



CANCER CLINICAL RESEARCH IN A CHANGING GLOBAL ENVIRONMENT

EXECUTIVE SUMMARY

9-11 FEBRUARY 2026
HYBRID, GHENT (BE)



CDDF Annual Conference 2026

Cancer Clinical Research in a Changing Global Environment

9 - 11 February 2026, Ghent (BE)

The Cancer Drug Development Forum (CDDF) Annual Conference is a neutral, non-competitive platform that addresses topical issues and recent innovations in oncology drug development with the goal of improving cancer treatment. The conference facilitates multi-stakeholder discussion and collaboration, bringing together leading voices from academia, the healthcare industry, regulatory authorities, and patient advocacy groups.

The 2026 edition focused on the rapidly evolving global environment of cancer clinical research. The discussion covered key topics such as global clinical development, representativeness in global clinical trials, patient relevant endpoints, the use of big data in oncology drug development, and diversity in clinical trials.

The meeting provided participants with a unique opportunity to engage in open debate and thought-provoking dialogue, emphasizing the importance of collaborative endeavors across all stakeholder groups. Key takeaways are as follows:





SESSION 1: WHAT'S HOT IN GLOBAL CLINICAL DEVELOPMENT?



KEY TAKEAWAYS FROM “FDA PERSPECTIVE”

- **Importance of novel endpoint development and application**
 - Example: Minimal Residual Disease (MRD) in Multiple Myeloma (MM)
 - April 2024 Oncology Drug Advisory Committee (ODAC) Meeting Voting
 - Question: Does the evidence support the use of MRD as an accelerated approval endpoint in MM clinical trials? – 12 Yes; – 0 No
- **Mitigating Risks associated with Novel Endpoints – Overall Survival (OS) as a Safety Endpoint**
 - BELLINI Trial: A Cautionary Tale
 - OS results – Need evaluation of endpoints that can be assessed at both early timepoints and late timepoints that provide definitive evidence of clinical benefit
 - For FDA approval, trial population needs to reflect demographics of patients with the condition in the US



NEXT STEPS FROM “FDA PERSPECTIVE”

- Center of Excellence initiative to enhance the development of endpoints in oncology drug development
- Explore potential uses for early, novel endpoints
- Foster engagement with the broader community
- Advance the use of more established late endpoints



KEY TAKEAWAYS FROM “INTERNATIONAL COALITION OF MEDICINES REGULATORY AUTHORITIES (ICMRA) PERSPECTIVE”

- ICMRA enables and facilitates regulatory **cooperation** and **convergence** at a global level between agencies.
- ICMRA is a unique **strategic platform** for Heads of Agencies globally to address matters of common interest.
- It played a key role during the pandemic in the efforts against the COVID-19 virus, ensuring alignment in regulatory practices and communication globally.
- ICMRA continues its **active post-pandemic** activities: workstreams that are relevant to support global developments include Artificial Intelligence, Real World Evidence, Pharmaceutical Quality Knowledge Management and Rare Diseases.
- EMA is strongly committed to **international collaboration**. In Oncology, EMA collaborates with the US-FDA and other international partners, through several initiatives that contribute to facilitating global development, assessment and authorisation of new medicines.



FIRESIDE CHAT MODERATED BY MARK LAWLER



KEY TAKEAWAYS

- Unique perspective from a global regulatory leader
- Fascinating insight on how to address a global crisis – Covid-19
- Emphasising continued pandemic preparedness
- Lessons learned in how innovative thinking addressed key challenges
- New ways of working
- Optimistic: A golden age of pharmaceutical activities



SESSION 2: CDDF & AAADV JOINT SESSION ON REPRESENTATIVENESS IN GLOBAL CLINICAL TRIALS



KEY TAKEAWAYS

- For patients, representativeness is “knowing lived experience matters” and patients should be involved in trial design early. Patients are partners, not variables.
- The patient’s local environment will impact recruitment, so their involvement in early study design will optimize chances for study enrollment.
- Shifting patterns of drug development from West to East has highlighted the importance of representative populations in clinical trials, and recognition by Western regulatory agencies that assuming representativeness is not sufficient.
- There are statistical challenges in increasing representativeness, as it leads to greater heterogeneity in the trial population when analysed.
- Representativeness involves broad categories, and should consider the upper and lower age groups as well as race, gender and access to previous/concurrent therapies that may confound the interpretation of results.



SESSION 2: CDDF & AAADV JOINT SESSION ON REPRESENTATIVENESS IN GLOBAL CLINICAL TRIALS

NEXT STEPS

- Move to design trials strategically, starting with patients and considering the diversity of the population and local needs to ensure the practicality of delivering the trial in the appropriate population.
- Diversity action plans that were required by US FDA are still being submitted.
- Representative sub-populations analysed within trials should be considered descriptive; “we are not aiming for perfection but representation.”





SESSION 3: PATIENT RELEVANT ENDPOINTS



KEY TAKEAWAYS

- Collecting Patient Experience Data (PED) adds a valuable data source reflecting patients' realities that can improve drug development and the assessment of Marketing Authorisation Application (MAA).
- Patient-Reported Outcomes (PROs) should not only be used to think about efficacy, but also about the treatment risks. PROs are rarely used to guide dosing decision-making. This raises the question as to whether the safety of a medicine can be reliably assessed if PROs were not measured.
- The inclusion of a dedicated PED section into the assessment report and the publication of the draft EMA reflection paper on patient experience data are milestones that have been accomplished. Further progress on the EMA priority action plan is welcomed.
- PROs can support HTA decision-making and reduce uncertainty around real-life benefits. However, many PROs are not decision-ready and may end up adding noise rather than clarity.

SESSION 3: PATIENT RELEVANT ENDPOINTS

KEY TAKEAWAYS

- Results from patient preference studies (PPS) can add a real value-dimension to inform medicine development and decision-making. There is a need to run more PPS and to actually publish and disseminate the data. It remains to be seen by whom these studies will be conducted.
- Industry is willing to integrate PED into medicine development, yet practical, organizational, and regulatory constraints remain.
- Resolving the challenges can only be accomplished through more transparency about what really matters to patients and through close collaboration with all stakeholders. This includes the co-design of an early PRO strategy.



SESSION 4: THE USE OF BIG DATA IN ONCOLOGY DRUG DEVELOPMENT



KEY TAKEAWAYS

- Standardisation of data sets is essential to allow data sharing and interoperability.
- There are opportunities to use real world evidence throughout the whole development pathway for a medicinal product.
- Ensuring an adequate balance between data sharing, data use and data access requires thoughtful planning.



NEXT STEPS

- Discussions should continue on how to harness big data in a consistent and equitable manner using platforms under development, such as DARWIN EU and EHDS.



SESSION 5: DIVERSITY IN CLINICAL TRIALS



KEY TAKEAWAYS

- The CDDF Diversity Initiative, launched in 2024, aims to address diversity in clinical trials relevant for European patients.
- The initiative focuses on the definition of necessary variables such as sex & gender, age, intrinsic and extrinsic factors, and on data evaluation and analysis.
- Diversity in clinical trials is essential to correct the underrepresentation of subpopulations relevant for the use of the medicinal product under development. This also involves a better definition of the variables driving the diversity.
- Anticipation and planning are key for protocol design and data collection, analysis, reporting and evaluation, and should be considered across the lifecycle of the Clinical Development Programme. Using existing data and knowledge of the demographics of the patient population and tumour epidemiology are necessary. Under-representation may arise from failure to include certain groups in clinical trials and from a failure to collect the data needed to identify them or to conduct the necessary analysis.
- The initiative emphasizes the continuous involvement of patient advocates in all stages of the development process.

SESSION 5: DIVERSITY IN CLINICAL TRIALS

NEXT STEPS

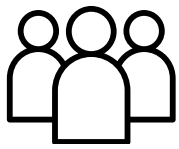
- The CDDF Diversity Initiative will produce a white paper summarizing consensus recommendations from key stakeholders in 2026.
- There is good regulatory guidance at the European and International level, and implementation is the key to achieving diversity that is representative of the population who need to be treated.
- Clinical developers should address diversity from phase I to IV on the clinical development plan level as well as on the level of the individual clinical trial.
- Implement pre-planned data analysis of subgroups to avoid biases and manage data heterogeneity, respecting the relevant EMA and FDA guidelines on subgroup analysis for a structured approach to data analysis.





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



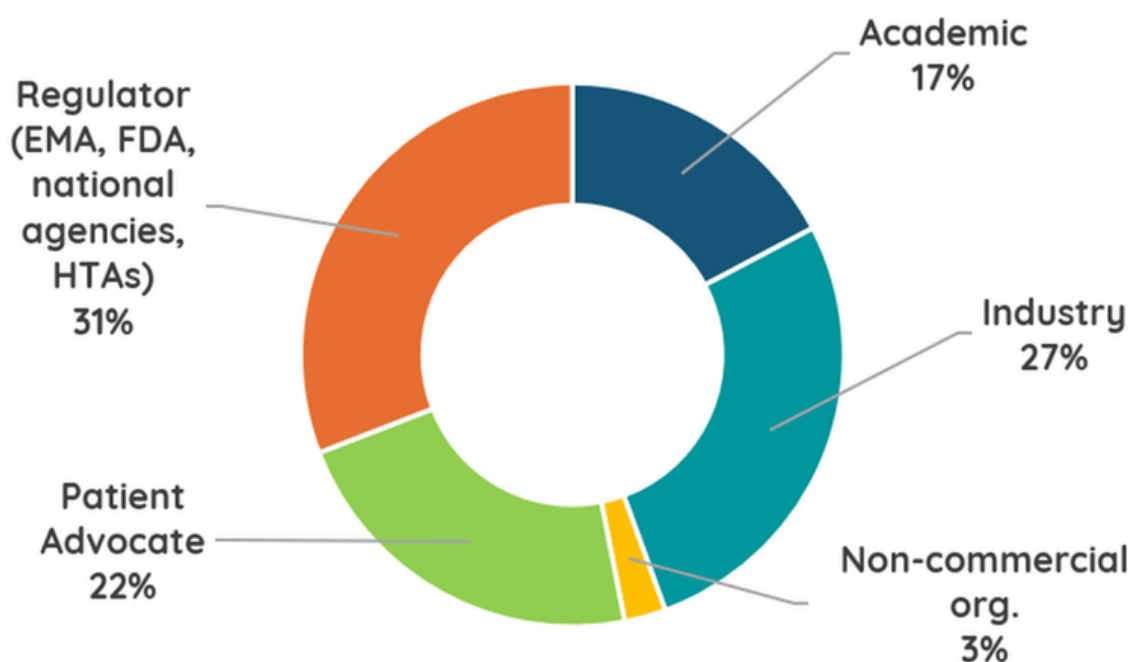


AUDIENCE AT THE CDDF CONFERENCE

CDDF 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**.



Participants & Speakers



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

84

**IN-PERSON
ATTENDEES**

177

**ONLINE
ATTENDEES**



WHAT PARTICIPANTS SAY ABOUT CDDF'S DISCUSSION?

"It's always great to have colleagues and stakeholders who are interested in clinical research and who want to make clinical research better. And you see this here in the cancer area, in this conference. You see that you've got a combination of clinical research organisations, industry, patients, regulators, in fact all the stakeholders. And it's only through multi-stakeholder collaboration that you can really make a difference."

Emer Cooke
Executive Director, the European Medicines Agency (EMA)

"I think it's really interesting to see such a diverse stakeholder group come together and to have such thoughtful discussions on cancer drug development."

Aedín Culhane
Professor, University of Limerick

"I liked most at the CDF conference to meet people that are actually engaged in patient experience data that really want to make it happen and I think it's the perfect place to discuss that because we have a lot of patient advocates here, people from industry, people from clinical, people from regulatory so it's the perfect place to think about collaboration, how we can jointly make this happen."

Jan Geissler
Founder and CEO, Patvocates

"Patient-Relevant Endpoints was really a very interesting session. It really puts the perspective of all the work we do, especially in oncology, where we are driving improvement in survival, but it also has to come with how patients feel and how their reported outcomes matter to be able to improve their quality of life. And it really reflects that we have to have a call in action for everything we do to make sure that patients' voice is heard and that patient-reported outcomes are implemented as part of our clinical trials."

Kiran Patel
Vice President - Global Head, Solid Tumor Clinical Development and Diagnostic, Johnson & Johnson

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 DISCUSSIONS

MULTI-STAKEHOLDER MEETINGS




MULTI-STAKEHOLDER WORKSHOP

Challenges in the Landscape of a Global Development Strategy, including patient access

30 - 31 March 2026
Brussels, BE (hybrid)



[Programme](#)

[Registration](#)

Session Topics

- 1 ICH E22 Guideline on Patient Preferences
- 2 Navigating the Regulatory Maze: Towards Global Harmonization
- 3 Endpoints and Patient Voice: Cornerstones of Successful Global Drug Development and Reimbursement
- 4 Expediting the Road to Pivotal Trials




CDDF & EORTC JOINT WORKSHOP

Health Technology Assessment in Cancer Drug Development

5 - 6 October 2026
Brussels, BE (hybrid)




[Save the date](#)

Provisional Session Topics

- 1 Setting the Scene: HTA Landscape and Societal Needs
- 2 Implementation of HTA Regulation: Practical Learnings
- 3 HTA Regulation and Methodological Foundations
- 4 Looking Ahead: Preparing for Future Innovation



CDDF'S UPCOMING DISCUSSIONS



CDDF LIVE WEBINARS (Dates TBC)

- **AI and Big Data Series 5: Use of AI in clinical trials**
- **AI and Big Data Series 6: Transparency and risk assessment**
- **CDDF Diversity Initiative paper**
- *and more on key topics in oncology*

Visit [the CDDF website](#) and follow us on [LinkedIn](#) to stay informed about upcoming webinars

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.

Cancer Drug Development Forum (CDDF)

Registered office: c/o BLSI, Clos Chapelle-aux-Champs 30, 1200 Woluwe Saint Lambert, Belgium
Register of legal entities: the French Speaking Enterprise Court in Brussels
Enterprise number: 738.523.752

 info@cddf.org

 www.cddf.org