PHARMA ASI

CLINICAL TRIALS
CENTRAL & EASTERN EUROPE

25–26 April 2017 | Novotel Budapest Centrum

CLINICAL TRIALS
IN CENTRAL & EASTERN EUROPE FORUM

The leading event for all parties involved in the clinical trials market in CEE

Csilla Pozsgay
Director General
National Institute of Pharmacy and Nutrition

Francis Crawley
Executive Director
GCPA & Ethics Working Group, European Academy of Paediatrics (EAP)

Szabolcs Barótfi
Clinical Research Director CEE2
MSD

Divya Chadha Manek
Head of Business Development
NIHR Clinical Research Network

István Balla
MD, Country Head, Site Management & Monitoring EMEA, R&D, Clinical Operations
AbbVie

Marco Salami
Senior Clinical Outsourcing Manager
Chiesi Farmaceutici SpA

Gjon Mirdita
Vice President, Site Management Regional Head, Key Markets R&D Solutions NEMEA & CESE
QuintilesIMS

Ottó Skorán
MD, President of Board, MCRN Hungary and Chief Executive Officer
Svabhegy Paediatric Hospital

Organised by

Adam Smith CONFERENCES

Sponsored by

synevo CENTRAL LABS

SanaClis

LongTaal

MEDICODOSE SYSTEMS 3C SOLUTION COMPLIANCE COUNTERFEIT CLINICAL TRIALS

CLINERION clinical research solutions

Vector Logistic

www.clinicaltrialscee.com T.: +7 495 232 4060/+44 20 8004 5707/ E. events@adamsmithconferences.com

PHARMA ASI

CLINICAL TRIALS

CENTRAL & EASTERN EUROPE

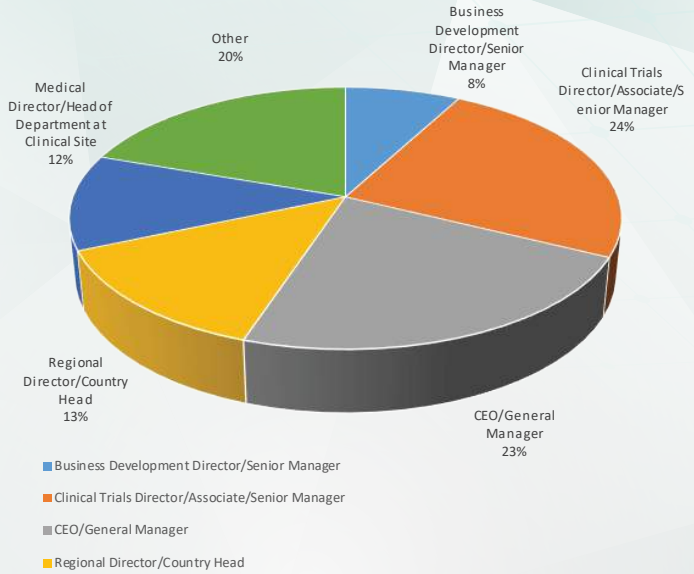
A great number of willing patients, highly experienced researchers and EMA-compliant legislation make the CEE region an attractive research destination. CEE is also the region with the lowest percentage of inspections that required official or voluntary action. The data at large suggest that the high productivity of CEE sites are accompanied by regulatory compliance and data quality standards that are not inferior to those in Western regions. Six countries from CEE (Hungary, Czech Republic, Estonia, Bulgaria, Slovakia and Latvia) rank among the top 10 countries globally in terms of accessibility of industry R&D clinical trials to patients. However, the clinical trials landscape is shifting rapidly and with the increasing competition from the South-East Asian region, the global industry is expecting further improvement of the business and regulatory environment in the CEE region.

Join us at the Clinical Trials in CEE Forum to meet with international and local pharmaceutical companies, biotech companies, CROs, SMOs, investigators and other parties operating or interested in conducting clinical trials in the CEE region. This year, now in Budapest, we would like to capitalise on the success of the previous Forum and host regional and international KOLs, CROs, sponsors, research site representatives, state officials, bioethics and patient organisations.

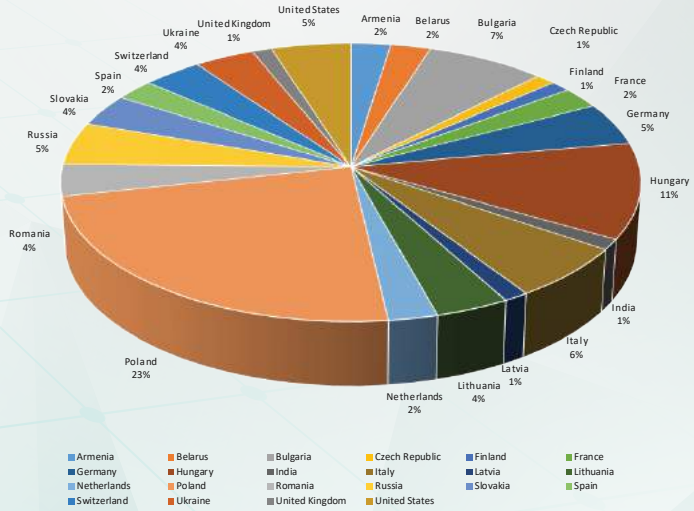
With Kind Regards,
Kristina Dutchak
Programme Director

FORUM IN NUMBERS

Job Titles, 2016–2017



Countries representation, 2016–2017



ATTENDING COMPANIES 2016-2017

- A4PBio
- AbbVie
- Actelion
- Adamed Group
- Anapharm Europe
- Argint International Kft
- Association for Good Clinical Practice in Poland
- BC Children's Hospital
- Biomapas
- Center of Bioethics of the Supreme Medical Council
- Central Clinical Hospital, Ministry of Interior in Warsaw
- Centrum Badań Klinicznych PI-House
- Chiesi Farmaceutici
- Clinerion
- Clinica Dr Rosu
- Clinical Research Center
- Clinical Trial Center of the Jagiellonian Center of Innovation
- Clinmark Clinical Research
- ClinTec International
- Comac Medical
- Covance Clinical and Periapproval Services
- Cromsource
- CTI Clinical Trials
- Debiopharm
- Deloitte Legal Erdős and Partners Law Firm
- Dnepropetrovsk Medical Academy
- Dokumeds
- EFGCP
- EFPIA
- EGIS Pharmaceuticals Public
- Eli Lilly and Company
- European Academy of Paediatrics
- Global Clinical Trials
- Goldberg Research Institute of Pharmacology and Regenerative Medicine
- Good Clinical Practice Alliance – Europe (GCPA) & Ethics Working Group, European Academy of Paediatrics (EAP), Belgium
- Hasco-Lek Pharmaceutical Production Company S.A
- Hungarian Clinical Trials - Global Kft.
- Interfarmaks
- Julius Center for Health Sciences and Primary Care/ University Medical Center Utrecht
- KCR CRO
- Krka
- Lazarski University
- LongTaal
- MAK College of Pharmacy
- MC Medica Plus
- MedConsult
- Medical University of Łódź, Bieganski Hospital Łódź
- MediScience
- Merck
- Ministry of Health (Poland)
- Ministry of Interior (Poland)
- MSD
- MTZ Clinical Research
- National Institute for Health Research Clinical Research Network
- National Institute of Pharmacy and Nutrition (Hungary)
- NIHR Clinical Research Network (CRN)
- Nubilaria
- OPIS
- Orion Pharma
- PI-House - Centrum Badan Klinicznych
- PLIVA
- PRA Health Sciences
- Proper Medical Writing / European Medical Writers Association
- Quinta-Analytica
- QuintilesIMS
- Roche
- SanaClis s.r.o. (Slovak Republic)
- Sanofi-Aventis
- Sensitech EMEA
- Servier
- Slovak Research Center
- SSS Clinical Research
- Svabhegy Paediatric Hospital
- Synevo
- Synevo Division
- Synexus Polska
- Synthetic Biologics
- Thrombotargets Europe
- Tonus-Les
- University of Warsaw
- Yuria-Pharm
- ZIAJA

FORUM'S HIGHLIGHTS:

How a regulatory agency can support earlier access to medical products – agencies in new role?

Csilla Pozsgay
MD, Director General of the National Institute of Pharmacy and Nutrition (OGYEI)

Advancing Paediatric Clinical Trials in CEE Countries and the Review/Revision of the EU Paediatric Regulation

Francis P. Crawley
Good Clinical Practice Alliance – Europe (GCPA) & Ethics Working Group, European Academy of Paediatrics (EAP), Belgium

Planning for the Impact of the New EU Clinical Trials Regulation No 536/2014

Martine Dehlinger-Kremer, President of EUCROF, MEMBER of the BOARD, EFGCP, Germany

Conclusions from a Social Media Campaign of Subject Recruitment into Clinical Study

István Balla, MD, Country Head, Hungary, Site Management & Monitoring, EMEA, R&D, Clinical Operations, AbbVie

Innovations in Clinical Trials

Barótfi Szabolcs, Clinical Research Director CEE2, MSD

Divya Chadha Manek, Head of Business Development, NIHR Clinical Research Network (CRN)

Exciting feature: quick-fire showcase session:

REGIONAL SITES FOR CLINICAL RESEARCH – Case studies by sites' managers addressing therapeutic specialisation, patient availability, terms, resolved bottlenecks and achievements. Followed by discussion on prospects of introduction of a unified standard for all the clinical research sites

Wojciech Cyrul, PhD, LL.M, DEA, General Director Clinical Trial Center of the Jagiellonian Center of Innovation

Tomasz Miszalski Jamka, MD, PhD, Medical Director Clinical Trial Center of the Jagiellonian Center of Innovation

Michaela Vancova, Clinical Operations Director, Co-Founder, Slovak Research Center

Jaroslav Rejnek, Clinical Research Director, PENTA Hospitals

Seminar on Medical Writing: ESSENTIAL DOCUMENTATION IN CLINICAL TRIALS

Rosemary Bischoff, MSc, Workshop Leader, Proper Medical Writing / European Medical Writers Association

8:30–9:30
Registration and morning coffee

9:30–9:35
Welcoming from the organiser

9:35–9:55
Session 1: The outlook for the clinical trials in Central & Eastern Europe

Analysis of the key growth areas and new initiatives that differentiates CEE region. Has the region managed to retain its competitive advantage? What are the growth drivers that will attract business to the CEE region in the next couple of years?

Latest geographic trends in industry clinical trials–are emerging markets losing their allure?

9:55–11:25
Session 2: Update on regulation, compliance, legal & ethical legislative developments

Keynote presentation: How a regulatory agency can support earlier access to medical products–agencies in a new role.

Analysis of the latest regulatory initiatives represented by the state bodies in regards to the clinical trials. Policies exchange and country-by-country update of the developments from across Europe & CEE. Country-specific update on the implementation of the EU Regulation No. 536/2014 and development of a greater transparency of the regulatory process in clinical trials.

11:25–11:55 Coffee and networking

11:55–1:10
Session 3: Patients – the cornerstone of the clinical trials

What should be done in order to develop effective, mutually empowering relations between Patients, Sponsors, CROs and Sites on national and organisational level?

Analysis of the legislative framework and general practices that help to increase patients' involvement throughout the research process. Initiatives that improve public trust, understanding and awareness and has positive impact on participation and retention rates. Case-studies of educational patients programmes.

1:10–1:35

Spotlight presentation: The role of the COMBACTE public-private consortium in antibiotic–and antibacterial drug development

1:35–2:35 Lunch

2:35–3:20
Session 4: Effective monitoring of clinical investigations and management of clinical trials: case studies and practical exchange

Innovative approaches to trial development and design. RBM vs Centralised monitoring case study. Adaptive monitoring and management of clinical research data management and quality control.

3:20–3:50 Coffee and networking

3:50–5:30
Session 5: Investigators' panel: what does it take to increase the speed and maintain the high quality research? What would improve on the quality of the CI process?

Practical showcases by the leading investigators across various therapeutic specialisation. Spotlight presentation by MCRN (Hungary): «Role of paediatric clinical research networks in improving research quality and standards». Do we really have to hire CT managers at sites?

5:30–7:30
Evening reception & networking

Welcome Cocktail Reception

Discuss the day and network with your peers at the «Most beautiful coffee house in the world» in the New York Café in Budapest

To secure you place, kindly RSVP to **A.Bruce@adamsmithconferences.com**

Vladimir Misik, Founder & Managing Partner, LongTaal

Csilla Pozsgay, Director General, National Institute of Pharmacy and Nutrition

Francis Crawley, Executive Director, Good Clinical Practice Alliance – Europe (GCPA) & Ethics Working Group, European Academy of Paediatrics (EAP)

Martine Dehlinger-Kremer, EUCROF President & Vice President, Global Medical and Regulatory Affairs, SynteractHCR & EFGCP Board Member

István Balla, MD, Country Head, Hungary, Site Management & Monitoring, EMEA, R&D, Clinical Operations, AbbVie

Barış Erdoğan, PhD, Head of EEMEA Region, Clinerion

Tunde Koltai, Head / President, BEMOSZ (Association of Patients' Organizations in Hungary) /Hungarian Coeliac Society

Ron de Winter, Program Coordinator European Projects, Julius Center for Health Sciences and Primary Care/ University Medical Center Utrecht

Zoltan Koleszar, Site Relationship Operational Lead (Hungary, Slovakia, Czech Republik and Ukraine), Merck

Prof. Andrzej Fal, MD, PhD, MBA, FAAAAI, Head of the Department of Internal Medicine and Allergology, Central Clinical Hospital, Ministry of Interior in Warsaw

Ottó Skorán, MD, President of Board, MCRN Hungary and Chief Executive Officer, Svabhegy Paediatric Hospital

Katarzyna Juszczyńska, MD, MPH, Organization and Management of Clinical Trials, Programme Director, Lazarski University

Dénes Páll, MD, PhD, DSci, Director of Coordinator Center for Drug Development and Vice Director, Department of Medicine, University of Debrecen

9:00–9:30
Registration and morning coffee

9:30–11:30
Session 6: Innovations in Clinical trials

Advanced data collection and wearable health monitors/smartphone apps – what works best at present? Restrictions due to the patients profile (age, lifestyle and social factors).

mHealth era: analysis of the new technological advances and opportunities that they bring along and usage restrictions? How mHealth could help improving data accuracy and patient experience?

11:30–12:00 **Coffee and networking**

12:00–1:30
Session 7: What makes it work: CRO-SPONSOR-SITE-PATIENT case study and exchange of good practices, factors and ideas for successful collaboration. Case studies of trouble-shooting practices.

- Case-study by CRO
- Case-study by Sponsor
- Case-study by Site Rep
- Case-study by Lab

1:30–2:30 **Lunch**

2:30–3:55
Session 8: Quick-fire showcase session: regional sites for clinical research

Case studies by sites' managers addressing therapeutic specialisation, patient availability, terms, resolved bottlenecks and achievements.

Followed by discussion on prospects of introduction of a unified standard for all the clinical research sites.

3:55–4:15 **Coffee and networking**

4:15–7:15
Seminar on Medical Writing: «ESSENTIAL DOCUMENTATION IN CLINICAL TRIALS»

- Deciding precisely what scientific question the study will ask (study objective/ study hypothesis)
- Translating the study objective into the appropriate study design (control groups)
- Selecting outcome variables and study visits (schedule of evaluations)
- Selecting inclusion/exclusion criteria (to what extent will results be 'generalisable')
- Transforming a protocol into the Methods Section of the report (CSR sections 1-9)
- The Disposition of Patients Table
- Using the Schedule of Evaluations to drive the results sections
- Cross referencing to the appendices
- Reports to be published online (EMA policy 0070)

7:15 **Close of the Forum**

Divya Chadha Manek, Head of Business Development, NIHR Clinical Research Network (CRN)

Gjon Mirdita, Vice President, Site Management Regional Head, Key Markets R&D Solutions NEMEA & CESE, QuintilesIMS

Szabolcs Barótfi, Clinical Research Director CEE2, MSD

Marcin Stefanowicz, PhD, MSc, Regional Study Manager Central and Eastern Europe/ Regional Study Manager Central and Eastern Europe Ambassador and Member of Europe Innovation & Technology Group , Roche

Nadir Benouali, Founder & CEO, Medicodose Systems

Marco Salami, Senior Clinical Outsourcing Manager, Chiesi Farmaceutici SpA (Italy)

Ramón López, Clinical Research Manager, Thrombotargets Europe

Rahul Chaudhary, Director Business Development–Histopathology, Synevo Division

Wojciech Cyrul, PhD, LL.M, DEA, General Director, Clinical Trial Center of the Jagiellonian Center of Innovation

Tomasz Miszalski Jamka, MD, PhD, Medical Director, Clinical Trial Center of the Jagiellonian Center of Innovation

Jaroslav Rejnek, Clinical Research Director, PENTA Hospitals

Michaela Vancova, Clinical Operations Director, Co-Founder, Slovak Research Center

Rosemary Bischoff, MSc, Workshop leader, Proper Medical Writing / European Medical Writers Association

The Forum offers an excellent opportunity to meet people, share experiences in the field of clinical trials. Excellent organisation and networking

Aleksandra Puchała, Clinical Trials Specialist at PPF Hasco-Lek

SPONSORS

Medicodose Systems specialises in the R&D and commercialisation of innovative patient adherence technologies in a form of smart pharmaceutical packaging and a clinical software suite allowing investigators, CRO & Sponsors real time access to ambulatory clinical human subject adherence data. Thus, accelerating qualitative endpoints that faithfully report how the human subject feels as the trial progresses. Also, besides the process of source data verification that we offer, our innovative technology is a de-facto tool for a successful RBM deployment. We can help a site or a CRO with predictive non-adherence behavior and protocol deviations as they happen and on a continuous basis through out the duration of a trial. Decision can thus be taken on an on-going basis rather than months after the facts. Therefore, the ability to run and manage a centralized and remote monitoring allows investigators, CRAs and other trial staff to perform data checks, review potential inconsistencies while evaluating risk factors and determining and preparing for human-subject site visits only when necessary. The benefits are tenfold through unmatched savings to sites, CROs and Sponsors alike with faster access yet, qualitative, data endpoints.

Visit our website medicodose.com

Synevo Central Labs is the largest wholly-owned, fully-harmonised and GCLP accredited network of central laboratories in Europe dedicated exclusively to support clinical trials. Our facilities in Poland, Romania, Ukraine, Germany, Belarus, Bulgaria, Serbia, Moldova, Georgia, Turkey and in Russia operate with the same analytical platforms, materials and reagents and under identical procedures. We offer a comprehensive organisation of a clinical trial laboratory part, starting from study-specific kits preparation and investigator site personnel training through sample logistics management and specimen analyse to lab results reporting and final database transfer. We provide our clients with 24/7 access to a real-time data through our web-based, secured and user-friendly application, known as LabOne.

Visit our website
www.synevo-centrallabs.com

Clinerion enables early patient access to innovative treatments through solutions for clinical trial patient recruitment, real-world evidence, and market access. Clinerion's Patient Recruitment System accelerates clinical research by radically improving the efficiency and effectiveness of trial recruitment. Key tools for Clinerion's patient data services include data-assisted protocol optimisation, site feasibility evaluation and patient identification. Clinerion's solutions allow member hospitals to participate in leading-edge, industry-sponsored trials and save time in patient recruitment. They enable pharmaceutical companies to gain time and cost savings by streamlining operations and gaining strategic intelligence. Clinerion's proprietary Big Data analytics technologies leverage real-time data from electronic health records which remain under the full control of participating hospitals. Clinerion is a global data technology company headquartered in Switzerland. Clinerion's solutions follow international patient privacy and data security standards.

Visit our website www.clinerion.com

Description: LongTaal provides industry's first class clinical trials intelligence, enabling pharma companies, investigators, regulators, academics and CROs fast access to essential data for trial planning & management. Our clients are thus able to understand sponsors' clinical development strategy, understand the market dynamics in the pharma industry and achieve higher feasibility accuracy. Access www.longtaal.com to request additional information or live demo of our analytics.

Visit our website www.longtaal.com

SPONSORS

SanaClis was founded in 2000 by seasoned industry experts all of whom have had executive level positions in leading pharma companies and large global CROs. SanaClis is a full-service CRO offering a comprehensive range of services for clinical trials in Central and Eastern Europe.

SanaClis is one of the very few CROs offering customs brokerage, warehousing and distribution of clinical trial materials in Ukraine and Russia in its own premises and by own professional staff, in addition to clinical monitoring and regulatory services. SanaClis facilities/depots and processes meet criteria of the most stringent international standards and local requirements.

In 2012, SanaClis s.r.o. was rated positively by reputable business agency Creditreform and for 2013 and 2014 was awarded and certified with the AA rating by Bisnode rating agency. SanaClis has earned its place on Nice Insight's survey of Top Ten lists of Clinical Research Organisations (CROs) for 2015, based on customer perceptions of quality.

This is the first time a Slovakia-based CRO has finished among the leaders in the CRO industry, reflecting intensive investments and quality assurance measures. In 2015, Sanaclis was awarded with the CRO Leadership Award in the category Reliability.

Core products and services:

- Regulatory
- Clinical Monitoring
- IMP & CTS Management
- Customs clearance & brokerage
- Site Contracting & Payments
- Project Management
- Quality Management
- Central Laboratory Russia - incl. Bioequivalence Studies
- Data management, Statistics & Medical writing

Visit our website www.sanaclis.eu

Vector Logistics C specialises in providing customs representative (broker) services, for Pharmaceutical and Medical spheres, since 1996.

Vector Logistics is one of the pioneer Russian companies which provides Cold Chain logistics services and Customs Clearance Turn Key solutions for Clinical & Pre-Clinical trials, Scientific Researches, Drugs Registrations and Pharmaceutical Expertises.

Over than 20 years of experience in organizing international and domestic transportations of non-hazardous and hazardous goods with or without temperature control storage conditions, commercial and non- commercial. Wide spectrum of transportation logistics solutions for both temperature controlled and ambient shipments, warehousing services, documents coordination, licenses and certificates acquiring for import/ export purposes.

Visit our website www.vector-logistics.ru

Networking Opportunities

Networking is what makes your conference experience both enjoyable and useful. With over 200 delegates and speakers from different organisations and locations, you will always be making connections with other attendees and exchanging information, whether you are attending our Cocktail Reception, grabbing coffee in between sessions, or just talking to people in the lobby during a break.

The Networking App

Search who is attending the event and message them up to 2 weeks in advance to make the most out of your time at the Forum. It also gives you up to date timetable changes and details.

The Exhibition Area

Exhibition stands offer you the chance to speak with the developers of new industry projects, product experts & industry consultants.

Meet Speakers and Attendees at the Lunch and Coffee Breaks

This is your chance to meet your peers and to quiz the speakers on the elements of their presentation that really appealed to you.

Evening Cocktail Reception

We conclude day one by offering the delegation the chance to discuss the day and network with pears at the drinks reception.

For information on sponsorship and exhibition opportunities,
please contact: **Rebecca Pickering**

+44 20 8004 5703

rebecca@adamsmithconferences.com