



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 November 2024
EMA/468836/2024

Agenda – 13th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines.

22 November 2024, C.E.T.: 09:00–14:00 hybrid meeting: meeting room 02-A and WebEx

Chair: Alberto Gañán Jiménez

Item	Topic
	Welcome / Introductions
1.	Transitional measures to implement the new variation regulation
2.	ePI Pilots readout, learnings and next steps
3.	Focus group on cancer medicines pathfinder regulatory interactions
	Coffee Break
4.	Dynamic Regulatory Assessment
5.	Ongoing initiatives on the centralised procedure
6.	Clinical Study Data Pilot
	Coffee Break
7.	Public consultation to review the QRD template for product information
8.	Lifecycle management of combination products at post-authorisation
9.	Clinical Data Publication - next steps consultation
	Summary of follow-up item

