CDDF
Cancer Drug Development Forum
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MULTI-STAKEHOLDER WORKSHOP

Clinical Research in Central and Eastern Europe
New Approaches for the Next Level of Development

15-16 April 2024
Krakow, Poland
Hybrid Workshop

www.cddf.org

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

- Programme chair's: Axel Glasmacher (CDDF, DE) & Mark Lawler (CDDF, UK)
- Pawel Przewiezlikowski (Ryvu, PL)
- Birgit Wolf (Bayer, DE)
- Hendrik Nogai (Ryvu, PL)
- Susan Bhatti (Merck Healthcare, NL)
- Ewa Mark-Pawłowicz (Astrazeneca, PL)

TARGET AUDIENCE

The target is a multidisciplinary audience of academia representatives, EU and US regulatory bodies (EMA, FDA, National Agencies), pharmaceutical Industry, HTAs and patient advocates.

WORKSHOP VENUE

AC Hotel by Marriott
al. 3 Maja 51, 30-062 Kraków, Poland.

HYBRID WORKSHOP

The workshop will be held in Krakow, Poland. However, participation online via the Brella event platform will also be possible. Only approved participants will receive the link and log-in details to access the virtual platform.

CONTACT

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PROGRAMME

Day 1 : Monday 15 April 2024

SESSION 1: CURRENT STATUS OF CLINICAL TRIALS IN CEE

Chairs: Prof. Mark Lawler (CDDF, UK); Prof. Axel Glasmacher (CDDF, DE)

12:00 - 12:50	Lunch
12:50 - 13:00	Welcome note
13:00 - 13:10	Introduction
13:10 - 13:40	Conversation on Cancer: Accelerating Oncology Drug Development through Innovation with Dr Richard Pazdur (FDA, US) & Prof. Grzegorz S. Nowakowski (Mayo Clinic, US)
13:40 - 13:50	Patients in Poland – building the bridge between old and new Joanna Frątczak-Kazana (Alivia, PL)
13:50 - 14:00	Impact of Ukraine conflict on clinical trials in CEE Prof. Mark Lawler (CDDF, UK)
14:00- 14:40	Panel discussion
14:40 - 15:10	Coffee Break

SESSION 2: IMPROVING CLINICAL TRIALS IN CEE

Chairs: Dr Susan Bhatti (Merck Healthcare, NL); Lidia Zielinska (MPNE, PL)

15:10 - 15:15	Session opening
15:15 - 15:25	Ongoing challenges from the site's perspective Prof. Ewa Kalinka (Institute of Polish Mother's Health Center, PL)
15:25 - 15:35	Initiatives to improve clinical trials in Poland Dr Karolina Nowak (Medical Research Agency, PL)
15:35 - 15:45	Regulatory Initiatives - National and European Aspects Dr Keiu Heinla (Estonian State Agency of Medicines, EE)
15:45 - 16:15	Panel discussion Guest panelist: Ewa Mark-Pawłowicz (AstraZeneca, PL)
16:15 - 16:45	Coffee break

SESSION 3: CLINICAL TRIALS IN CEE - INDUSTRY PERSPECTIVE

Chairs: Dr Richard Pazdur (FDA, US); Prof. Axel Glasmacher (CDDF, DE)

16:45 - 16:50	Session opening
16:50 - 17:00	Global industry perspective Wiktor Janicki (AZ, PL)
17:00 - 17:10	Pharmaceutical innovation in CEE with the focus on clinical trials Dr Radek Špíšek (SOTIO, CZ)
17:10 - 17:20	How to build a sustainable biotech hub in an emerging economy - Poland as the new source of biomedical innovation Pawel Przewięźlikowski (Ryvu, PL)

17:20 - 18:05	Panel discussion Guest panelists: Dr Chitkala Kalidas (Bayer, US) Dr Laura Huggins (Merck Healthcare, CH) Alexander Hope (Daiichi Sankyo, UK)
19:30 - 21:30	Onsite Dinner Guest speaker: Agnes Saint-Raymond, (Former EMA Head of International Affairs Division, FR)

Day 2 : Tuesday 16 April 2024

SESSION 4: INNOVATIVE CONCEPTS IN CEE

Chairs: Dr Birgit Wolf (Bayer, DE); Teodora Kolarova (International Neuroendocrine Cancer Alliance (INCA, BG)

08:30 - 08:35	Session opening
08:35 - 08:45	Clinical trials in CEE - opportunities and challenges - Poland as example Dr Piotr Rutkowski (President of the Polish Society of Oncology, PL)
08:45 - 08:55	Accelerating global clinical trials conduct: access, decentralization and technology Dr Grzegorz S. Nowakowski (Mayo Clinic, US)
08:55 - 09:05	Facilitating innovation in clinical trials Olga Kholmanskikh (FAMHP, BE)
09:05 - 09:15	Patient access to innovative drugs in oncology - Bulgarian Perspective Teodora Kolarova (International Neuroendocrine Cancer Alliance (INCA, BG)
09:15- 09:25	Cross-border access to clinical trial Dr Susan Bhatti (Merck Healthcare, NL)

09:25 - 10:00	Panel Discussion
10:00 - 10:30	Coffee Break

SESSION 5: CLINICAL TRIALS IN EUROPE - REGULATORY PERSPECTIVE

Chairs: Francesco Pignatti (EMA, NL) and Dr Richard Pazdur (FDA, US)

10:30- 11:30	Panel Discussion: Olga Kholmanskikh ((FAMHP, BE) Peter Šišovský (SUKL, SK) Eva Hrušková Reinová (SUKL, CZ) Dr Keiu Heinla (Estonian Stage Agency of Medicines, EE)

SESSION 6: ROUNDTABLE TO FORMULATE CONSENSUS FOR NEXT STEPS

Chairs: Prof. Axel Glasmacher (CDDF, DE); Prof. Mark Lawler (CDDF, UK)

11:30 - 12:15	Panel Discussion: Dr Piotr Rutkowski (President of the Polish Society of Oncology, PL) Paweł Przewięźlikowski (Ryvu, PL) Dr Richard Pazdur (FDA, US) Laura Huggins (Merck Healthcare, CH) Lidia Zielinska (MPNE, PL)
12:15 - 12:30	Farewell message
12:30 - 13:00	Sandwich lunch and departure