

CDDF Multi-Stakeholder Workshop

ENABLING SMARTER CLINICAL TRIALS
TO OPTIMISE PATIENT CARE



EXECUTIVE SUMMARY

17-18 NOVEMBER 2025
HYBRID, BRUSSELS (BE)



CDDF Multi-Stakeholder Workshop

Enabling smarter clinical trials to optimise patient care

17-18 November 2025 , Brussels (BE)

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 CDDF workshop on **“Enabling Smarter Clinical Trials to Optimise Patient Care”** took place on 17-18 November 2025 in Brussels (BE). The meeting addressed **how best to deploy smarter cancer clinical trials and use Real World Evidence (RWE) studies** in order to deliver innovation and achieve better outcomes for cancer patients. It brought together key leaders in this rapidly developing field from a **scientific, clinical, patient and regulatory affairs perspective**. A key emphasis of the entire workshop was “What Really Matters” implementing proportionate, risk based approaches in trial design and conduct. Speakers presented some of the latest studies, combined with current and future thinking about how best to define and deploy the latest evidence to ensure that it becomes an integral part of how we drive innovation forward.

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



SESSION 1: CLINICAL TRIALS AND REAL WORLD EVIDENCE: WHAT REALLY MATTERS



KEY CHALLENGES IDENTIFIED

- **Need for proportionality and harmonisation, and more patient centricity. Over-complex and uneven clinical trial implementation:** trials remain administratively heavy and inconsistently proportionate across member states, limiting participation; successful national models shared during the session show advances are possible but not yet harmonised.
- **Data quality challenges. Variable quality and fitness-for-purpose of real-world data:** Oncology RWD often lacks essential variables and consistent mapping, reducing confidence in their use for regulatory and HTA decisions.
- **Cancer medicine shortages: fragmented evidence for shortages and critical medicines:** The EU remains vulnerable due to external manufacturing dependence and a lack of integrated data, while China benefits from vertically integrated, strategically supported production.
- **Misalignment of expectations concerning cancer medicines across stakeholders:** regulators, HTA bodies, clinicians, industry and patients lack a shared standard on when RWE or pragmatic trials are sufficient, slowing adoption of more efficient, patient-centred evidence approaches.





SESSION 1: CLINICAL TRIALS AND REAL WORLD EVIDENCE: WHAT REALLY MATTERS



NEXT STEPS

- **Co-develop guidance on proportionate, patient-centred trial design:** CDDF can convene a multi-stakeholder group to produce practical, oncology-focused guidance on risk-based, decentralised and pragmatic trial elements.
- **Invest in oncology-ready RWE infrastructure and methods for data collection that is fit per purpose:** efforts such as DARWIN EU and ONCONET should be expanded to improve and incentivise data completeness and run pilots where RWE is assessed alongside clinical trial evidence.
- **Build an EU collaborative, competitiveness and resilience framework for critical medicines:** Governments should invest in onshoring and diversifying manufacturing while creating an integrated early-warning system combining supply, regulatory and real-world utilisation data.
- **Create a shared learning agenda on RWE acceptability and impact, including among patients:** CDDF can lead iterative pilots and workshops to define clear criteria for RWE use and produce consensus principles on what constitutes decision-ready evidence.

SESSION 2: USE OF PRAGMATIC ELEMENTS IN CLINICAL TRIALS



KEY TAKEAWAYS

- From a **patient perspective**, it was emphasized that treatments and trials should be **pragmatic from all perspectives**.
 - One of the issues of the traditional randomised trials is that patients can be randomised to a potentially inferior drug, and patients with complex cases (e.g. those with brain metastases) are often excluded.
 - "Don't punish patients if they under-report side effects because they want to stay on the trials."
- From a **trial design perspective**, it was recommended to always **start from the scientific question/ intention** and **what the trial aims to achieve** (match trial design to trial intention).
- **Streamlined safety data collection (ICH E19)** should be considered based on the knowledge and trial population. **Registry based trials** can be used to incorporate pragmatic elements.



SESSION 2: USE OF PRAGMATIC ELEMENTS IN CLINICAL TRIALS



KEY TAKEAWAYS

- From a **regulatory perspective**, there is interest to explore use of pragmatic trials, and it is important that sponsors and regulators discuss such approaches proactively.
- From an **EFPIA perspective**, industry is interested in **building awareness, experience and confidence** in the concept of pragmatic trials through **case studies** and **co-designing trials** with all involved stakeholders, including patients and regulators.
 - Opportunities for such interactions include focus working groups and workshops.
 - For each pragmatic element, there is dimension of pragmatism and the available evidence and experience will inform the dimension of pragmatism.



SPECIAL DISCUSSION SESSION: WORLD CAFÉ



CDDF organized the first "World Café" session, which received very positive feedback from participants. The session featured four key questions around which the audience spontaneously divided themselves into four groups for discussion:

- **Q1:** How can we make the best use of real-world evidence and patient-reported outcomes in cancer clinical research and trials?
- **Q2:** How can the use of Artificial Intelligence and Digital/Data platforms in practice address clinical trial bottlenecks?
- **Q3:** How can we enhance multinational academic clinical trials through better alignment between regulatory authorities, researchers, and public health research priorities?
- **Q4:** How can clinical trial frameworks support patients with significant clinical burden from disease and/or therapy (including metastatic disease) and those who wish to continue working/caring for family or other life commitments during treatment?

The process involved each group rotating through the questions, dedicating approximately 15 minutes to discussion per topic. A CDDF representative moderated each discussion by capturing key points on a flipchart, ensuring the discussion content remained group-driven and collaborative. The detailed outcomes and findings will be disseminated in the coming months.





SESSION 3: DRIVING RESEARCH USING HEALTH DATA



KEY MESSAGES

- **A vision for Patient-Guided Clinical Evidence Generation** was presented: actions to harness patients' voices and real-world data (RWD) were described in order to guide clinical evidence generation and provide knowledge supporting decisions to improve therapeutic outcomes for all patients. See publication <https://pmc.ncbi.nlm.nih.gov/articles/PMC11924165/>. Processes for scientific advice and clinical trial application advice can be combined. Regulators and ethics committees in Europe are working on how to include patient input to clinical trial design and conduct.
- **Innovative Patient Data Collection Approaches:** patients presented advanced, innovative, patient-driven data collection methods using a number of apps for data collection from patients (in this case lymphoma patients in different disease sub-typers). Their uptake and use are expanding, and the potential for such data to be included in marketing authorisation or HTA dossiers and evaluation is significant, whether as stand-alone data collection or as part of clinical trials, registry data and their applications in oncology research. Use examples have already been achieved including in HTA. Their validation and uptake are expanding, and additional use cases for similar approaches can be envisioned. Qualification of such applications is an additional possibility.

SESSION 3: DRIVING RESEARCH USING HEALTH DATA



KEY MESSAGES

- **Industry Applications of Real-World Evidence (RWE):** Practical examples were provided of how the pharmaceutical industry is using RWE sources to design protocols. For instance, RWE is used by testing inclusion/exclusion criteria against data sets as part of clinical trial design to i) enhance the representativeness of the trial population, ii) underpin the feasibility of enrolment of the trial population and iii) design site selection and location criteria. Industry use of RWE, including RWE for external control leverage, supports clinical development and regulatory decisions. Whilst the experience described was mainly US-based, there is a need to enable such approaches also in Europe. Data sources included census data, disease, and health registries, EHR, and previous clinical trial databases.
- **Regulatory, Industry, and Patient Perspectives:** Perspectives from regulators, industry, and patients on health data use need to be aligned. To achieve this, there is a real need for all to work together as peers and partners throughout the drug development lifecycle both at policy and at specific drug development level.
- **Advancing Data-Driven Research and Therapeutic Innovation:** The Vision for 2030, the experience with DARWIN (session 1 also), ICH E19 (session 2), the progressing implementation of standard data models and the development of the European Health Data Space, which is legally mandated and will start to roll out over the coming years, all present significant potential.

SESSION 3: DRIVING RESEARCH USING HEALTH DATA

➤ TAKEAWAYS & NEXT STEPS

- **Patients are key players in clinical trial design and implementation.** We need to ensure that the input of all involved - patients, developers, regulators, researchers and healthcare professionals is constantly engaged in the design of clinical development programmes and the trials they incorporate.
- **Sponsors should reach out to regulators for discussion and scientific advice on clinical trials and development programmes** - this can have a real and beneficial impact on the value of the research in truly answering the key questions that need to be answered.
- **The opportunities provided by existing and newly available digital data sources need to be recognised, and the methodology to underpin their use need to be developed, validated and constantly evolved.** This is not only for collecting clinical trial data but to support trial design and enable use of RWE for external control arms, and new types of studies. This has been long practiced in pharmacovigilance but is increasingly being integrated into the study of benefit-risk, effectiveness and quality of life. These are all important features needed to support enhanced outcomes for patients and to empower them to make informed and beneficial choices about their healthcare.



SESSION 3: DRIVING RESEARCH USING HEALTH DATA

TAKEAWAYS & NEXT STEPS

- **The potential for patients to act themselves as originators and collectors of data that reflect their experience - as part of a clinical trial or use of a medicine in practice - holds new and important possibilities.** This can enhance knowledge about therapeutic options, feeding into marketing authorisation and HTA evaluation, and support post authorisation treatment optimisation to deliver the best options for patients, which include their own perspectives and data.
- **Data need to be used in order for their quality to be improved and usefulness demonstrated.** It is essential that those generating data and entering into EHRs, registries or other sources can benefit from use of that data in their medical practice, management of healthcare institutions and to support health policy and future directions in health case.
- **Data needs to be available for use and practical utility developed** for those funding data collection and curation, those carrying out the data collection and those who may benefit from its uses. It therefore needs to be available, without unreasonable barriers to use (whilst protecting patient privacy, data quality and the quality of the use and outputs) - for use by different parties with the range of management, patient care, research or public policy objectives they may have.
- **We all need to disseminate what we have heard and learned** in order for the potential of these innovative approaches, and the value of constant multistakeholder engagement, to be realised. The collective information sharing, discussion and new ideas from this multistakeholder workshop need to be disseminated into the communities and peer groups and organisations of all involved - patients, developers, researchers, regulators/HTAs/payers and healthcare professionals.



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



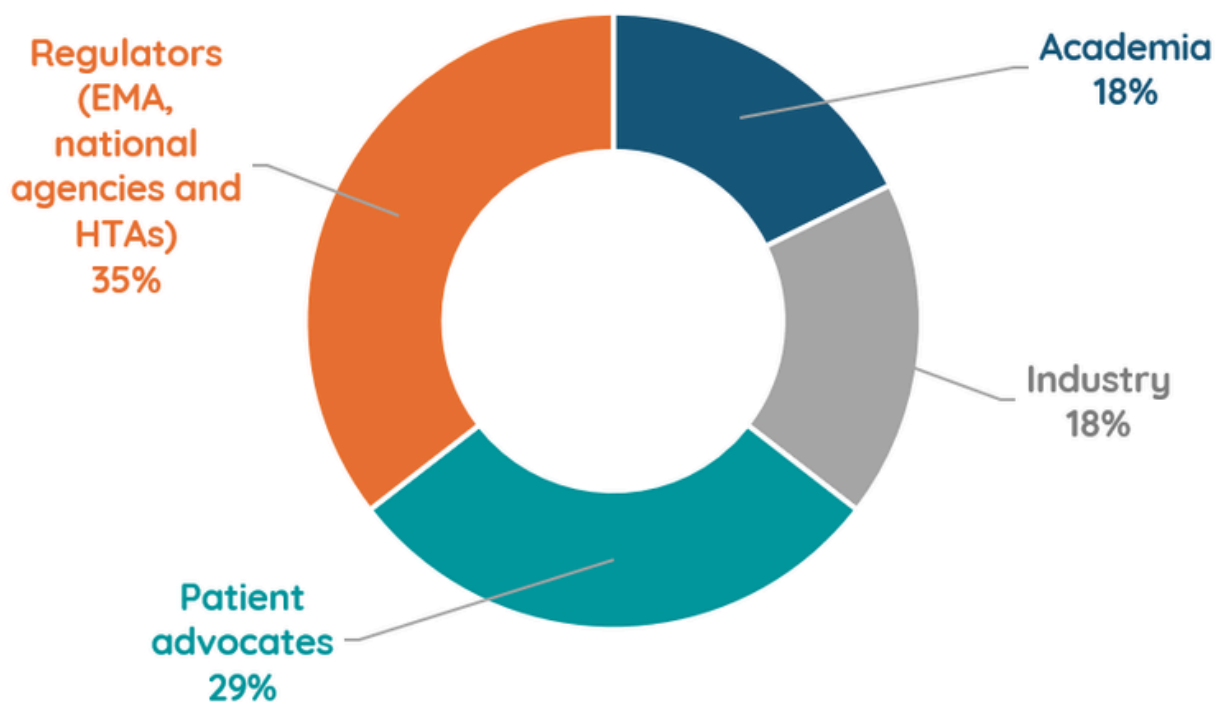


AUDIENCE AT THE CDDF WORKSHOP

The CDDF's meetings present a **wide range of perspectives** 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.

76

**IN-PERSON
ATTENDEES**

56

**ONLINE
ATTENDEES**



WHAT PARTICIPANTS SAY ABOUT CDDF'S DISCUSSION?

"I like the environment for an **open dialogue** over **critical issues** in anticancer medicines life cycle, aiming to tackle misalignments and ensuring **patient/participant centrality**. I found Session 1 extremely insightful and comprehensive, in terms of addressing the life cycle of medicinal products, from early development to shortages, and **multistakeholder involvement in discussions**. From clinical trials perspective, the presentation from the Spanish Agency emphasized deeper understanding of factors leading to successes and failures within European and global context."

Hugues Malonne
Federal Agency for Medicines and Health Products (AFMPS - FAGG), BE

"I like the audience, the **composition of the audience**. There are a lot of representations from patient advocacy groups and key regulatory agencies, which is extremely helpful and provides a lot of insight. And the discussion is very, very open."

Zhanna Jumadilova
Pfizer, US

"**Bringing all stakeholders**, including patients around the same table, is really a fantastic idea. I think it contributes a lot to the **mindset shift**, which is so important today. And the **hybrid format**, I love it a lot, as it allows everyone to take part of the talk and to raise his or her voice."

Béatrice Serck
Japan National Cancer Center, JP

"This workshop has been the opportunity to **share different opinions** between various stakeholders regarding clinical trials. It's very important that **the voice of the patients** is heard. Patients sometimes want to go beyond the safety and effectiveness of drugs. They want to have less side effects to have a better quality of life. I think that can be integrated and that can be very useful also for the sake of the clinical trials and a paradigm change in the idea of clinical trials in the European Union."

Francisco Rodriguez Lozano
Cancer Patients Europe, ES

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.

MULTI-STAKEHOLDER MEETINGS

Cancer Drug Development Forum (CDDF)

ANNUAL CONFERENCE 2026

Cancer Clinical Research in a Changing Global Environment

9-11 February 2026
Ghent, BE



[Programme](#)

[Registration](#)

Session Topics

- 1 What's hot in global clinical development?
- 2 Representativeness in global clinical trials
- 3 Patient relevant endpoints
- 4 The use of big data in oncology drug development
- 5 Diversity in clinical trials
- 6 Wrap-up and next steps



MULTI-STAKEHOLDER WORKSHOP

Clinical Development Plans: Global Development and Global Strategies

30 - 31 March 2026
Brussels, BE (hybrid)



[Programme](#)

[Registration](#)



The future of cancer therapy

CDDF & EORTC JOINT WORKSHOP

Health Technology Assessment in Cancer Drug Development

5 - 6 October 2026
Brussels, BE (hybrid)



Save the date



CDDF'S UPCOMING MEETINGS & DISCUSSION

CDDF LIVE WEBINARS



LIVE WEBINAR

Long term outcomes of in utero exposure to cytotoxic therapy: is involving pregnant patients an absolute no-go in cancer drug development?

Frédéric Amant (UZ Leuven)

4 December 2025
16:00-17:00 CET, Online



[Webinar Outline](#)

[Registration](#)



LIVE WEBINAR SERIES: ACT EU

ACT EU: Collaborating with stakeholders to define priorities for clinical trials and working collectively to address them

Marianne Lunzer (Austrian Medicines Agency)
Laura Pioppo (EMA)

15 December 2025
16:00-17:00 CET, Online



[Webinar Outline](#)

[Registration](#)

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



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

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