



7 November 2025
EMA/356849/2025 Rev. 3
Updated 5 December 2025

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

16 December 2025, 09:30 – 12:35 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
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.	<p>Electronic product information (ePI)</p> <p>Elizabeth Scanlan Product Owner for ePI, EMA</p> <p>Evinn Drusys Network Product Owner for ePI, AEMPS</p> <p>Q&A and feedback session</p>	<p>20 min</p> <p>11:10 – 11:30</p>
8.	<p>Regulatory Procedure Management (RPM) for Product Lifecycle Management on IRIS</p> <p>Madalina Duta-Mare Product Owner for RPM, EMA</p> <p>Sara Santos Subject Matter Expert for RPM, EMA</p> <p>Q&A and feedback session</p>	<p>30 min</p> <p>11:30 – 12:00</p>
Research & Development Value Stream (R&D VS)		12:00 – 12:15
9.	<p>Clinical Trials Information System (CTIS) modernisation – new CTIS safety module</p> <p>Ana Rodriguez Product Owner for CTIS, EMA</p> <p>Q&A and feedback session</p>	<p>15 min</p> <p>12:00– 12:15</p>
Monitoring Value Stream (MON VS)		12:15 – 12:30
10.	<p>Antimicrobial Sales & Use (ASU) platform</p> <p>Anastasia Pickford Product Owner for ASU, EMA</p> <p>Q&A and feedback session</p>	<p>15 min</p> <p>12:15 -12:30</p>
Product Lifecycle Management Value Stream (PLM VS)		12:30 – 12:35
11.	<p>Data Analytics Platform (DAP) – Business Intelligence (BI) reports for National Competent Authorities</p> <p>Michael Vogl Product Owner for DAP BI, EMA</p> <p>Q&A and feedback session</p>	<p>5 min</p> <p>12:30-12:35</p>
Closing of the demo		12:35