Minutes – Cancer Medicines Forum

December 4, 2023, 10:00 am – 13:00 pm CET; Teams meeting

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

Co-chairperson: Caroline Voltz-Girolt on behalf of 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 Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR)

Introduction and adoption of the minutes of the previous meeting

The Chairs welcomed the new representatives from ESMO and EHA and the guests (NCAPR representatives from the Belgian, Dutch, Portuguese, Slovenian and Spanish agencies). The minutes from the previous meeting were adopted without comments.

Industry participation to the CMF

The current industry representative has been invited by the CMF Chairs. It was proposed that a call for interest to industry for nomination of representatives is launched after the CMF workshop (taking place on 5th April 2024).

Update on CMF achievements

A summary of the activities/achievements of the CMF was presented by EORTC. A total of five meetings occurred, being the first meeting constitutional and focused on identifying the challenges of conducting independent clinical research in the fields of treatment optimisation and effectiveness of innovative medicines.

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.

Stakeholders were involved in the second meeting and shared their concerns related to the absence of a process to optimise the use of medicines.

At the third meeting, EMA's decision tree to identify the need for post-authorisation studies was explored, aiming to highlight the current framework as well as to discuss possible improvements. In addition, possible improvements in the pre-approval setting were also discussed.

During the fourth meeting, a decision tree that could serve as a methodological guidance tool for the design of treatment optimisation studies was finalised. Additionally, delivering a regulatory strategy for treatment optimisation research was defined as a priority.

At the fifth meeting, the who, how, and when of treatment optimisation research based on a collaborative table was discussed, establishing the CMF view.

The future of the CMF includes focusing on the deliverables, practical aspects, solution roadmap for implementation of treatment optimisation research and set-up partnerships with health care systems.

EMA progress report on addressing regulatory milestones

EMA gave a presentation on the current regulatory framework, sharing possible solutions to address treatment optimisation research questions in the pre-authorisation setting as well as in post-authorisation studies.

It was highlighted that treatment optimisation aspects should ideally take place and be discussed during the development phase, namely through scientific advice/protocol assistance and post-approval studies. Treatment optimisation research questions could include posology, treatment duration, dose and specific patient populations.

It was also highlighted that funding mechanisms, specifically in the post-marketing setting, would need to be further discussed.

CMF workshop

The CMF workshop will be hosted by the EMA and will take place on April 5th 2024, at EMA Headquarters. The objectives of the workshop are:

- to communicate externally CMF's achievements and expand stakeholders' participation.
- to discuss the principles to structure treatment optimisation in the regulatory process.
- to identify regulatory tools and joint initiatives, as well as supporting and prioritising independent clinical research on treatment optimisation.

The target audience includes academic researchers, cooperative groups, drug developers, regulatory affairs officers, patients, civil society/citizens, HTA bodies, payers, representatives from governments and representatives of EU institutions and associated groups.

Next CMF meetings

The CMF will keep the periodicity of the meetings (quarterly) and below an overview of the dates for 2024.

- 26th February
- 23rd May
- 1st October
- 17th December