Scientific Programme

Monday, 26 February 2018

8:30-10:00	Registration & Welcome Coffee

Room: Olympia Mancini 2

Opening of the Conference

Chair: Martine Dehlinger-Kremer, EUCROF President; Vice President, Global Scientific and Medical Affairs, Synteract; Chair of the EUCROF Paediatric Working Group, Germany

TIME	TOPIC
10:00-10:15	**Conference Opening, Welcome Message from the EUCROF President** **Martine Dehlinger-Kremer** EUCROF President; Vice President, Global Scientific and Medical Affairs, Synteract, Germany
10:15-11:00	**How Did This Happen? – A Fresh Look at Health Care** **Peter Kapitein** Patient advocate at Inspire2Live, The Netherlands

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Clinical Trials Regulation (EU) No 536/2014

Chair: Dagmar Chase, Managing Director Clinrex GmbH, Germany

Co-chair: Ulrike Lorch, Co-Founder and Medical Director, Richmond Pharmacology Limited, United Kingdom

11:05-11:30	**European Clinical Trials Regulation (CTR): Status Quo** **Anabela Marcal** Head of Committees and Inspections Department, Inspections, Human Medicines Pharmacovigilance & Committees Division, European Medicines Agency (EMA), United Kingdom
11:30-11:55	**Clinical Trials Regulation (EU) No 536/2014 – Any Pitfalls for Industry?** **Sini Eskola** Director, Regulatory, Drug Development and Manufacturing, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium
11:55-12:20	**What Will Change for Investigator Initiated Trials (ITTs)?** **Heiko von der Leyen** CEO, Hannover Clinical Trial Center GmbH (HCTC), Germany
12:20-12:45	**How Will Ethic Committees be Impacted by the EU Clinical Trials Regulation?** **Joerg Hasford** Institute for Medical Informatics, Biometry, and Epidemiology (IBE), LMU Munich; Chair of the Working Group of the German Ethics Committees, Germany
12:45-13:00	Discussion
13:00-14:00	Lunch Break & B2B Meetings
14:00-14:30	**Gold Partner's Lecture: Latest Geographic Trends in Global Industry Clinical Trials: Who is Winning, Who is Losing** **Vladimir Misik** Member of the Board, SanaClis s.r.o.; Managing Partner Longtaal s.r.o., Slovakia

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Good Clinical Practice, the New Addendum E6 (R2), Part 1: Risk Based Quality Management **Chair: Michèle Garot**, Managing Director CLINcellence, Belgium	
TIME	TOPIC
14:30-15:00	**Risk-Based Monitoring: Where Are We in 2018? An Inspector's Experience** **Gabriele Schwarz** Head of GCP Inspectorate, Federal Institute for Drugs and Medical Devices (BfArM), Germany
15:00-15:30	**The Good, the Bad and the Site in Risk Based Monitoring, the Sites' Perspective Over the Years** **Vivienne van de Walle** CPI Director PT&R, Member of the Leadership Council the Society of Clinical Research sites (SCRS), The Netherlands
15:30-16:00	**Risk-Based Monitoring Implementation: A Sponsor's Perspective** **Claudia Kriebaum** Manager, Risk Based Monitoring, Eli Lilly, Regional Operations GmbH, Austria
16:00-16:30	**Computerized Clinical Trials? A Modern Way to Gain Quality in Study Design and Optimise Drug Development** **Francois-Henri Boissel** CEO, Novadiscovery, France
16:30-17:00	Coffee Break
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Part 2: Operating Models Further Re-enforced by New Regulations & Guidelines **Chair: Yoanni Th. Matsakis**, President Telemedicine Technologies S.A.S., France	
17: 00-17:30	**Inspection Findings from eTMF Implementations** **Andy Fisher** Senior GCP Inspector, GCP Inspectorate, MHRA, United Kingdom
17:30-18:00	**General Data Protection Regulation (GDPR) & Big Data in the Healthcare Sector: How to Draw Value for Patients and Companies Out of the New EU Framework and Its Challenges?** **Cecilia Álvarez** European Data Protection Officer Lead, Pfizer, Spain **Cécile Théard-Jallu** Partner Attorney, De Gaulle Fleurance & Associés, France
18:00-18:30	**Investigator Site eSource Readiness Assessment Tool (eSRA): Is Your EHR System Suitable for Originating Records that Will Be Used in Regulated Clinical Trials?** **Yvonne Rollinger** Managing Director, Omnicomm Europe, Representative of the eClinical Forum eSRA Initiative, Germany
20:00	Networking Dinner in the Hotel Savoyen, Vienna

Tuesday, 27 February 2018

1st Parallel Sessions:		
	Room: Olympia Mancini 1	Room: Olympia Mancini 2
	GCP Compliance of E-Systems and Technical Solutions **Chair: Alan Yeomans**, Quality Manager, PCG Solutions; Co-chair of the eClinical Forum Regulatory Expert Group; Co-chair of the EUCROF Working Group New Technologies, Sweden	**Clinical Trials in the Paediatric Population** **Chair: Martine Dehlinger-Kremer,** EUCROF President; Vice President, Global Scientific and Medical Affairs, Synteract; Chair of the EUCROF Paediatric Working Group, Germany **Co-chair: Georg Mathis**, CEO Appletree CI Group AG, Switzerland
TIME	TOPIC	TOPIC
08:30-09:00	**What Makes a Good Audit Trail Dataset?** **Andy Fisher** Senior GCP Inspector, GCP Inspectorate, MHRA, United Kingdom	**The Paediatric Regulation Revision/ Update** **Marek Migdal** Deputy Head of Children's Memorial Health Institute; Member EMA Paediatric Committee (PDCO), Poland
09:00-09:30	**Contractual Requirements on the Responsibilities of E-Systems Vendors With Regards to GCP** **Wolfgang Summa** Head of Clinical Applications and Technologies, Merck Group, Germany	**Pan-European Paediatric Clinical Trials Network** **Mark Turner** Institute of Translational Medicine, University of Liverpool; Chair European Network of Paediatric Research at EMA, United Kingdom
09:30-10:00	**Risk Based Validation and Agile Development** **Jesper Rosendal** Senior Manager Corporate Quality Assurance IT, Lundbeck, Denmark	**Set Up of a Network for Paediatric Clinical Trials. The Italian Example** **Francesca Rocchi** INCIPIT – Italian Network for Paediatric Clinical Trials, Academic Department of Pediatrics, IRCCS Bambino Gesù Children Hospital, Italy
10:00-10:30	**Panel Discussion**	**Patient Involvement in Paediatric Clinical Research** **Claas Röhl** Founder NF Children; Chair Austrian EUPATI platform; EUPATI fellow, Austria
10:30-11:00	Coffee Break	

2nd Parallel Sessions:		
	Room: Olympia Mancini 1	Room: Olympia Mancini 2
	European Medical Device Regulations **Chair: Antoinette van Dijk**, Scientific Director AICRO, Italian association of CROs; Co-chair of the EUCROF Working Group Medical Devices	**New European Data Privacy Regulation** **Chair: Isabelle Abousahl**, President Alcoam by Design SAS; Member of the EUCROF Working Group New Technologies, France **Co-chair: Thierry Lepoutre**, Managing Director, Lambda Plus; Member of the EUCROF Working Group New Technologies, Belgium
TIME	TOPIC	TOPIC
11:00-11:30	**Highlights and Challenges of the EU Medical Device Regulations** **Stefan Menzl** Principal Consultant Regulatory Affairs, Qserve Group, The Netherlands	**Data Protection and Clinical Trial Agreements, Seen Through the Eyes of a Trial Site** **Markus Kastelitz** Data Protection Officer; (formerly) Medical University of Vienna, Austria
11:30-12:00	**MDR Impact Assessment for Manufacturers** **Luca Orlandini** Vice President Global Medical Affairs, Smith & Nephew Orthopaedics AG, Switzerland	**How to Comply with the GDPR in a Global and Innovative Environment?** **Sarah Taïeb** Global Data Privacy Manager, IPSEN, France
12:00-12:30	**Clinical Evaluation According to MEDDEV 2.7/1 Revision 4 and Medical Device Regulation** **Carolina Gualtieri** Member Medical Device Group SSFA, Fondazione Policlinico Gemelli, Italy	**PhUSE Data Transparency Working Group: Providing De-identification Standards to CDISC Data Models** **Jean-Marc Ferran** Consultant & Owner, Qualiance; Data Transparency Working Group Lead, PhUSE; Denmark
12:30-13:30	Lunch Break & B2B Meetings	

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Peri and Post-approval Research Environment in 2020: Boldly Shaping the Future while not Going Overboard of This Shaken Ship

Chair: Xavier Fournie, Mapi Group Medical Director, Executive Vice-President Global Medical Affairs, Mapi Real World Evidence, France

TIME	TOPIC
13:30-14:00	**Real World Data in Observational Research: Myth or Reality?** **Vasa Curcin** Senior Lecturer in Health Informatics, Faculty of Life Sciences & Medicine, King's College London, United Kingdom
14:00-14:30	**Adaptive Pathways, Post-Authorisation Efficacy Studies, Health Technology Assessment needs… Are We Going to Finally See the Development of Pragmatic/ Low-intervention Trials in the Near Future?** **Patrice Verpillat** Head of Global Epidemiology, Merck KgaA; EFPIA observer at ENCePP Steering Committee, Darmstadt, Germany
14:30-15:00	**Engagement and Impact of Patients in (Peri- and Post-approval) Clinical Research; Why, What, How? Some Considerations and Learning Points** **Eric Roos** Board Member Dutch Clinical Research Foundation; Chairman Dutch Parkinson's Association, University of Amsterdam, The Netherlands
15:00-15:30	**Transparency and Scientific Independence Throughout the Post-authorisation Research Process; the ENCePP/EMA Code of Conduct** **Rosa Gini** Head of Pharmacoepidemiology Unit, Agenzia Regionale di Sanità della Toscana (ARS); Member of ENCePP Steering Group and ENCePP Working Group 2 Independence and Transparency, Italy

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European Union Redesigned

Introduced by Martine Dehlinger-Kremer, EUCROF President; Vice President, Global Scientific and Medical Affairs, Synteract; Chair of the EUCROF Paediatric Working Group, Germany

TIME	TOPIC
15:30-16:00	**Brexit: Everything that You Want (& Need?) to Know!** **Virginia Acha** Executive Director – Global Regulatory Policy, MSD R&D Innovation Centre, Association of the British Pharmaceutical Industry (ABPI), London, United Kingdom
16:00-16:10	**Conference Closure, Good Bye Message from the EUCROF President** **Martine Dehlinger-Kremer** EUCROF President; Vice President, Global Scientific and Medical Affairs, Synteract; Chair of the EUCROF Paediatric Working Group, Germany
16:10-17:00	Good-bye Coffee