



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 August 2025
EMA/260297/2025 Rev 1.
Updated 2 September

Agenda – System Demo Q3 2025 **FINAL**

17 September 2025, 09:00 – 12:30 CEST (Live Broadcast)

Item	Agenda	Time
1.	Welcome / Introductions Jean-Michel Becar Head of Portfolio Management Office, EMA	09:00 - 09:05
Research & Development Value Stream (R&D VS)		09:05 – 09:45
2.	Clinical Trials Information System (CTIS) modernisation – roles simplification and safety Ana Rodriguez Product Owner for CTIS, EMA Q&A and feedback session	15 min 09:05 – 09:20
3.	Trial Map IJsbrand den Rooijen Developer for Trial Map, EMA Q&A and feedback session	10 min 09:20 – 09:30
4.	Scientific Explorer Jane Moseley Subject Matter Expert for Scientific Explorer, EMA Q&A and feedback session	15 min 09:30 – 09:45
Product Lifecycle Management Value Stream (PLM VS)		09:45 – 12:10
5.	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 09:45 – 10:00



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6.	Product Management Service (PMS) Marcos Fernandez Gomez Co-Product Owner for PMS, EMA Q&A and feedback session	25 min 10:00 – 10:25
7.	Product user interface (PUI) Marcos Fernandez Gomez Co-Product Owner for PUI, EMA Q&A and feedback session	25 min 10:25 – 10:50
	<i>Break</i>	<i>10 min</i>
8.	Electronic application forms (eAF) Kristiina Puusaari Epic Owner and Product Owner for eAF, EMA Q&A and feedback session	15 min 11:00 – 11:15
9.	Electronic product information (ePI) Elizabeth Scanlan Product Owner for ePI, EMA Evin Drusys Network Product Owner for ePI, AEMPS Q&A and feedback session	25 min 11:15 – 11:40
10.	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 11:40 – 12:10
Monitoring Value Stream (Monitoring VS)		12:10 – 12:25
11.	EudraVigilance data analysis system (EVDAS) – automated compliance reports Sophie Groeneveld Product Owner for EVDAS, EMA Tom Paternoster-Howe Subject Matter Expert for EVDAS, EMA Q&A and feedback session	15 min 12:10 – 12:25
Managing the Agency Value Stream (MTA VS)		12:25 – 12:45
	Early Notification System (ENS) Diana Lupescu Product Owner for ENS, EMA Q&A and feedback session	20 min 12:25 – 12:45
Closing of the demo		12:25