CDDF
Cancer Drug Development Forum

CDDF Multi-Stakeholder Workshop

CLINICAL RESEARCH IN CENTRAL AND EASTERN EUROPE: NEW APPROACHES FOR THE NEXT LEVEL OF DEVELOPMENT

EXECUTIVE SUMMARY

15-16 APRIL 2024
KRAKOW (PL)

CDDF Multi-Stakeholder Workshop

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

15-16 April 2024 , Krakow (PL)

Cancer Drug Development Forum (CDDF) Multi-Stakeholder Workshops are neutral, non-competitive meetings that address topical issues and recent innovations in oncology drug development with the aim of improving cancer treatment. The workshops facilitate multi-stakeholder discussion and collaboration, bringing together leading voices from academia, the healthcare industry, regulatory authorities, and patient advocacy groups.

The workshop on "Clinical Research in Central and Eastern Europe" took place on 15-16 April 2024 in Krakow (PL). It focused on the **rapidly evolving clinical trial landscape in Central Eastern Europe** (CEE) and discussed the **current state of play**, **challenges** and **collaborative next steps** to enhance innovation in the region. A multi-stakeholder group of experts provided insights on important topics such as patient access to innovative oncology drugs and cross-border access to clinical trials. Through in-depth discussions, attendees explored the future direction of clinical research in CEE and discussed how best to enhance patient care in the area.

This interactive meeting generated fruitful dialogue and the following take-home messages that emphasize collaborative efforts among all stakeholders:

SESSION 1: CURRENT STATUS OF CLINICAL TRIALS IN CEE

KEY TAKEAWAYS

- Global perspective of clinical trials: how the **worldwide recruitment** related to efforts to make trials more representative, particularly in Central and Eastern Europe.
- **Russian Invasion in Ukraine** led to major disruption of the well-developed cancer care research ecosystem. Poland Stepped up massively to address the challenges.
- **Patients in Poland** do not have sufficient access to adequate information about clinical trials that they may be able to participate in.
- **Patients treated in research active hospitals** have better outcomes than those who are not – cancer research is a necessity, not a luxury.

NEXT STEPS

- Use more **online tools** to make trials more accessible to patients.
- Reflect and discuss **early site selection** and **patient recruitment** with regulatory agencies.
- **Identify opportunities** to be innovative in the development of novel drugs and the delivery of cancer clinical trials in the region.

SESSION 2: IMPROVING CLINICAL TRIALS IN CEE

KEY TAKEAWAYS

- **Trials need to be simplified to make them more feasible for site staff and investigators**. There needs to be more dialogue between sponsors and site investigators and administrative tasks should be reduced. Also the regulatory requirements from the Agencies (worldwide) need to be kept limited to those that are essential for the approval of the drug – not more and more added on. We need more communication tools with all stakeholders to provide cooperation, facilitate documentation and better manage the tasks in clinical trials.

- **Patients and physicians need to be able to find information on clinical trials in up-to-date databases.** This is currently very difficult for patients in CEE countries as the databases are difficult to search and many physicians are not aware of the options that clinical trials can offer their patients. More education on clinical trials is needed and patient organizations should be involved in these efforts to create a trusted clinical research ecosystem.

SESSION 2: IMPROVING CLINICAL TRIALS IN CEE

KEY TAKEAWAYS

- **The Polish Medicines Agency** is leading the way by **setting up public private partnerships** with academic sites and industry to foster clinical trials. Also the **creation of a network of clinical research sites** will be very helpful to share experience and encourage collaboration and best practices between investigators, the Agency and trial sponsors.

- **The Estonian Agency** have **embraced the new Clinical Trial Regulation** and have **adapted their processes** and **provided extensive training** to enable the legislation to work for assessors and the new Ethics Committee. They are also going to integrate **Medical Device assessment** into the process – this is an important aspect. From March 2024 the Agency is also offering **scientific advice to sponsors** for several therapeutic areas. **ACT-EU** offers an opportunity to facilitate clinical trials in Europe, and **MedEthicsEU** will help to harmonize the part 2 requirements for the Ethics Committees and ensure a smoother overall approval of trials in Europe.

SESSION 3: CLINICAL TRIALS IN CEE - INDUSTRY PERSPECTIVE

KEY TAKEAWAYS

- **Strong educational infrastructure** and **motivated talents** foster the development of clinical trials and pharmaceutical industry in the CEE region.
- To establish leadership and career development of investigators, the establishment of **early stage clinical development** is necessary.
- **Efficient start-up procedures** and **national support programs** for clinical sites are very helpful to include also smaller countries from the region in clinical trials.
- **Research and Development hubs** from the pharmaceutical industry in the region have been proven to accelerate the contribution to clinical trials and the development of specialised structures at the sites.

SESSION 4: INNOVATIVE CONCEPTS IN CEE

KEY TAKEAWAYS

- **Adequate funding** and **resources** including people are a key measure to foster innovative cancer research in the region (i.e. Medical Reseaerch Agency, Poland).
- While access to clinical trials improves the trials themselves, **access is still far from optimal**.
- Lack of robust Information about availability of trials and trial complexity is a major challenge.
- **Regulatory initiatives** support and foster **patient-centered approach** (DCT, local labs), emerging technologies/ methodologies should be applied when feasible.
- All patients are entitled to **equal access to the drugs** with high clinical value in a timely manner.
- Very **variable experience** with accessing **cross-border clinical trials** in EU/CEE.

SESSION 4: INNOVATIVE CONCEPTS IN CEE

NEXT STEPS

- Move towards a **decentralized model** of delivering care and conducting clinical trials.
- **Increase efficiency** avoiding unnecessary duplication or repetition of unsuccessful trials.
- **Introduce patient-centered approach** to methodologies, i.e. involve patients/representatives in the assessment process.
- Explore the potential role of **adaptive pathways** and **joint HTA–EMA procedures** in assuring timely and equal patient access to oncology medicines in the European Union.
- Lower the barrier by **ensuring transparency** in cross-border clinical trials process to facilitate access.
- **Multi-stakeholder collaboration** (e.g. ACT.EU, EU-X-CT) and sharing learning across CEE (from PL as example) will be key to advance innovative concepts and improve patient access.

SESSION 5: CLINICAL TRIALS IN EUROPE - REGULATORY PERSPECTIVE

KEY TAKEAWAYS

- Requirements of the **Clinical Trial Regulation** are new:
  - Implementation may differ: There is a need to co-ordinate and share experience to strive for alignment between EU Member States.

- Opportunities to develop **common guidance on clinical trial methodology** by the European Medicines Regulatory Network to help navigate among the different legal frameworks (e.g., Pharmaceutical Legislation; Medical Devices): Multi-stakeholder approaches.

- Need to maintain focus on **improving patient centricity**, in terms of consultation, participation, and information: Sharing experience and measuring effectiveness are paramount.

- Need to strive to **reduce the bureaucratic burden**, including to support academic trials for questions that go beyond drug approval.

SESSION 5: CLINICAL TRIALS IN EUROPE - REGULATORY PERSPECTIVE

NEXT STEPS

- Identify opportunities for **multi-stakeholder** and **international collaboration**, sharing of experience; **joint training** in collaboration with learned societies.

- Discuss further **workshops to support guidance development** on clinical trial methodology to facilitate the implementation of innovative approaches.

- **Follow-up activities** through the **Accelerating Clinical Trials in the EU** (ACT EU) initiative: ACT EU workplan for 2023-2026 published - European Union (europa.eu).

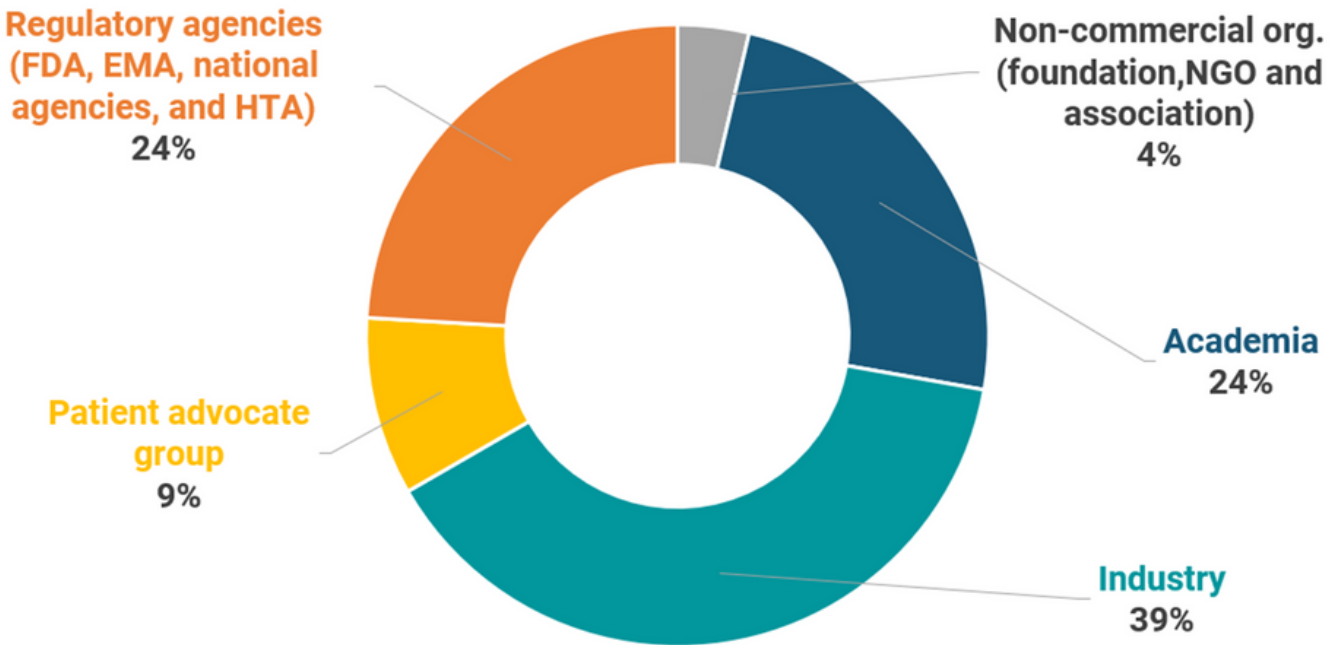
Meeting recordings and presentation slides are available to CDDF Members, regulators, patients and academics via the CDDF intranet platform (https://cddf.org/member-access/)

Collaboration and open dialogue among **all stakeholders** is **key** to accelerating and improving oncology drug development for patients

AUDIENCE AT THE CDDF WORKSHOP

The CDDF's meetings present **a wide range of prespectives** from **various stakeholders** who are involved in the development of oncology drugs. Our **multi-stakeholder, collaborative approach** facilitates a productive dialogue in a neutral, non-competitive space in order to **accelerate effective cancer drug development.**

Onsite Participants & Speakers



The graph illustrates the distribution of online and onsite speakers/chairpersons/panelists alongside onsite attendees.

58
IN-PERSON ATTENDEES

50
ONLINE ATTENDEES

WHAT PARTICIPANTS SAY ABOUT CDDF'S DISCUSSION?

"What I appreciate most is the number of different kinds of stakeholders attending the workshop and the huge expertise of people there. It was amazing to have Richard Pazdur from FDA, Francesco Pignatti from EMA, as well as regulators from Eastern European countries providing their insights and initiatives. It was absolutely fabulous."

Dr. Susan Bhatti
Merck Healthcare, NL

"I am very glad that CDDF focused on Central and Eastern Europe. We feel like we are a small part in Europe in a way because of the number of clinical trials and patients' access to treatment. The workshop was great especially for patients because regulators and industry seems to focus also on this region. It gives us hope that our position in the world map will improve."

Prof. Edward Laane
Estonia State Agency of Medicines, EE

"I liked interactions between people, investigators and patients, looking at how clinical care and trials are done in Eastern Europe, particularly here in Poland. It was really an eye-opening discussion with challenges and successes that we have seen in Eastern Europe, incorporating clinical trials into these countries."

Dr. Richard Pazdur
FDA, US

"CDDF is a unique experience for me because it brought together different stakeholders, not only regulators and sponsors, but also researchers and patient advocacy groups. This is important because we are looking at cancer drug development from various perspectives. We now see lots of heterogeneity and diversity with access to trials."

Prof. Piotr Rutkowski
Polish Oncological Society,
National Research Institute of Oncology, PL

The views expressed in this page are the personal views of the participants and may not be understood as being made on behalf of or reflecting the position of the regulatory agency/agencies or organisations with which the participants are employed/affiliated.

CDDF'S UPCOMING MEETINGS & DISCUSSION

MULTI-STAKEHOLDER MEETINGS

Focus of Discussion

1. **Challenges, Collaboration & Needs**
2. **Innovative Trial Designs**
3. **Innovative Solutions to Improve Access**
4. **Wrap-up & Next Steps**

Programme | Registration

CDDF-ESMO JOINT SESSION

Focus of Discussion

1. **Specifics of CHMP Assessment of Cancer Drugs**
   Aaron E. Sosa Mejia (Danish Medicines Agency)
2. **Current Status and Implications of the In Vitro Diagnostics Regulation (IVDR)**
   Audrey Wolf (EFPIA)
3. **Initiatives for a Joint EU HTA Assessment**
   Marcus Guardian (Dierks+Company)
4. **Q&A and Discussion**

Programme | Registration

CDDF'S UPCOMING MEETINGS & DISCUSSION

CDDF LIVE WEBINARS

Webinar Outline | Registration

Webinar Outline | Registration

CDDF BREAKS DOWN SILOS IN THE ONCOLOGY COMMUNITY AND FACILIATES OPEN, MEANINGFUL DIALOGUE AMONG ALL STAKEHOLDERS

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ACKNOWLEDGEMENTS

We thank all our program committee members, speakers, panelists, Industry members, and participants for their invaluable inputs and engagement.

Cancer Drug Development Forum (CDDF)

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