

CDDF Multi-Stakeholder Workshop

Clinical Research in Central and Eastern Europe

New Approaches for the Next Level of Development

15-16 April 2024

Krakow, Poland

Event Outline

- This workshop focusses on the fast-developing clinical trial landscape in Central and Eastern Europe (CEE), by bringing key stakeholders and international experts from regulatory agencies, state research organisations, pharmaceutical industry, academia, and patient advocacy organisations together for open discussions of the current state of play, important challenges and collaborative next steps to enhance innovation in the region.
- The CEE region in the European Union is delivering strongly increasing numbers of clinical trials, driving the development of clinical research hubs by multinational pharmaceutical companies, and – most remarkably – empowering a growing regional pharmaceutical industry.
- The war in Ukraine has severely disrupted cancer care and clinical trials in the country/region. Other countries in the region, esp. Poland, have stepped up to care for Ukrainian patients. The global impact of this crisis has brought support from international organisations. We will discuss how best to support ongoing cancer care and clinical research in the region, given these challenges.
- Another key aspect of the workshop is to foster collaboration between key stakeholders to address some of the challenges that are particular to the region.
- One of the especially important topics is patient access to innovative drugs, including cross-border access to clinical trials.
- The workshop will involve engaging lectures, intensive discussions with the in-room and online audience, as well as Q&A sessions with panels of experts. It aims to create enduring connections to support the further development of clinical trials in the region.
- A White paper from the Workshop will provide key recommendations on the direction of travel and how best to boost clinical research and clinical trials and enhance patient care in the region

Learning objectives

- Enhance innovation and foster collaboration between key stakeholders in Central and Eastern Europe.
- Ensure the adequate support in ongoing cancer care and clinical research in the region, considering the political context.
- Ensure patient access to innovative drugs, including the cross-border access to clinical trials.

Programme committee

- Committee chairs: Axel Glasmacher (CDDF, DE); Mark Lawler (CDDF,UK)
- Pawel Przewiezlikowski (Ryvu, PO)
- Birgit Wolf (Bayer, DE),
- Hendrik Nogai (Ryvu, PO)
- Susan Bhatti (Merck Healthcare, NL)
- Ewa Mark-Pawłowicz (Astrazeneca, PL)

Meeting Secretariat

Caroline Marissal (CDDF Event Coordinator), caroline@cddf.org; info@cddf.org

Draft Agenda

Day 1 - 15 April 2024

<https://pubmed.ncbi.nlm.nih.gov/36812845/> - paper on the impact of the war in Ukraine that we have just published - potential topic for workshop (or webinar)

Session 1: Current Status of Clinical Trials in CEE

15-minute lectures + 5-minute Q&A

Session chairs: Mark Lawler & Axel Glasmacher

Key points:

- Comparability of therapeutic standards in CEE vs rest of Europe
- Consequences of the war in Ukraine
- Cultural factors (e.g., attitudes to vaccination)
- Capacity for clinical trials
- Opportunities, challenges and hurdles

12:00-13:00 Lunch

13:00-13:10 Introduction

Programme chair

13:10-13:30 Keynote lecture (global perspective)

Richard Pazdur (FDA, US)

13:30-13:50 Patient Perspective

Joanna Frątczak-Kazana (Ailvia, PL)

13:50-14:10 Impact of Ukraine conflict on clinical trials in CEE

Mark Lawler (CDDF, UK)

14:10-14:30 Global industry perspective

Wiktor Janicki (AZ, PL)

14:30-15:10 Panel Discussion

15:10-15:40 Coffee Break

Session 2: Improving Clinical Trials in CEE

15-minute lectures + 5-minute Q&A

Session chairs:

Key points:

Each stakeholder to describe what is needed to improve cancer clinical research for the benefit of current/future patients and oncology drug development. What should the future look like? What is needed to achieve this?

15:40-15:45 Session opening

15:45-16:05 Introductory talk that addresses the areas that should be improved (investigator perspective)

Prof. Ewa Kalinka (Institute of Polish Mother's Health Center, PL)

- Access to personalized diagnostics
- Access to supportive therapy

- Reduction of bureaucratic hurdles, incl. patient access

16:05-16:25	Regulatory Initiatives (Medical Research Agency) Dr Radoslaw Sierpinski (Medical Research Agency, PL)
16:25-16:45	Regulatory Initiatives Keiu Heinla (Estonian State Agency of Medicines, EE)
16:45-17:05	Other country perspective Radek Spisek (SOTIO, CZ)
17:05-17:35	Coffee Break
17:35-18:15	Panel Discussion
19:00-21:00	Onsite Dinner

Day 2 - 16 April 2024

08:30-08:40	Summary of Day 1 Program Committee Chairs
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Session 3: Innovative Concepts in CEE

15-minute lectures + 5-minute Q&A

Session chairs: Birgit Wolf (Bayer, DE)

Key points: Look at industry, academic, patient advocacy and regulatory initiatives (established or planned) across the region. Discuss patient access to innovative drugs pre- and post-EU approval

08:40-09:00	How to build a sustainable biotech hub in an emerging economy - Poland as the new source of biomedical innovation Pawel Przewiezlikowski (Ryvü, PO)
09:00-09:20	Facilitating innovative trial designs in CEE countries
09:20-09:40	Patient access to innovative drugs in oncology Teodora Kolarova (International Neuroendocrine Cancer Alliance (INCA), US)
09:40-10:00	Cross-border access to clinical trials Susan Bhatti (Merck Healthcare, NL)
10:00-10:20	ACT EU (Accelerating Clinical Trials in the EU)
10:20-10:40	Academic perspective Piotr Rutkowski (Maria Skłodowska-Curie Memorial Cancer Center, PL)
10:40-11:10	Panel Discussion
11:10-11:40	Coffee Break

Session 4: Roundtable to Formulate Consensus for Next Steps

Session chairs: Axel Glasmacher and Mark Lawler (CDDF)

Key points:

Formulate consensus points that can be published in a meeting white paper and implemented in local practice in a reasonable time frame.

11:40-12:25 Panel Discussion

12:25-12:30 Farewell Message

12:30-13:00 Packed lunch and departure