Clinical Trials in Central & Eastern Europe

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

PHARMA ASI
CLINICAL TRIALS
CENTRAL & EASTERN EUROPE

Day 1 - Tuesday 25 April 2017

08:30 - 09:30

Registration and morning coffee

09:30 - 09:35

Welcome by the organiser

09:35 - 10:05

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?

Title: Latest geographic trends in industry clinical trials - are emerging markets losing their allure?

Vladimir Misik,
Founder & Managing Partner,
LongTaal

10:05 - 11:35

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.

Csilla Pozsgay,
Director General,
National Institute of Pharmacy and Nutrition (Hungary)

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

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

11:35 - 12:05

Coffee and networking

12:05 - 13:20

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.

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

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

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

13:20 - 13:50

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

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

13:50 - 14:50

Lunch

14:50 - 15:50

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.

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

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

15:50 - 16:20

Coffee and networking

16:20 - 18:00

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?

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 (Poland)

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

18:00 - 19:55

Evening reception & networking

Day 2 - Wednesday 26 April 2017

09:00 - 09:30

Registration and morning coffee

09:30 - 10:50

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).

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

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?

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

10:50 - 11:20

Coffee and networking

11:20 - 12:50

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
- Case-study by Patient Organisation

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

Ramón López,
Clinical Research Manager,
Thrombotargets Europe

Rahul Chaudhary,
Director Business Development - Histopathology, ,
Synevo Division

12:50 - 13:50

Lunch

13:50 - 15:15

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.

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

15:15 - 15:35

Coffee and networking

15:35 - 18:35

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 'generalizable')
- 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)

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

18:35 - 18:40

Close of the Forum