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1st Kiev Clinical Research Forum

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9-10 November, 2017

President Hotel, 12, Hospitalna street, Kiev, Ukraine

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Nov, 8th, 2017			
20:00 – 22:00	Arrival of Speakers and Delegates	Receipt Party	
Day 1, Nov 9th, 2017			
General Session			
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 at GxP Compliance & Training Partners (Switzerland)
9:30 - 10:00	Key Note	New technology tools and approach in patient-centricity idea within clinical trials.	**Marcin Stefanowicz**, CEE Study Manager, Roche (Poland)
10:00-10:30	Hot Topic	Understandings of Biosimilars and Biosimilars Development	**Racho Jordanov**, President at JHL Biotech (Taiwan)
10:30-11:00	ICH-GCP	Implementation roadmap for ICH E6 (R2) Addendum, what should you have done already!	**Andy 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
11:30 - 12:00	Coffee break		

Day 1, Nov 9th, 2017, Branch 1				Day 1, Nov 9th, 2017, Branch 2		
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**, CEO, ClinCellence (Belgium)
13:00 - 13:30	Clinical Operations	How a Clinical Trial Liaison can provide optimal site support and enhance site performance	**Martin Olbrich**, Independent Patient Recruitment Specialist (Germany)	Risk Based Approaches	Electronic health record and risk based monitoring	**Mariusz Olejniczak**, Grupa NEUCA (Poland)

13:30 - 14:00	Clinical Operations	Comparative Analysis of site audit findings in Western and Eastern Europe	**Volodymyr Linevych**, Independent GCP auditor (Ukraine)	Risk Based Approaches	Risk Based Monitoring	Panel Discussion
14:00-15:30	Lunch					
Day 1, Nov 9th, 2017, Branch 1				**Day 1, Nov 9th, 2017, Branch 2**		
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, Nova Medica (Russian Federation)	Medical Affairs	DMC / DSMB – Relevance and Practical Implementation	**Dagmar Chase**, CEO, Clinrex GmbH (Germany)
16:00-16:30	Clinical Operations	Development of Oncology Clinical Sites: Success Story	**Prof. Igor Bondarenko,** Dnipro Medical Academy (Ukraine)	Medical Affairs	Medical monitoring in clinical trials settings. Craft or Art	**Mark Tulchinskiy**, Medical Affiars, 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**, Vice-President, Mapi Group (France)

17:00-17:30	Clinical Operations	Challenges in cell therapy - recruitment and regulatory hurdles	**Stefan Siegmund**, Convidia (Germany)			
Day 1, Nov 9th, 2017 – Branch 3						
12:00 – 12:30		Bioequivalence 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 Studies	Genetic Polymorphism and Pharmacokinetics of Highly Variable Medicines	**Igor Kuznetsov**, Director of PHARMBIOTEST LLC (Ukraine)		
13:30 – 14:00		Bioequivalence Studies	Bioequivalence assessment of the hypoglycemic medicines.	**Olena Oksamytna**, Head of Medical & Pharmacological Department, Farmak JSC (Ukraine)		
14:00- 15:30		Lunch				
15:30 – 16:00		Bioequivalence 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 Studies	Truncated AUC in bioequivalence studies	**Pawel Olszewski**, Synevo (Poland)

Day 2, Nov 10th, 2017						
Day 2, Nov 10th, 2017, Branch 1				**Day 2, Nov 10th, 2017Branch 2**		
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 (Ukraine)	Outsourcing in Clinical Trials	Metrics in the collaboration of Sponsor and CRO	**Philippe Van Der Hofstadt**, EU President, B&C Group (The Netherlands)
9:00 - 9:30	Regulatory	EU Clinical Trials Regulation 536/2014 – An Overview	**Dagmar Chase** 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**, VP, 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 - 10:15	Coffee break					

10:15-10:45	Regulatory	EU Regulations	**Prof. Stefano Marini**, University of Rome (Italy)	Outsourcing in Clinical Trials	Best practices for qualification of clinical trial vendors	**Michał Ławniczak**, Head of Project Management, Clinmark (Poland)
10:45 - 11:15	Regulatory	Experience of regulatory inspections in Ukraine	**Sergii Rasputniak**, Chief Inspector, MOH Ukraine (Ukraine)	Outsourcing in Clinical Trials	Site Support & Pateint Enrollment Practices in Ukraine: Legal Aspects	**Lana Sinichkina**, Partner, Arzinger (Ukraine)
11:15 - 11:45	Regulatory	Review of clinical trials by Competent Authorities of Ukraine	**Lesya Yankova**, Chief Clinical Trials Expert, MOH Ukraine	Outsourcing in Clinical Trials	New approach to patient-centricity – can family physicians help in clinical trials?	**Janusz Kabata**, CEO, MedConsult (Poland)
11:45 - 13:00	Lunch					
13:00 - 13:30	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**, VP, 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, Georgia and Iran	**Anush Perikhanyan**, Head of QA, FMD K&L (Armenia)
15:30 - 15:45	Coffee break					
15:45 - 16:00	Wrap Up	Closing remarking	**Sergii Myronenko**, Chairman of Organising Committee			

Day 2, Nov 10th, 2017 – Branch 3			
08:30 – 09:00	Medical Devices	ISO 14155 revision: What is new?	**Danielle Giroud**, CEO, MD-Clinical (Switzerland)
09:00 – 09:30	Medical Devices	Methodology in clinical trials of medical devices in oncology	**Lucio Fumi**, CEO, Wyfold Medical Consultancy (UK)
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 – 10:15	Coffee Break		

10:45 – 11:15	Medical Devices	The Medical Device Industry: Global Vision	**Arjun Sharma**, CEO, Medical Devices Consultant LLC (USA)
11:15 – 11:45	Medical Devices	Clinical evaluation of medical devices: focus on the US	**Ievgeniia Kushch**, Senior Medical Writer, Medtronic (USA)
11:45 - 13:00	Lunch		
13:00 – 13:30	Medical Devices	Unique Practical Aspects in Designing Medical Device Studies	**Yoram Solberg**, VP Clinical Affairs, Brainsgate (Israel)
13:30 – 14:00	Medical Devices	Panel discussion: Challenges in Medical Devices Trials	Moderator: **Danielle Giroud**