www.pharmasich.com

2nd Kiev Clinical Research Forum

Programme

16-17 May, 2019; Mercury Kyiv Congress; Kiev, Ukraine

(draft; subject to modifications)

May 15th, 2019 (Mercury Hotel)			
14:00 – 20:00	Arrival of Delegates	Registration (Reception)	
20:00 – 22:00	Arrival of Delegates	Receipt Party	
May 16th, 2019 (Mercury Congress Hall)			
8:00 – 9:00	Arrival of Delegates	Registration	
General Session Chair: **William Andrew Lawton**, CEO, Risk Based Approach Ltd, United Kingdom			
Time	Session	Topic	Speaker
9:00 - 9:20	General	Opening Remarks	**Dr. Martine Dehlinger-Kremer** President of EUCROF and Vice President Pediatric Development at Synteract (Germany)
9:20 - 9:55	General	Can Innovation and Clinical Trials Coexist?	**Adrian Otte,** Independent Consultant; formerly VP Parexel, VP AstraZeneca, VP Amgen; formerly Senior Vice-President Pfizer (USA)

www.pharmasich.com

9:55 - 10:30	General	Ethics in Clinical Development: Studies in Vulnerable Subjects Groups	**Julian V. Platon**, Head of Medical & Clinical Affairs, Luye Pharma (Switzerland)
10:30 - 10:50	Coffee break		

Day 1, May 16th, 2019, Branch 1			
Clinical Operations Session Chair:			
Time	Session	Topic	Speaker
10:50 – 11:20	Clinical Operations	Updates on Fraud and Abuse in Clinical Research and false Claims Act	**Eric Green,** Independent Consultant (former VP of legal affairs at GE, Quintiles and Syneos) (USA)
11:20 – 11:50	Clinical Operations	Hot Topics in ATMP - the art of avoiding the pits	**Stefan Siegmund**, CEO, Convidia (Germany)
11:50 – 12:20	Clinical Operations	Clinical trial performance metrics	**Irit Gliko-Kabir**, Senior Director Clinical Operations, BiolineRx (Israel)

www.pharmasich.com

12:20 – 12:50	Clinical Operations	Detecting and handling fraud in clinical research	**Shelly Shiff**, Independent Consultant (former Associate Director of QA (Pfizer and GSK) (USA)
12:50 – 13:10	Coffee break		
13:10 – 13:40	Clinical Operations	How to speed up clinical trial revealing bottlenecks via EDC system	**Yuriy Lebed**, CEO, Pharmaxi (Ukraine)
13:40 – 14:10	Clinical Operations	Clinical Research Development in the Middle East and African Emerging market	**Nadia Cheaib**, CEO, ClinGroup Holding (Lebanon)
14:10 – 14:45	Clinical Operations	Smart logistics for successful ATMP studies	**Raffaele Laciti** Product Manager, Clinical Trial Supply, World Courier (Germany)

PHARMASICH

www.pharmasich.com

14:45 – 16:00	Lunch		
Time	Session	Topic	Speaker
16:00 – 16:30	Clinical Operations	Pragmatic, practice-based clinical trials	**Janusz Kabata,** CEO, GP4 Research (Poland)
16:30 – 17:30	Clinical Operations	Panel Discussion. Clinical Logistics	Moderator: **Rostislav Kachan,** Country Director, Corex (Ukraine); Panelists: **Yuriy Yeretin**, Business Development, Farmasoft (Ukraine) **Vadym Bondarchuk,** Business Development, CCR Ltd (Ukraine) **Raffaele Laciti**, Product Manager, Clinical Trial Supply, World Courier (Germany) **Vitaliy Shakhnazarov**, Quality Director, Corex Global (Russia)

Day 1, May 16th, 2019, Branch 2			
Outsourcing in Clinical Trials Session Chair: **Alexander Gissler**, CEO, Projectpharm (Czech Republic)			
Time	Session	Topic	Speaker
10:50 – 11:20	Outsourcing in Clinical Trials	Keep your studies on track by smart CRO management: - How to select the appropriate CRO? - How to manage the CRO/Sponsor interactions? - What are the Key Success Factors?	**Ulrike Maria Grimm**, Head Global Project & Alliance Management, Vice President, Vifor Pharma (Switzerland)
11:20 – 11:50	Outsourcing in Clinical Trials	Earned Value Management for Clinical Trials – stay on top of time and budget with a brilliant though simple technique	**Alexander Gissler**, CEO, Projectpharm (Czech Republic)
11:50 – 12:50	Outsourcing in Clinical Trials	Panel discussion. Clinical trials in low/middle cost countries vs. Western Europe/US	Moderator: **Aleksei Zhmuro,** Associate Director GRO, GSM PAREXEL (Ukraine);

www.pharmasich.com

			Panelists: **Frank Berger**, Head, Study Budget CoE / Budget Analytics, Global Clinical Operations, Boehringer Ingelheim; **Jelena Vukotic**, Managing Director, Cato Europe (Serbia); **Zac Beda**, Director, Upsilon Global (UK) **James D Fan**, Medical Director, PPD (China) **Graham Belgrave**, Senior Vice President, Advanced Clinical (UK)
12:50 – 13:10	Coffee break		
13:10 – 13:50	Outsourcing in Clinical Trials	Strategic Partnering with CROs - Benefits of Strategic outsourcing - Relationships to succeed - creating an environment of trust - Real life example - FDA audit with CRO	**Faidra van der Wal**, Associate Director Global Clinical Development, Janssen Pharmaceuticals (Netherlands)
13:50 – 14:20	Outsourcing in Clinical Trials	Fundamentals in Clinical Trial Budgeting	**Frank Berger**, Head, Study Budget CoE / Budget Analytics, Global Clinical Operations, Boehringer Ingelheim
14:20 – 14:50	Outsourcing in Clinical Trials	Evaluating various outsourcing strategies for staffing	**Marco de Wit**, CEO, MZD GmbH (Germany)
14:50 – 16:00	Lunch		
Time	Session	Topic	Speaker
16:00 – 16:30	Outsourcing in Clinical Trials	Internal management vs. CRO management for studies conducted in biotech companies	**Abi Vainstein-Haras**, Vice President Clinical and Medical Affairs, BiolineRx (Israel)

www.pharmasich.com

16:30 – 17:00	Pediatric drug development	Better Medicines For Children?! From Dogmas Towards Science	**Klaus Rose,** Klausrose Consulting (Switzerland)
17:00 – 17:30	Outsourcing in Clinical Trials	Decision pending	**Julianna Tarnai,** Deputy Director, National Institute of Pharmacy and Nutrition (Hungary)

Day 1, May 16th, 2019, Branch 3			
Site Solutions & Patient Centricity Session Chair: **Vivienne van de Walle**, independent research site PT&R (Netherlands)			
Time	Session	Topic	Speaker
10:50 – 11:20	Site Solutions & Patient Centricity	Risk Based Monitoring from site's perspective	**Vivienne van de Walle**, Co-founder, independent research site PT&R (Netherlands)
11:20 – 11:50	Site Solutions & Patient Centricity	Experience of computerizing Site Management Processes	**Igor Bondarenko**, Prof. Igor Bondarenko, MD, PhD, Head of Oncology and Medical Radiology Dept. Dnepropetrovsk Medical Academy (Ukraine)
11:50 – 12:20	Site Solutions & Patient Centricity	Post ICH GCP E6 R2: Institution/Investigator Qualifications and Oversight of External parties in Clinical Trials.	**Ella Grach**, CEO, M3-Wake Research (USA)
12:20 – 12:50	Site Solutions & Patient Centricity	Specific boundary conditions and the conflict of interest triangle between sponsor, CRO and clinical site / SMO in early drug development	**Karl M. Eckl**, Consultant, Innoxphar (Germany)
12:50 – 13:10	Coffee break		

www.pharmasich.com

Time	Session	Topic	Speaker
13:10 – 13:40	Site Solutions & Patient Centricity	Patient centricity as a way to manage adherence and compliance in clinical trials	**Elizabeth Tarshish**, Head of Clinical Affairs, Lycored (Israel)
13:40 – 14:10	Site Solutions & Patient Centricity	Medical Imaging Endpoint in Clinical Research: Rationale, Design, and Results	**Michael Sheppard Silver**, CEO, Medical Innovations Technology (Israel)
14:10 – 14:40	Site Solutions & Patient Centricity	Conducting clinical trials at home, a best pratice combined with IoTs	**Claudine Richon**, Export Project Director, Popsi Cube (France)
14:40 – 16:00	Lunch		
Time	Session	Topic	Speaker
16:00 – 17:00	Site Solutions & Patient Centricity	Panel Discussion. How to select the right enrollment strategy for your study	Moderator: **Nigel Goodman**, CEO, Gaea Clinical (Estonia); Panelists: **Martin OIbrich**, Independent Patient Enrollment Consultant (Germany); **Suzanne Pozsonyi,** Syncon International (Hungary) **Michaela Vancova**, Clinical Operations Director Slovak Research Center s.r.o. (Slovakia) **Ella Grach**, CEO, M3-Wake Research (USA)
17:00 – 17:30	Site Solutions & Patient Centricity	Lessons learnt from the failed clinical trials – investigator's standpoint.	**Prof. Sergii Kozhukhov**, Strazhesko Institute of Cardiology (Ukraine)

Day 2, May 17th, 2019, Branch 1

www.pharmasich.com

Regulatory Session Chair: **Stefano Marini**, Vice-President EUCROF (Italy)			
Time	Session	Topic	Speaker
9:00 - 9:30	Regulatory & Development	Changes in the Pediatric Landscape	**Dr. Martine Dehlinger-Kremer** President of EUCROF and Vice President Pediatric Development at Synteract (Germany)
9:30 - 10:00	Regulatory & Development	Inspections under the Clinical Trial Regulation, be prepared to changes?	**Michele Garot,** CEO, Clincellence (Belgium)
9:00 - 9:35	Regulatory & Development	Last minute update on the CTR and Portal implementation and their impact on Sponsors, Investigators and CROs	**Stefano Marini**, Vice President EUCROF (Italy)
9:35 - 11:10	Regulatory & Development	Code of Conduct in Data Protection	**Yoani Matsakis**, CEO, Telemedicine Technologies (France)
11:10 – 11:30	Coffee break		
Medical Affairs Session Chair: **Stefano Marini**, Vice-President EUCROF (Italy)			

www.pharmasich.com

11:30 – 12:30	Regulatory & Development	Cooperation between Medical Affairs, Clinical Development and Clinical Operations	Moderator: **Julian V. Platon,** Head of Medical & Clinical Affairs, Luye Pharma (Switzerland); Panelists: **Piotr Wlodarczyk** (Poland); **Shari Lennon**, Consultant Clinical Operations, Strongbridge Biopharma (USA); **Gina Ayala Gonzalez**, Senior MSL Manager, Deciphera Pharmaceuticals (Netherlands); **Maxim Belotserkovsky**, Global Head Medical Affairs, PSI Group (Germany) **Daniela Pirvu**, Clinical Operations, CTG Cardiomed CRO (Romania)
13:10 – 13:40	Regulatory & Development	Caution my harm – Why adolescents should not be excluded from adult oncology trials	**Cesare Spadoni**, Chairman of aPODD Foundation (accelerating Paediatric Oncology Drug Development) (UK)
13:40 – 14:10	Regulatory & Development	Traditional medicine- prevention for health and source of innovation (NCEs)	**Ivana Haluskova Balter**, Consultant Public Health, Science and research partnership (France)
14:10 – 15:00	Lunch		

PHARMASICH

www.pharmasich.com

Day 2, May 17th, 2019, Branch 2			
Risk Based Approaches & Quality Session Chair: **Rino Coladangelo**, CEO, Rephine (UK)			
Time	Session	Topic	Speaker
9:00 - 9:35	Risk Based Approaches & Quality	Preparation of BE/BA Unit for FDA Inspections	**Marika Pecena**, Independent Consultant (Czech Republic)
9:35 - 10:10	Risk Based Approaches & Quality	Protocol design process and management of the associated risks	**Rino Coladangelo**, CEO, Rephine (UK)
10:10 -11:10	Risk Based Approaches & Quality	Panel Discussion. CROs and Sponsors: Oversight and Compliance in FDA regulated studies.	Moderator: **Sarah Moeller,** The Greenlight Group (USA); Panelists: **Wojciech Smoron**, Project Director (Switzerland); **Shari Lennon**, Consultant Clinical Operations, Strongbridge Biopharma plc (USA); **Shelly Shiff**, Independent Consultant (former Associate Director of QA (Pfizer and GSK) (USA)
11:10- 11:30	Coffee break		
Time	Session	Topic	Speaker

www.pharmasich.com

11:30- 12:00	Risk Based Approaches & Quality	The regulations and guidances require us to perform Oversight - what is acceptable oversight	**William Andrew Lawton**, CEO, Risk Based Approach Ltd (UK)
12:00- 12:30	Risk Based Approaches & Quality	Centralised monitoring as part of a Risk Based Approach: advantages and risks	**Eric Klaver**, Director, GCP Trainer & Auditor, Fourplus Clinical (Netherlands)
12:30 – 13:00	Risk Based Approaches & Quality	What is wrong with clinical trials? Innovation trends to increase a chance for successful studies delivery.	**Michał Ławniczak**, Head of Clinical Consulting, Clinmark (Poland)
13:00 – 14:10	Risk Based Approaches & Quality	Workshop: Risk Based Monitoring	**Andy Lawton**, CEO, Risk Based Approach Ltd (UK)
14:10 – 15:00	Lunch		

Day 2, May 17th, 2019, Branch 3			
Domestic Ukrainian Session (working language: Ukrainian) Chair: **Oleksandr Koval** (Novartis)			
Time	Session	Topic	Speaker
9:00 – 10:10	Domestic Ukrainian	Panel Discussion. What to do today to prosper tomorrow? Advantages and areas for improvement of Ukrainian clinical research market.	Moderators: **Kateryna Kovinia** (Ukraine); **Oleksandr Koval** (Novartis Ukraine); Panelists: **Dmytro Reshotko,** Investigator (Consilium Medical), **Dmytro Semeniuta,** Country Director (PPD),

www.pharmasich.com

			Kateryna Kornienko, Director (CCR Ltd), **Igor Svitlyk**, Lawyer (Dentons)
10:10 – 11:10	Domestic Ukrainian	Panel Discussion. Open discussion with the clinical trials regulators of Ukraine	Moderator: **Oleksii Mikheev**, Verum (Ukraine); Panelists: **Ruslan Salutin**, Head of Transplantology Department, MoH Ukraine; **Oleksandr Komarida**, Head of Pharmaceutical Directorate, Health Ministry of Ukraine; **Tetiana Dumenko**, Director, State Expert Centre, MoH Ukraine; **Liudmyla Kovtun**, Deputy Director, State Expert Centre, MoH Ukraine; **Sergii Rasputniak**, Chief Inspector, State Expert Centre, MoH Ukraine
11:10 – 11:30	Coffee break		
Niche Topics Session Chair: **Donato Bonifazi**, CEO, Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF) (Italy)			
11:30- 12:00	Niche Topics	Preclinical development, Research Infrastructures and CRO partnership.	**Donato Bonifazi**, CEO, Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF) (Italy)
12:00 – 12:30	Niche Topic	Challenge of early development phase-less trials	**Riccardo Belli**, Director, Novartis Oncology (Switzerland)
12:30 – 13:00	Niche Topic	Optimizing Your Clinical Trial in Eastern Europe	**Jeffrey Apter**, President, Global Clinical Trials, LLC (USA)

www.pharmasich.com

12:30 – 13:00	Niche Topic	"Rely On Your EDC Provider". Innovative EDC Solutions for Clinical Research Industry.	**Franco Schiannini**, Owner, Nubilaria Srl (Italy)
13:00 – 13:30	Niche Topic	Use of Chimeric Antigen Receptors in Oncology: specificity and challenges	**Lucien Gazi,** Global Trial Program Head (Switzerland)
13:30 – 14:10	Niche Topic	Clinical Trials for Medical Food / FSMP / Nutraceuticals: are they food or pharma?	**Lucio Fumi**, Director of Medical Affairs Piramal Enterprises Limited (UK)
14:10 – 15:00	Lunch		
Final Session			
15:00 – 16:00	Final Session		**Mixael Laufer** (USA)
16:00 – 16:15	Final Session	Closing remarking	**Sergii Myronenko**, Chairman of Forum