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1st Kiev Clinical Research Forum

A global discussing platform for the clinical research industry in Eastern Europe

9-10 November, 2017

President Hotel, 12, Hospitalna street, Kiev, Ukraine

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Nov, 8th, 2017 (President Hotel)			
14:00 – 20:00	Arrival of Delegates	Registration (Reception)	
20:00 – 22:00	Arrival of Delegates	Receipt Party (European Hall, 3rd floor)	
Day 1, Nov 9th, 2017 (President Hotel)			
7:45 – 8:30	Arrival of Delegates	Registration (European Hall Area, 3rd floor)	
General Session European Hall Area, President Hotel, 3rd floor Chair: William Andrew Lawton, CEO, Risk Based Approach Ltd, United Kingdom			
Time	Session	Topic	Speaker
8:40 - 9:00	Opening	Opening Remarks	**Martine Dehlinger-Kremer**, President of EUCROF(Germany)
9:00 - 9:30	Key Note	The Pharma Industry: Global Vision	**Amer Alghabban**, VP, GxP Compliance & Training Partners (Switzerland)
9:30 - 10:00	Key Note	Innovative approach and mind-set in clinical trials	**Marcin Stefanowicz**, Innovation and Technology Group Europe, Roche (Poland)
10:00- 10:30	Hot Topic	Start up Planning of Multinational Studies	**Julian V. Platon**, Clinical Research Expert (Switzerland)

10:30-11:00	ICH-GCP	Implementation roadmap for ICH E6 (R2) Addendum, what should you have done already!	**William Andrew Lawton**, CEO, Risk Based Approach Ltd (UK)
11:00-11:30	ICH-GCP	Sponsor and CRO responsibilities with ICH E6: what is the boundary?	Panel Discussion (Moderator: **William Andrew Lawton**)
11:30 - 12:00	Coffee break		

Day 1, Nov 9th, 2017, Branch 1 Conference Hall, 1st Floor Chair: Yoanni Th. MATSAKIS, President, Telemedicine Technologies, France				**Day 1, Nov 9th, 2017, Branch 2** A+C Hall, 1st Floor Chair: Michèle Garot, Managing Director CLINCellence, Belgium		
Time	Session	Topic	Speaker	Session	Topic	Speaker
12:00 - 12:30	Clinical Operations	Clinical trials in cardiology: trends and perspectives	**Oleksii Mikheiev**, CEO, Verum (Ukraine)	Risk Based Approaches	Quality Tolerance Limits introduced with ICH E6 (R2)	**Andy Lawton**, CEO, Risk Based Approach Ltd (UK)
12:30 - 13:00	Clinical Operations	Disease Modifying Trials in Alzheimer	**Jeffrey Apter**, President, Global Clinical Trials (USA)	Risk Based Approaches	Risk Based Monitoring, practices, outcome, satisfaction: myth or reality?	**Michele Garot**, Managing Director, ClinCellence (Belgium)

13:00 - 13:30	Clinical Operations	How a Clinical Trial Liaison can provide optimal site support and enhance site performance	**Martin Olbrich**, Patient Recruitment Expert (Germany)	Risk Based Approaches	Electronic health record and risk based monitoring	**Mariusz Olejniczak**, New Product Development Business Partner, MonitorCR (Poland)
13:30 - 14:00	Clinical Operations	Challenges in cell therapy - recruitment and regulatory hurdles	**Stefan Siegmund**, General Manager & Co-founder, Convidia (Germany)	Risk Based Approaches	Risk Based Monitoring	Panel Discussion
14:00-15:30	Lunch (European Hall, 3rd Floor)					
Day 1, Nov 9th, 2017, Branch 1 Conference Hall, 1st Floor Chair: Yoanni Th. MATSAKIS, President, Telemedicine Technologies, France				**Day 1, Nov 9th, 2017, Branch 2** (A+C Hall, 1st Floor) Chair: Xavier Fournie, Medical Director & Executive Vice-President, Mapi Group (France)		
Time	Session	Topic	Speaker	Session	Topic	Speaker
15:30-16:00	Clinical Operations	Quality Management Systems and Sponsor Oversight in the context of GCP R2 and GVP implementation.	**Dmitry Manuilov**, Head of R&D, Maxwell Biotech Group (Russian Federation)	Medical Affairs	DMC / DSMB – Relevance and Practical Implementation	**Dagmar Chase**, Managing Director, Clinrex GmbH (Germany)

16:00-16:30	Clinical Operations	New technology tools and approach in patient-centricity idea within clinical trials	**Yoanni Th. MATSAKIS,** President, Telemedicine Technologies (France)	Medical Affairs	Medical monitoring in clinical trials settings. Craft or Art	**Mark Tulchinskiy**, Medical & Clinical Operations Director CEE, Pivotal (Spain)
16:30-17:00	Clinical Operations	Overcoming challenges related to orphan drug clinical trials	**Lale Ozturanli**, Medical Affairs Manager, ZEINCRO (Turkey)	Medical Affairs	Medical Monitoring in Non-interventional Observational Studies: The need for medical leadership and primary care management of the study	**Xavier Fournie**, Medical Director & Executive Vice-President, Mapi Group (France)
17:00 – 17:30	Clinical Operations	Development of Oncology Clinical Sites: Success Story	**Prof. Igor Bondarenko,** Dnipro National Medical Academy (Ukraine)	Medical Affairs	Site Support & Patient Enrollment Practices in Ukraine: Legal Aspects	**Lana Sinichkina**, Partner, Arzinger (Ukraine)
19:00 – 22:00	Gala-dinner (European Hall, 3rd Floor)					
Day 1, Nov 9th, 2017 – Branch 3 B+D Hall, 1st Floor Chair: Prof. Igor Kuznetsov, Director, PHARMBIOTEST LLC, Ukraine						
12:00 – 12:30	Bioequivalence/Early Phase Studies	Achievements and prospects of bioequivalence stuides in Ukraine	**Nadia Zhukova**, Head of the Department of Bioequivalence Ministry of Health (Ukraine)			

12:30 – 13:00	Bioequivalence/Early Phase Studies	Genetic Polymorphism and Pharmacokinetics of Highly Variable Medicines	**Igor Kuznetsov**, Director of PHARMBIOTEST LLC (Ukraine)
13:30 – 14:00	Bioequivalence/Early Phase Studies	Bioequivalence assessment of the hypoglycemic medicines.	**Olena Oksamytna**, Head of Medical & Pharmacological Department, Farmak JSC (Ukraine)
14:00- 15:30	Lunch (European Hall, 3rd Floor)		
15:30 – 16:00	Bioequivalence/Early Phase Studies	Statistical aspects of significant factors in the interpretation of bioequivalence studies	**Pavlo Babych**, State Expert Centre, Ministry of Health (Ukraine)
16:00 – 16:30	Bioequivalence/Early Phase Studies	Truncated AUC in bioequivalence studies	**Pawel Olszewski**, Synevo (Poland)
16:30 – 17:00	Bioequivalence/Early Phase Studies	The Boundary Conditions in BE and Early Phase I Studies	**Karl M. Eckl**, Consultant for Clinical Research (Germany)
19:00 – 22:00	Gala-dinner (European Hall, 3rd Floor)		

Day 2, Nov 10th, 2017 (President Hotel)

Day 2, Nov 10th, 2017, Branch 1 Conference Hall, 1st Floor Chair: Stefano Marini, Vice-President of EUCROF				**Day 2, Nov 10th, 2017, Branch 2** A+C Hall, 1st Floor		
Time	Type	Topic	Speaker	Type	Topic	Speaker
8:30 - 9:00	Regulatory	Clinical Trials Regulatory Landscape in Ukraine	**Liudmyla Kovtun**, Deputy Head of State Expert Centre, MOH Ukraine	Outsourcing in Clinical Trials	Metrics in the collaboration of Sponsor and CRO	**Philippe Van Der Hofstadt**, EU President, CSM Europe (The Netherlands)

9:00 - 9:30	Regulatory	EU Clinical Trials Regulation 536/2014 – An Overview	**Dagmar Chase,** Managing Director, Clinrex GmbH (Germany)	Outsourcing in Clinical Trials	Performance of a Virtual CRO model in CEE vs a top 10 tier CRO – Case Study.	**Alexander Gissler**, CEO, Projectpharm (Czech Republic)
9:30 - 10:00	Regulatory	Paediatric Research: where are we today?	**Martine Dehlinger-Kremer**, Vice President, Global Medical and Regulatory Affairs, SynteractHCR (Germany)	Outsourcing in Clinical Trials	Outsourcing Strategy & Vendor Management Strategy: Effective tools for a successful relationship	**Heike Schon**, CEO, Lumis International (Germany)
10:00 - 10:30	Coffee break (European Hall, 3rd Floor)					
10:30- 11:00	Regulatory	EU Regulations	**Prof. Stefano Marini**, Vice President of EUCROF; University of Rome (Italy)	Outsourcing in Clinical Trials	Best practices for qualification of clinical trial vendors	**Michał Ławniczak**, Head of Project Management, Clinmark (Poland)
11:00 - 11:30	Regulatory	Experience of regulatory inspections in Ukraine	**Sergii Rasputniak**, Chief Inspector, of State Expert Centre, MOH Ukraine	Outsourcing in Clinical Trials	An effective strategy for upscaling operations and entering new regions: Utilising the benefits of a freelance workforce	**Zac Beda**, Director, Upsilon Global (UK)

11:30 - 12:00	Regulatory	Review of clinical trials by Competent Authorities of Ukraine	**Lesya Yankova**, Chief Clinical Trials Expert, State Expert Centre, MOH Ukraine	Outsourcing in Clinical Trials	New approach to patient-centricity – can family physicians help in clinical trials?	**Janusz Kabata**, CEO, MedConsult (Poland)
12:00 - 13:30	Lunch (European Hall, 3rd Floor)					
Day 2, Nov 10th, 2017, Branch 1 Conference Hall, 1st Floor Chair: Dagmar Chase, Managing Director Clinrex GmbH, Germany				**Day 2, Nov 10th, 2017, Branch 2** A+C Hall, 1st Floor Chair: Donato Bonifazi, Head of TEDDY Network (Italy)		
13:30 - 14:00	Special Aspects of Clinical Trials	Innovative technologies that will transform clinical trials arena	**Josip Aralica**, CEO, Altiora (Croatia)	Regional Focus: Emerging Markets	Overcoming the challenges of conducting CNS Studies in Ukraine and EE	**Jeffrey Apter**, President, Global Clinical Trials, LLC (USA)
14:00 - 14:30	Special Aspects of Clinical Trials	The Social Media Blueprint: Top 3 Tips for the New Patient Advocacy and Recruitment	**Jerome Chiaro**, Vice-President, Studykik (USA)	Regional Focus: Emerging Markets	Clinical Trials Challenges in Eastern Europe in the Global Prospective	**Sergii Myronenko**, CEO, PharmaSich CRO (Ukraine)
14:30 - 15:00	Special Aspects of Clinical Trials	EDC system Validation and Verification: how to prove that system works in strict accordance to the protocol demands	**Yury Lebed**, CEO, Pharmaxi (Ukraine)	Regional Focus: Emerging Markets	Clinical Research in Albania: the lesson learned from the first ongoing paediatric trials	**Donato Bonifazi**, Head of TEDDY Network (Italy)
15:00 - 15:30	Special Aspects of Clinical Trials	Development of Advanced Therapy Medicinal Products	**Astrid Pañeda**, Clinical Research Director, Sermes (Spain)	Regional Focus: Emerging Markets	Clinical trials in Armenia	**Anush Perikhanyan**, Head of QA, FMD K&L (Armenia)

Day 2, Nov 10th, 2017 – Branch 3 B+D Hall, 1st Floor Chair: Danielle Giroud, CEO, MD-Clinical, Switzerland			
09:00 – 09:30	Medical Devices	ISO 14155 revision: What is new?	**Danielle Giroud**, CEO, MD-Clinical (Switzerland)
09:30 – 10:00	Medical Devices	The impact of the new Medical Devices Regulations on clinical affairs	**Zuzanna Kwade,** Safety Manager, Genae Group (Belgium)
10:00 – 10:30	Coffee Break		
10:30 – 11:00	Medical Devices	The Medical Device Industry: Global Vision	**Arjun Sharma**, CEO, Medical Devices Consultant LLC (USA)
11:00 – 11:30	Medical Devices	Clinical evaluation of medical devices: focus on the US	**Ievgeniia Kushch**, Senior Medical Writer, Medtronic (USA)
11:30 – 12:00	Medical Devices	Unique Practical Aspects in Designing Medical Device Studies	**Yoram Solberg**, Vice-President, Clinical & Medical Affairs, BrainsGate Ltd. (Israel)
12:00 - 13:30	Lunch (European Hall, 3rd Floor)		
13:30 – 14:00	Medical Devices	Methodology in clinical trials of medical devices in oncology	**Lucio Fumi**, CEO, Wyfold Medical Consultancy (UK)

14:30 – 15:30	Medical Devices	Panel discussion: • Global clinical investigation strategy – how to coop with the changing regulations in the different parts of the world. • Compassionate use for innovative medical devices – what is acceptable?	Moderator: **Danielle Giroud**
			Conference Closure European Hall, 1st Floor
15:45 - 16:00	Conference Closure	Closing remarking	**Sergii Myronenko**, Chairman of Organising Committee