# Minutes – Cancer Medicines Forum

February 26, 2024, 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: Centre for Clinical Therapeutics, Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences.

**Welcome and adoption of the minutes of the previous meeting**

The Chairs welcomed the members, observers and the guests (researchers from the Centre for Clinical Therapeutics, Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences). The minutes from the previous meeting were adopted without comments.

**CMF workshop**

The CMF workshop will be hosted by the EMA and will take place on April 5th 2024, at EMA Headquarters (agenda available here). 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. 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.

EMA provided an update on the registration status and an overview of the planned advertisement actions, namely on social media.

During the discussion, some recent achievements were highlighted, specifically the increased visibility of the importance of treatment optimisation research at the level of the European Parliament as well as the European Commission (including the Cancer Mission Board). Additionally, the stakeholders discussed options for the inclusion of treatment optimisation research within the current drug development framework, that would ideally be initiated pre-approval (possibly through scientific advice) and continued post-authorisation, namely resorting to post-authorisation safety and efficacy studies.

**Final results of the study: feasibility of post-authorisation RCTs for conditionally authorised anticancer medicines based on single arm trial**

The final results of a study conducted by Utrecht University was presented, that aimed to investigate on the feasibility of randomised studies for conditionally authorised anticancer medicines in the post-marketing setting. An overview of the research project was presented and the following facilitating factors were highlighted: the inclusion of patient-centred endpoints, such as quality of life and overall survival; patient's access to new medicines, while HTA and pricing discussions are ongoing; and patients' empowering. As impeding factors, the authors highlighted the risk of randomization to the control arm, specifically when blinding is considered not feasible; burden to investigators; and expectations about the clinical benefit. These results have been compiled in a manuscript that is currently under review by a peer-review journal.

**Finalising WHO-WHEN-HOW: Optimisation as a Spectrum along- side the development process**

Stakeholders discussed possible future deliverables of the CMF, namely:

- Implementation of treatment optimisation research/pragmatic clinical trials in the regulatory process
- Interaction with relevant stakeholders aiming implementation in health policy
- Development of a mechanism that selects and prioritises treatment optimisation research questions
- Development of case studies
- Set-up of partnerships, namely with the healthcare systems (payers)

- Addressing practical as well as organisational aspects of treatment optimisation research

**Pragmatic trials in Europe: sharing EORTC experience under the CTR**

EORTC shared its experience in the set-up and conduct of treatment optimisation studies resorting to pragmatic clinical trials under the new Clinical Trials Regulation. One of the challenges highlighted was the interpretation of the member states on the categorisation of trials as low-interventional. The stakeholders reviewed possible actions in this field, namely discussions with the European Commission so that the interpretation of the regulation is clarified.

**Next CMF meetings**

The CMF will have quarterly meetings in 2024 and below is an overview of the dates for 2024:

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