EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Methodology and process to be used to identify post-marketing treatment optimisation studies

Cancer Medicines Forum 1st October 2024

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European Medicines Agency

The views expressed in this presentation are the personal views of the speaker and may not be understood or quoted as being made on behalf of or reflecting the position of the EMA committees or working parties

CMF workshop – 5th April 2024

Cancer Medicines Forum (CMF)– a way forward for treatment optimisation

Chaired by Denis Lacombe (EORTC) and Francesco Pignatti (EMA)

12:30 **Joining and technical checks**

13:00 **Welcome and opening speech**

Presentation
Emer Cooke, Executive Director, EMA

Welcome (video)
Frank Vandenbroucke, Deputy Prime Minister and Minister of Health and Social Affairs

13:15 **Session 1: Setting principles and rationale for treatment optimisation**

Cancer Medicines Forum: rationale and achievements 20'
Denis Lacombe, Chief Executive Officer, EORTC

Examples of drug development and optimisation questions/trials 30'
Iphigenie Korakis, Department of Medical Oncology, Institut Universitaire du Cancer de Toulouse-Oncopole (IUCT-O), Toulouse, France
Bertrand Tombal, department of Surgery and Urology UCL, Brussels BE
Martin Kaiser, European Haematology Association

How could EU policies benefit of the work of the CMF? 20'
Richard Sullivan, Kings college London, UK

Cancer Medicines Forum treatment optimisation framework 15'
Caroline Voltz-Girolt, advanced therapy and haematological diseases office, EMA

14:40 **Q&A**

14:50 **Session 2: Developing a new regulatory dimension for treatment optimisation**

Cancer Drug Development as a Public Health Issue
Chris Booth, Queen's University Cancer Research Institute, Canada

The global Challenges of Post-market Optimisation Research
Daniel Goldstein, Tel-Aviv University

FDA Oncology centre of excellence: project PRAGMATICA
Donna Rivera, Associate Director of Pharmacoepidemiology, Real World Data and Real World Evidence, FDA

How does treatment optimisation apply to other fields of medicine?
Guy Brusselle, Ghent University Hospital, Belgium

15:55 **Q&A**

16:00 **Coffee break**

16:30 **Panel Discussion**

Regulator's perspective: *Pierre Demolis, ANSM, EMA*
HTA's perspective: *Beate Wieseler: Head of Department Drug Assessment, IQWIG*
Patient's perspective: *Ana Amariutei, European Patient Advocacy Institute*
Clinician's perspective: *Rosa Giuliani, HealthCare Professional Working Party*
Industry's perspective: *Michael Zaiac, Daiichi Sankyo*
Head of Medicines Agency's perspective: *Momir Radulovic, Agency for Medicinal Products and Medical Devices of the Republic of Slovenia*
Payer's perspective: *Ackbar Ketwaru, the Ministry of Health, Welfare and Sport, The Netherlands*
WHO Perspective: *Raffaella Casolino, World Health Organization*

18:00 **Closing remarks**

Wrap up: recommendations to the CMF and EU Policy makers Wrap up 15'
Denis Lacombe (EORTC) and Francesco Pignatti (EMA)

Identification of treatment optimisation questions

- Create the CMF mandate describing these objectives
- Post-marketing setting
- How EMA can facilitate optimisation trials?

- To give maximum resonance to the scientific research and public health needs
- Goes in parallel with FDA OCE project 5 in 5

Process engineering

CMF organisations consult internally and propose optimisation priorities

CMF agree on list and publish for consultation

Publication on EMA website

Public consultation comments on priorities and may add topics

CMF discuss priority list at public workshop

Trial proposals can be discussed at SA in collaboration with Clinical Trial Coordination Group