



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/501563/2023

25 September 2023

Agenda – 11th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines.

24 November 2023, C.E.T.: 09:00–13:30 hybrid meeting: meeting room 01-D and WebEx

Chair: Alberto Gañán Jiménez

Item	Preliminary Draft Agenda
	Welcome / Introductions
1.	Revised Variation Framework
2.	Updates on digitalisation: <ul style="list-style-type: none">- eAF for variations- Implementation of IRIS for variations 61.3 and MAH transfers and next steps
Coffee Break	
3.	Patient engagement in centralised procedure: from a patient centric drug development to authorisation
4.	Working parties and new ways of working
5.	Update on the Submission Predictability Focus Group
Coffee Break	
6.	Windsor protocol implementation aspects
7.	Update on Issues Raised During Validation of Type IB and Type II Variations
8.	New in 2024: Opportunity to submit Standard for the Exchange of Nonclinical Data (SEND) data packages in centralised procedures
	Summary of follow-up item

