

Minutes – Cancer Medicines Forum

October 1, 2024, 13:00 am – 16:00 pm CET; Teams Meeting

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

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

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) 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: National Payer's Evaluation Committee for Specialised Medicines and Companion Diagnostics (CieBAG), The Netherlands.

Welcome and adoption of the minutes of the previous meeting

The Chairs welcomed the members, observers and the guests (members of national competent authorities on pricing and reimbursement from the Netherlands). The minutes from the previous meeting were adopted without comments.

Key objectives of the CMF and stakeholder participation

The EMA presented a proposal outlining both the key objectives and stakeholders' participation to the CMF. The key objectives include:

- To identify research questions and priorities for treatment optimisation.
- To facilitate the process of addressing these priorities.

With respect to identifying research questions and priorities for treatment optimisation, the CMF will encourage member organisations to contribute to ideas, with the goal of generating a list of research priorities. The CMF's role will be to promote and facilitate efforts to address these priorities.

Regarding stakeholders' participation, a reclassification was explored to redefine current CMF observers as advisors, recognising their role in contributing to valuable insights. Additionally, the proposal suggests considering invitations for additional key advisors to participate.

The CMF agreed with the proposal regarding the key objectives and stakeholders' participation. The final list of stakeholders will be further discussed at the EMA Healthcare Professionals Working Party.

Methodology and process to be used to identify treatment optimisation research questions

The EMA presented a proposal outlining the methodology and process for identifying treatment optimisation research questions and priorities. The key steps proposed include:

- The identification of treatment optimisation research priorities by member organisations.
- Endorsement of the proposed research priorities by the CMF, followed by a public consultation.
- Review of public feedback and conducting discussions with key stakeholders during public workshops.
- Discussion of trial proposals with relevant stakeholders and organisations.

The CMF endorsed the proposed methodology and process to identify treatment optimisation questions and priorities. The process would be piloted and reassessed based on the insights gained. Member organisations were also invited to identify and propose treatment optimisation research priorities at the next meeting.

Methodology and process for implementing treatment optimisation research questions

The EORTC provided an overview of the challenges faced in implementing treatment optimisation research projects, including:

- The need for international collaborations, given the study's sample size and the importance of addressing research questions in a timely manner.
- The need for significant funding, and the fact that a systematic framework for investing in such trials is still lacking.
- The need of adaptive regulatory frameworks focused on risk-proportionate approaches.

It was acknowledged that creating a comprehensive list of research questions that are both clinically and societally relevant may contribute to raise awareness. Additionally, the importance of establishing a public consultation process to facilitate discussions was emphasised.

De-escalation current state of science in Multiple Myeloma

The EHA provided an overview of the current state of science in multiple myeloma in relation to de-escalation and dose-finding strategies. The stakeholders discussed several challenges in this disease field, including potential overtreatment, which arises from difficulties in identifying patients who would benefit most from treatment intensification or de-escalation strategies. Other challenges include the lack of data for better subclassification of the disease and the identification of subpopulations that could benefit from targeted treatments, as well as the absence of systematic label updates after long-term experience. Potential solutions were also discussed, such as incentivising the incorporation of centralised diagnostics into the value assessment process, promoting strategic public health and academic research, and establishing systems to facilitate the identification of prognostic factors and biomarkers.

Next CMF meetings

The CMF will meet on a quarterly basis and below an overview of the dates for 2024 and 2025:

- December 16th, 2024
- March 10th, 2025
- June 17th, 2025
- September 4th, 2025
- December 2nd, 2025