



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 October 2025
EMA/335419/2025

Agenda – 15th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines.

28 November 2025, C.E.T.: 09:00–13:00 hybrid meeting: meeting room 02-A and WebEx

Chair: Alberto Gañán Jiménez

Item	Topic
	Welcome / Introductions
1.	Implementation of the Classification Guideline on variations
2.	Update on IRIS, eAF and optional submission of CTD 4.0 in the CP
3.	Ongoing initiatives on the centralised procedure • REVAMP – draft final report findings • Update from the Pre-submission interactions focus group • Submission Predictability
	Coffee Break
4.	Instrument for Pre-accession assistance (IPA): Update on EMA activities and regulatory challenges
5.	Update on SEND proof of concept study
6.	Update on review of QRD template
	Coffee Break
7.	Patient experience data
8.	Update on Cancer Medicines Pathfinder industry focus group
	Summary of follow-up item

