12 May 2025
EMA/163710/2025

Agenda – 14th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines.

23 June 2025, C.E.T.: 13:00–18:00 hybrid meeting: meeting room 01-A and WebEx

Chair: Alberto Gañán Jiménez

Item	Topic
	Welcome / Introductions
1.	Variations Regulation and guideline implementation
2.	Ongoing initiatives on the centralised procedure: - Update on the Focus Group predictability - Update on the Focus Group revamp AR process, and ongoing pilot/future pilots
3.	Streamlining Regulatory Processes: A Discussion on EMA's Simplification Procedures
	Coffee Break
4.	Update on the ICMRA collaborative assessment and hybrid inspection pilots
5.	Update on implementation of IRIS for lifecycle management of medicinal products
6.	Regulatory challenges for biological medicinal products for human use
	Coffee Break
7.	Combination products
8.	Follow-up on the clinical study data pilot
	Summary of follow-up item

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union