Clinical Trials in Central & Eastern Europe

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

PHARMASI
CLINICAL TRIALS
CENTRAL & EASTERN EUROPE

Day 1 - Tuesday 17 April 2018

08:30 - 09:20

Registration and Morning Coffee

09:20 - 09:30

Opening Comments from the Organisers and the Chairperson

Session 1: Keynotes Day 1

09:30 - 10:00

KEYNOTE 1: The Global Landscape of Clinical Trials

A review of the current landscape of global clinical trials and perspectives of the CEE and its differentiators. Insights into trends and predictions as well as growth drivers that attract business to the region. Global factors that will affect clinical trials in the CEE and measures to strengthen its competitive advantage.

10:00 - 10:30

KEYNOTE 2: New EU Regulations and Compliance Updates

Analysis of the latest regulatory initiatives and compliance updates impacting clinical trials in Europe today. Results from the impact of Brexit on European trials and insight into the preparations for the implementation of the European data protection law

10:30 - 11:00

Coffee & Networking Break (with an opportunity for conversations and discussion)

Session 2: Regulations with CEE Focus

11:00 - 13:00

Presentations Followed by a Discussion

Hear country insights and regulatory updates impacting trials in the CEE. Speakers will address the impact of regulations in specific countries as well as the:

- Impact of GDPR enforcement
- Impact of national requirements on trial delivery
- Impact of regulations on timelines for trial delivery
- Guidelines impacting patient recruitment for trials

Discussion: Your Trial, Your Questions!

Have your say and ask our speakers about what's on your mind.

Topics that will be discussed include:

- The impact of upcoming regulations on trials
- Challenges of new regulations on multi-country trials
- Medical reform in the CEE
- Future predictions of clinical trial global shifts and emerging opportunities
- Challenges of implementing the Clinical Trial Directive
- Regulatory issues aired

Slovakia
Beata Cecetkova,
Clinical Research Director,
TWMA Clinical Research and Pharmacovigilance, Czech Republic

Poland
Piotr Drobek,
Deputy Director of the Social Education and International Department,
GIODO, Poland

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

Czech Republic
Lucie Špatenková,
Clinical Operations Manager,
CRC s.r.o. Czech Republic

13:00 - 14:30

Lunch and Networking

Session 3: Regulations in Practice

14:30 - 15:00

Interpretation of the EU 2016/679 Data Protection Regulation

The use of personal data is vital to ensure quality and reliability in trials and research. The regulation EU 2016/679 is to be enforced in May 2018. Its main objective is to harmonise the rules for protecting participants privacy when processing health data, genetic data and biometric data. This session shares the main key facts for industry to adapt their practices and ensure compliance to the law.

Piotr Drobek,
Deputy Director of the Social Education and International Department,
GIODO, Poland

15:00 - 15:30

The Impact of the EU 2016/679 on Clinical Research

Understanding the modern meaning of personal data (new categories, definitions and main principles like privacy by design, privacy by default and limited purpose rule) and its application to clinical trials practice will be addressed. Specific details on:

- Data processing (processes & rights)
- Transfer of data outside the EU
- Pseudonymisation/anonymization of data
- The role and function of Data Protection Officers (DPO)
- Joint Controllers responsibility
- Right to data portability and the right to be forgotten

Karol Szczukiewicz,
Regional Study Manager,
Roche, Poland

15:30 - 16:00

Preparing to Implement ICH GCP E6 (R2)

Join our speaker to find out how the ICH GCP E6 (R2) will impact clinical trials in the CEE. Details on the requirements that are related to third party oversight, as well as collection and maintenance of source documents will be shared.

Ingrid Klingmann,
MD, PhD, Chairman,
The European Forum for Good Clinical Practice (EFGCP)

16:00 - 16:30

Coffee & Networking Break (with an opportunity for conversations and discussion)

Session 4: Case Studies. Case Studies Followed by a Discussion

16:30 - 17:00

Case Study 1: Delivering Clinical Trials for Medical Devices

Hear the details of the ISO141155 clinical investigation of medical devices and how this will affect medical device trials. Hear first-hand how other organisations have successfully implemented the directive to deliver trials for medical devices.

Ramón López,
Clinical Research Manager,
Thrombotargets Europe

17:00 - 17:30

Case Study 2: Successful Inspection Readiness: Preparation, Practice and Study Case

Regulatory inspectors are knocking at your door - are you ready? Listen to practical advice on how to be prepared for inspections at any time. Read the study case to gain insight into new perspectives on inspection readiness to improve your clinical operations for guaranteed success. Learn how to implement quality and compliance for inspection readiness of your trials.

Oleksii Mikheiev,
MD,
Verum.de GmbH, Germany

17:30 - 18:00

Discussion: Multi-Country and Multi-Site Trials

Representatives from the site, the sponsor and the CRO share their expertise on multi-site and multi-country trials.

- Delivering multinational trials
- Developing international cooperation for clinical trials
- Multi-site trial issues
- Management of multi-site trials
- How to effectively disseminate experience between sites

18:00 - 19:30

Cocktail & Networking Reception

For Speaker Opportunities Please Contact: Dr Tahira Rashid; Tel: +44 20 800 45 694 T.Rashid@adamsmithconferences.com

Day 2 - Wednesday 18 April 2018

08:30 - 08:55

Morning Coffee & Networking

08:55 - 09:00

Opening Address from the Chairperson

Session 5: Keynote Day 2

09:00 - 09:30

KEYNOTE: Patients at the Core of Trials

Tamás Bereczky,
European Patients' Academy for Therapeutic Innovation (EUPATI), EUPATI Germany

All successful trials have one thing in common; engaged patients that endure the trial distance. It's no surprise then that a more actively involved patient population is essential to the success of any clinical trial. Challenges faced by trial centers such as raising awareness of trials in remote communities and how to involve the patient are addressed in this keynote session.

- Patient advocacy programmes
- Expert patients
- The future of patient involvement

Session 6: Patient Recruitment Strategies and Electronic Solutions

09:30 - 09:45

Practical Patient Recruitment Strategies Revealed

Horea Borogan,
Country Manager,
Synexus Romania, Romania

Recruitment challenges arise at the feasibility stage, prior to and during the screening process of a trial. Ensure you meet your recruitment targets by applying practical recruitment strategies gained from attending this presentation.

- Selecting the right investigators
- Critical factors for recruitment success
- Risk mitigation and fall back strategies
- The complete toolbox revealed

09:45 - 10:00

Electronic Solutions for Slow Recruitment in Clinical Trials

Technology advances in clinical trials allow us to record, report, gain consent and tabulate information electronically. Join this session to hear about technology that helps with the challenges related to recruitment and retention of participants in trials.

Invited Speaker: Przemyslaw Brzeski, Global Clinical Operations Director of Poland, Janssen, Pharmaceutical Companies of Johnson and Johnson, Poland

10:00 - 10:20

Spotlight Presentation: Experiences Using Real-Time EHR Based Patient Search/Identification to Accelerate Trials

Barış Erdoğan,
PhD, Head of EEMEA Region,
Clinerion Ltd.

Technology advances in clinical trials allow us to record, report, gain consent and tabulate information electronically. Join Dr Erdoğan to hear about technology that helps with the challenges related to recruitment and retention of participants in trials.

10:20 - 10:50

Coffee & Networking Break (with an opportunity for conversations and discussion)

Session 7: EVENT FEATURE: Putting Participants First. Presentations Followed by a Discussion

10:50 - 11:15

The Key to Patient Retention – A UK Perspective

The key to good patient retention is meaningful patient involvement

from the outset of a clinical trial. Gain first-hand experience of best practice working with patient groups in this unique joint presentation. The perspective of parents of young patients involved in trials will be shared alongside best practice in patient retention from the UK model.

- A route to good retention
- UK experiences of meaningful patient involvement and engagement
- Sharing best practice - GenerationR Young Person's Advisory Group (YPAG); European Young Person's Advisory Group Network (eYPAGnet); Patient Research Ambassadors
- Case Study: A young person and parents perspective

JOINT SPEAKER AND PATIENT PRESENTATION:

- Jennifer Preston, Patient and Public Involvement Priority Lead, NIHR Clinical Research Network, UK
- Sammy Ainsworth, Parent and Patient Research Ambassador, UK

Jennifer Preston,
Patient and Public Involvement Priority Lead,
NIHR Clinical Research Network, UK

Sammy Ainsworth,
Parent and Patient Research Ambassador, UK,

11:15 - 11:40

Case Study 3: Optimising Clinical Trials Design for Paediatrics

Paediatric trials are more challenging to conduct due to the uniqueness of the participants and the ethical concerns related to minors. Learn from this real-life case study on how to optimise your clinical trials for child populations from the experts.

Dr Filip Rybakowski,
Head of Child and Adolescent Psychiatry Department,
Institute of Psychiatry and Neurology (Poland)

11:40 - 12:00

Discussion: Putting Participants First

Patient issues are the top priority for those responsible for a trial. Hear experts the speakers discuss how they effectively manage challenges to deliver successful trials.

- Patient-centricity and using patient-centric approaches
- The real patient experience: what are their thoughts and fears?
- Discussing solutions and barriers to consent for trials
- Recruitment feasibility failures and feedback opportunities
- Managing recruitment expectations with CROs/Sponsors

12:00 - 13:30

Lunch and Networking

Session 8: Sponsors Outlook

13:30 - 13:50

Optimising Clinical Performance by Investing in CRO Relationships

Building relationships to deliver results on time and within budget still remain a challenge for many pharmaceutical companies. Focused efforts by YURiA-Pharma to intentionally improve relationships with sites for mutual benefit with be detailed in this presentation.

Iryna Berchak,
Head of the Department of Preclinical & Clinical Trials,
YURiA-Pharma LLC, Ukraine

13:50 - 14:10

Critical Elements of a Sponsor Oversight Plan

Sponsors that partner with CROs for the delivery of a clinical trial are responsible for many aspects of the study included in the sponsor oversight plan. Listen to the perspective of the sponsor that oversees outsourced studies and hear how good sponsor oversight can reduce cost and increase data quality of trials.

Fabio Miceli,
Associate Director, Country and Clinical Quality,
Norgine, The Netherlands

14:10 - 14:35

Techniques to Identify Producing Sites

Some countries are well known for their successful trial delivery and are consequently in high demand from multinational sponsors. Discover the factors used by sponsors in country selection and the techniques used to identify producing sites for clinical trials.

Dr Rosalida Leone, Clinical Development Manager - Operational Study Leader, GSK, UK

14:35 - 15:00

Discussion: Lessons from the Sponsors

- How are CROs performing against the quality agreement?
- Is the oversight plan working and what would you do differently next time?
- What major issues need to be addressed and when?
- What are the most effective ways of resolving issues whilst maintaining good relationships?

15:00 - 15:30

Coffee & Networking Break (with an opportunity for conversations and discussion)

Session 9: Cost and Financial Planning for Clinical Trials. Presentations Followed by a Discussion

15:30 - 16:00

Case Study 4: Effective Budget Negotiations for Clinical Trials

Negotiating clinical trial budgets is often a lengthy process between the institution and sponsor/CRO. Consequently, this process can greatly delay study start-up. Join our speaker to gain valuable insights into more effective and efficient budget negotiations when working in the CEE.

Michaela Vančová,
Clinical Operations Director,
Slovak Research Centre, Slovakia

16:00 - 16:30

Case Study 5: Cost and Financial Planning for Trials

There are numerous clinical trials initiated and run in North America. A number of these trials include participants from the CEE. Join us to hear about costing and financial planning for clinical trials prepared at BC Children's Hospital in Canada which is a university hospital with a long track record of delivering clinical trials. Find out how you can implement their experience in your own centres.

Vesna Popovska,
Director Research, Pediatric Neurology & Neurosurgery,
UBC Adult Neurosurgery, Canada

16:30 - 17:00

Discussion: Payment Challenges in Clinical Trials

This unique session shares the views and expectations of each stakeholder including sites, CROs and Sponsors. Issues that will be discussed include:

- Process cycle time reduction
- Support for visit and procedure-based negotiations and payments
- Planning payment management

Rostislava Dimitrova,
MD, CEO & Projects Manager,
Inno Smart Clinical Ltd, Bulgaria

17:00 - 17:10

Close of the Forum

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