



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 November 2025
EMA/356849/2025

Agenda – Public System Demo Q4 2025 **DRAFT**

16 December 2025, 09:30 – 12:15 CET (Live Broadcast)

Item	Agenda	Time
1.	Welcome / Introductions Jean-Michel Becar Head of Portfolio Management Office, EMA	09:30- 09:35
Product Lifecycle Management Value Stream (PLM VS)		09:35 – 12:00
2.	Electronic application forms (eAF) Kristiina Puusaari Epic Owner and Product Owner for eAF, EMA Q&A and feedback session	15 min 09:35 – 09:50
3.	Electronic Common Technical Document version 4 (eCDT4) Kristiina Puusaari Epic Owner and Product Owner for eCDT4, EMA Q&A and feedback session	15 min 09:50 – 10:05
4.	Union Product Database (UPD) Beyhan Mustafov Product Owner for UPD, EMA Saskia Schiemann Network Product Owner for UPD, BVL Q&A and feedback session	15 min 10:05 – 10:20
5.	Product Management Service (PMS) Marcos Fernandez Gomez Co-Product Owner for PMS, EMA Q&A and feedback session	15 min 10:20-10:35
	Break	15 min



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6.	Product user interface (PUI) Veronica Lipucci Di Paola Co-Product Owner for PUI, EMA Q&A and feedback session	20 min 10:50 – 11:10
7.	Electronic product information (ePI) Elizabeth Scanlan Product Owner for ePI, EMA Evin Drusys Network Product Owner for ePI, AEMPS Q&A and feedback session	20 min 11:10 – 11:30
8.	Regulatory Procedure Management (RPM) for Product Lifecycle Management on IRIS Madalina Duta-Mare Product Owner for RPM, EMA Sara Santos Subject Matter Expert for RPM, EMA Q&A and feedback session	30 min 11:30 – 12:00
Research & Development Value Stream (R&D VS)		12:00 – 12:15
9.	Clinical Trials Information System (CTIS) modernisation – roles simplification and safety Ana Rodriguez Product Owner for CTIS, EMA Q&A and feedback session	15 min 12:00– 12:15
Closing of the demo		12:15