Minutes – Cancer Medicines Forum

June 23, 2026, 2:00pm – 5:00pm CET; Teams Meeting

Chairperson: Francesco Pignatti (European Medicines Agency, EMA)

Co-chairperson: Denis Lacombe (European Organisation for Research and Treatment of Cancer, EORTC)

Scientific coordinator: Caroline Voltz-Girolt (EMA)

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

Advisors: HTA body (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG), patient representative (Patvocates), industry representative, International Association of Mutual Benefit Societies (AIM), European Social Insurance Platform (ESIP), Zorginstituut Nederland, European Society of Oncology Pharmacists, and European Cancer Leagues

Observers: Organisation for Economic Co-operation and Development (OECD)

Welcome and adoption of the minutes of the previous meeting

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

Composition of the CMF: results from the call for expressions of interest

The EMA presented an overview of the nomination process for the CMF following its formalisation under the Healthcare Professionals' and Patients' and Consumers' Working Parties after the call for expressions of interest launched by the EMA Stakeholders Division.

The framework foresees four categories of participation: members, advisors, observers, and invited guests, aimed at ensuring balanced and flexible stakeholder input across relevant groups. It was noted that the formal adoption of the membership and advisory composition is planned for September 2026, with the next renomination foreseen for September 2029, following a three-year mandate structure.

The CMF composition and governance structure was globally endorsed by the CMF. During the discussion, participants highlighted the importance of fostering optimal patient representation. Before discussing nominations, it is proposed to agree on criteria (to be discussed further) and launch a more specific call/process.

CMF topics prioritisation and next steps

The EMA provided an overview of the topics proposed for inclusion in the future action plan of the CMF, with the aim of developing a series of publications addressing key scientific and regulatory priorities in oncology treatment optimisation. Draft outlines will be further developed and presented during upcoming CMF meetings, followed by a public workshop. The EMA also presented the results of a survey in which CMF participants were invited to assess the relative importance of the proposed topics and indicate their willingness to contribute to their development.

The topics proposed for inclusion in the future action plan as well as topic leads were consolidated and endorsed by the CMF. During the discussion, participants were invited to further reflect on a publication strategy.

Diagnostic assumption-based optimisation strategies

The EHA presented current scientific perspectives on diagnostic-guided treatment optimisation, using multiple myeloma as an illustrative example to highlight broader methodological and systemic challenges in oncology care. The presentation emphasised the increasing potential of integrated diagnostic approaches, including risk stratification and response-based biomarkers, to support more personalised treatment pathways by tailoring treatment intensity and duration according to individual patient characteristics. It was also noted that implementing such approaches will require new models of evidence generation and closer integration of diagnostic in therapeutic development, while addressing methodological, regulatory and health technology assessment challenges.

During the discussion, participants highlighted the potential of diagnostic-guided treatment optimisation to support treatment de-escalation or discontinuation in selected patients while maintaining favourable clinical outcomes. The importance of prospective evidence generation, patient-centred decision-making, and collaboration across stakeholders was emphasised to support implementation of personalised treatment strategies. Participants also discussed the challenges posed by evolving therapeutic modalities, fragmented

diagnostic and funding frameworks, and limited evidence in rare diseases, underscoring the need for more integrated approaches to advance diagnostics-informed treatment optimisation.

FORCE consortium

European Cancer Leagues presented an overview of the FORCE consortium, a collaborative initiative bringing together European cancer charities to strengthen oncology research through pragmatic clinical trials addressing unmet needs in rare and hard-to-treat cancers. The initiative aims to develop a sustainable programme of multinational investigator-initiated trials, supported by patient involvement throughout the research process, while generating recommendations to inform future European policy on pragmatic oncology clinical trials. The first joint funding call was presented as a key step towards advancing treatment optimisation and improving quality of life through research with direct relevance to clinical practice.

During the discussion, the importance of generating evidence that can be effectively translated into routine clinical practice was emphasised, with the funding programme viewed as an opportunity to further refine pragmatic approaches to oncology research.

Recent publications: Uncertainties in regulatory benefit-risk decision-making for innovative anticancer medicines: a 2011-2025 review of extensions of indication

The EORTC presented the final results of a study examining regulatory uncertainties associated with extensions of indication for anticancer medicines approved in the European Union between 2011 and 2025. The analysis characterised the nature and frequency of uncertainties identified during regulatory assessments and explored factors associated with higher levels of uncertainty. The findings indicated that efficacy-related uncertainties were more common than safety-related uncertainties, with a substantial proportion relating to treatment optimisation, including treatment pathways, biomarker use, and dosing strategies. Higher levels of uncertainty were more frequently associated with medicines assessed through expedited pathways and those supported by non-randomised evidence.

During the discussion, participants noted that the findings were broadly consistent with previous research on regulatory uncertainties. During the discussion, participants reflected on the reporting of uncertainties in European Public Assessment Reports and its relevance for interpreting and comparing regulatory assessments.

Next CMF meetings

The CMF will meet on a quarterly basis. The 2026 meeting dates are as follows:

- 3 September at 2pm CET
- 8 December at 2pm CET