:15 - 11:45	CTR - a National Competent Authority Perspective	**Maria Antonia Serrano,** AEMPS, Spain
11:45 - 12:15	CTR - an Industry Perspective	**Pierre Omnes**, 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	**Isaac Rodriguez Chavez,** ICON Plc, USA
13:45 - 14:15	How in silico methods can help to reduce, refine and (partially) replace clinical trials	**Luca Emili**, InSilicoTrials, Italy
14:15 - 14:45	mHealthBelgium: a joint initiative for digital health by government and industry	**Steven Vandeput,** 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	**Monique Al**, CCMO, The Netherlands
15:45 - 16:15	Post Market Surveillance and Post Market Clinical Follow Up Plan under EU the MDR	**Philippe Auclair**, 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	**Marina Torre**, Istituto Superiore di Sanità, Italy
The rise of Big Data		
16:45 - 17:15	Taking the example of covid-19 vaccination	**To Be Confirmed**, 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**	

Tuesday | **8 February 2022**

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	**Sigrid Balser,** Boehringer Ingelheim, Germany
08:30 - 09:00	Update on ICH E6 (R3) "Good Clinical Practice" and ICH E19 "Optimisation of Safety Data Collection"	**Gabriele Schwarz**, 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)	**José Cabrera**, BMS, Spain
11:30 - 12:00	Consequences of eSourcing site performance	**Agustín Gómez de la Cámara,** Research Institute Hospital 12 de October in Madrid, Spain
12:00 - 12:30	Driving the Future Direction of Clinical Operations	**Guillermo Badenes**, 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	**Yoani Matsakis**, 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	**Alan Yeomans**, Viedoc, EUCROF, Sweden
The Future of Clinical Research		
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