







The European Medicines Agency (EMA) and the European Organisation for Research and Treatment of Cancer (EORTC) are co-chairing the Cancer Medicines Forum (CMF). The CMF was created to address the challenges with regards to treatment optimisation taking into consideration the <u>International Conference of Harmonisation E9(R1)</u>.

The main objectives of the CMF are to:

- Serve as a direct and official communication channel with the academic community in oncology.
- To identify key research questions and best methodological approach 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.

The CMF will be reporting its observations and preliminary solutions to address treatment optimisation at a hybrid workshop and discuss the proposed way forward.

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

	Wrap up: recommendations to the CMF and EU Policy makers Wrap up Denis Lacombe (EORTC) and Francesco Pignatti (EMA)	15′
18:00	Closing remarks	
	WHO Perspective: Raffaella Casolino, World Health Organization	
	Payer's perspective: Ackbar Ketwaru, the Ministry of Health, Welfare and Spor Netherlands	t, The
	Products and Medical Devices of the Republic of Slovenia	
	Industry's perspective: Michael Zaiac, Daiichi Sankyo Head of Medicines Agency's perspective: Momir Radulovic, Agency for Medic	rinal
	Clinician's perspective: Rosa Giuliani, HealthCare Professional Working Party	
	Patient's perspective: Ana Amariutei, European Patient Advocacy Institute	
	HTA's perspective: Beate Wieseler: Head of Department Drug Assessment, IQWIG	
	Regulator's perspective: Pierre Demolis, ANSM, EMA	
16:30	Panel Discussion	
L6:00	Coffee break	
13.33	Aau	
L5:55	Q&A	
	Guy Brusselle, Ghent University Hospital, Belgium	
	How does treatment optimisation apply to other fields of medicine?	20′
	Donna Rivera, Associate Director of Pharmacoepidemiology, Real World Data and Real World Evidence, FDA	
	FDA Oncology centre of excellence: project PRAGMATICA	15′
	Daniel Goldstein, Tel-Aviv University	
	The global Challenges of Post-market Optimisation Research	15′
	Cancer Drug Development as a Public Health Issue Chris Booth, Queen's University Cancer Research Institute, Canada	15′