Minutes – Cancer Medicines Forum

March 31, 2025, 10:00am – 1:00 pm CET; Teams Meeting

Chairperson: Denis Lacombe (European Organisation for Research and Treatment of Cancer, EORTC)

Co-chairperson: Francesco Pignatti (European Medicines Agency, EMA)

Cancer Medicines Forum members: European Organisation for Research and Treatment of Cancer (EORTC), European Society of Medical Oncology (ESMO), European Haematology Association (EHA) and International Society of Geriatric Oncology (SIOG)

Observers: Organisation for Economic Co-operation and Development (OECD), HTA body (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG), patient representative (Patvocates), industry representative, European Society of Paediatric Oncology (SIOPE), International Association of Mutual Benefit Societies (AIM) and European Social Insurance Platform (ESIP)

Guests: Zorginstituut Nederland, The Netherlands; Accelerating Clinical Trials in the EU; Clinical Trials Coordination Group EU

Welcome and adoption of the minutes of the previous meeting

The Chairs welcomed the members, observers and the guests. The minutes from the previous meeting were adopted without comments.

Summary of CMF objectives and achievements

In 2022, the EMA and EORTC established the Cancer Medicines Forum (CMF) to address a key gap in the clinical research and drug development framework: the lack of a structured approach to promote and prioritise treatment optimisation research. The EORTC has since presented a summary of the CMF's activities and achievements.

The CMF objectives include:

- To serve as a direct and official communication channel with the academic community in oncology.
- To identify key research questions and best methodological approaches to improve the clinical use of cancer medicines.
- To discuss the uptake of academic work in the wider context of regulatory decision-making in oncology.

In April 2024, a public workshop was held at the EMA headquarters (report available here). Participants explored concrete next steps and actions, including:

- Integrating the CMF into existing processes and systems to promote and prioritise treatment optimisation research.
- Exploring policy actions to support optimisation in broader contexts while fostering collaboration among stakeholders, including payers, academia, and regulators, to transition from national approaches to effective international partnerships.

At the most recent meeting, member organisations were invited to propose priorities and questions for treatment optimisation research. Several proposals were presented, encompassing both general study themes and specific research concepts (meeting minutes available here).

Update on the study determining the optimal treatment duration of an antibody-drug conjugate in patients with previously untreated advanced urothelial cancer

The EORTC provided an update on the treatment optimisation study in bladder cancer, that aims to determine the optimal treatment duration of an antibody-drug conjugate in patients with previously untreated advanced urothelial cancer. To support discussions with potential funders, a return on investment analysis has been conducted using a tool designed to demonstrate the potential financial benefits of this de-escalation study. The next steps include piloting the model and initiating funding discussions. Moreover, anticipated regulatory challenges related to the conduct of the trial, such as the potential classification of the intervention as an Investigational Medicinal Product, are being addressed.

During the discussion, stakeholders emphasised the importance of contributing not only to the development of a structured framework for systematically identifying treatment optimisation research questions and facilitating trial execution, but also to addressing, in parallel, the challenges associated with implementing and adopting the results of these studies in clinical practice.

Introduction to ACT EU and the work of the Clinical Trials Coordination Group

The Accelerating Clinical Trials in the European Union (ACT EU) initiative provided an overview of its objectives and future plans. Launched in 2022 with the implementation of the Clinical Trials Regulation

(CTR), ACT EU is a joint effort by the European Commission, the Heads of Medicines Agencies (HMA), and the European Medicines Agency (EMA). Its goal is to make clinical trials in the EU better, faster, and more efficient, ultimately making the region a more attractive place for clinical research.

Key priorities include supporting CTR implementation and addressing specific challenges, such as requests for information, assessment timelines, adoption of risk-based approaches, low-intervention trials, methodological innovation, and regulatory alignment across the CTR, In Vitro Diagnostic Regulation (IVDR), and Medical Devices Regulation (MDR).

The Clinical Trials Coordination Group (CTCG), a working group under the HMA, also shared an update on its responsibilities and ongoing work. The group includes experts from national regulatory agencies and focuses on improving the EU/EEA's appeal for clinical trials through harmonisation and streamlined processes, while safeguarding participant rights and safety. Current CTCG activities include:

- Weekly assessors' roundtables for training, information exchange, and alignment of views across EU/EEA Member States.
- Monthly meetings to agree on best practices and provide guidance for Member States and sponsors, including engagement with Ethics Committees.
- A project focused on patient involvement in clinical trial design.
- Ongoing evaluation and refinement of existing guidance, including those on complex clinical trials, risk-proportionate approaches, and pragmatic trials.

During the discussion, stakeholders highlighted the challenges of conducting pragmatic trials within current regulatory frameworks, emphasising the need for clear definitions, improved alignment among stakeholders, and simplification of bureaucratic processes. These improvements could lead to more efficient and streamlined pathways for conducting such trials. The Chairs welcomed continued dialogue on this topic, recognising its potential to advance the implementation of treatment optimisation studies and pragmatic clinical trials.

Update on the CMF mandate

The EMA provided an update on the draft mandate for the Cancer Medicines Forum (CMF), developed under the Healthcare Professionals Working Party (HCPWP) and the Patients and Consumers Working Party (PCWP). This initiative may contribute to enhancing the Forum's visibility and elevating its communications and positions to a broader audience. The draft mandate will be circulated to member organisations and observers for review and feedback.

During the discussion, participants acknowledged that further outreach, such as webinars or an additional workshop, could contribute to increased awareness and improve understanding of the CMF's objectives, particularly among key stakeholder groups.

Update on publications on pragmatic clinical trials and CMF workshop

The EORTC provided an update on two manuscripts: one reporting on the multistakeholder workshop organised by the EORTC on pragmatic clinical trials, and the other summarising the outcomes of the CMF workshop.

The first manuscript, *Defining the Role of Pragmatic Clinical Trials in Cancer Clinical Research: Outcomes of a Collaborative Workshop Hosted by the European Organisation for Research and Treatment of Cancer*, presents a multistakeholder consensus across four key areas: the definition of pragmatic clinical trials, their methodological characteristics, design recommendations, and their role in cancer research. It also includes stakeholder perspectives on the value of pragmatic trials and outlines key challenges related to their implementation. The manuscript is expected to be included in the May issue of *The Lancet Oncology*.

The second manuscript, which reports on the CMF workshop, is structured to reflect both the content shared by stakeholders during the event and the broader achievements of the CMF since its inception. The first draft is currently under review, with submission planned to the Journal of Cancer Policy.

Next CMF meetings

The CMF will meet on a quarterly basis and below an overview of the remaining dates for 2025:

- 17 June at 2pm CET
- 4 September at 2pm CET
- 2 December at 2pm CET