

Minutes – Cancer Medicines Forum

March 2, 2026, 10:00am – 13:00pm 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 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 and European Society of Oncology Pharmacists

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.

Data on impacts of late life-cycle innovation

An analysis of late life-cycle innovation in medicines, focusing on post-launch indication expansion, was presented. The analysis highlighted that post-approval innovation is a significant driver of medicine lifecycle development, with around half of medicines receiving at least one additional indication and oncology accounting for a substantial share of these expansions. Findings indicated that later-life indications often occur several years after initial approval and are less frequently associated with expedited regulatory pathways, while maintaining comparable clinical value scores.

During the discussion, it was noted that dose optimisation appears relatively uncommon in later-life indications and that value assessments should be interpreted in the context of evolving standards of care. The potential benefits of integrating optimisation earlier in the development process were emphasised, alongside the regulatory expectation that dosing is generally established at the time of marketing authorisation, while recognising the continued role of post-authorisation optimisation.

Paediatric and young adult oncology: regulators' and clinicians' perspective

The EMA outlined key considerations to improve evidence generation for adolescents and young adults (AYA) with cancer. Age-inclusive research was identified as a key approach to closing evidence gaps, supported by initiatives such as joint EMA–FDA recommendations encouraging the inclusion of adolescents in adult oncology trials where appropriate. Operational challenges in implementing age-inclusive research were discussed, and the potential value of a more structured framework for trial assessment was highlighted. Overall, the importance of improving outcomes for AYA patients across the care continuum was emphasised, with continued collaboration considered essential to support effective evidence generation.

The EORTC provided an overview of the current state of science in AYA oncology, highlighting variability in definitions and care organisation across countries. Despite generally favourable survival outcomes, the increasing number of long-term survivors underscores the importance of addressing late effects and broader patient needs. Patient-centred care was emphasised, including fertility, education, employment, and psychosocial outcomes, alongside the role of patient organisations in shaping models of care. Challenges in clinical trial access for AYA were highlighted, with low participation rates linked to limited age-specific trial designs and structural barriers between paediatric and adult oncology systems. Examples of collaborative research initiatives and tools to improve quality-of-life assessment were also noted.

During the discussion, participants emphasised the need to better integrate clinical research and care for AYA patients, particularly in rare cancers. Barriers to trial participation, ethical considerations, and the importance of innovative trial designs and cross-sector collaboration were discussed. The need to strengthen treatment optimisation efforts was also highlighted, alongside the importance of early integration of such strategies into development plans.

CMF composition and governance structure

The EMA presented the proposed composition and governance structure of the CMF following its formalisation under the Healthcare Professionals' and Patients' and Consumers' Working Parties. The

framework foresees four categories of participation: members, advisors, observers, and invited guests, aimed at ensuring balanced and flexible stakeholder input across relevant groups.

During the discussion, participants highlighted the importance of ensuring meaningful patient involvement and appropriate representation of HTA bodies and payers, potentially through existing European coordination structures.

Follow-up from November 2025 CMF–industry meeting: action plan

The EMA presented a proposed action plan outlining priority thematic areas for future work. The objective is to prioritise topics that may be advanced in the short term into structured outputs. Priority areas include treatment optimisation, incentives to support optimisation research, collaborative industry–academia models, data sharing and tissue banks, improved approaches to assessing toxicity and benefit, and best practices for pragmatic clinical trials in oncology.

During the discussion, participants highlighted the importance of addressing operational barriers to optimisation research, including differences in interpretation of regulatory requirements and challenges in clinical trial conduct. The importance of strengthening industry–academia collaboration was also emphasised.

Next CMF meetings

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

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