



11 May 2026
EMA/87593/2026 Rev. 1
Updated 8 June 2026

Agenda – Public System Demo Q2 2026 **Final**

25 June 2026, 09:00 – 12:40 CEST (Live Broadcast)

Item	Agenda	Time
1.	Welcome / Introductions Jean-Michel Becar Head of Portfolio Management Office, EMA	09:00 – 09:05
Product Lifecycle Management value stream (PLM VS)		09:05 – 11:15
2.	Union Product Database (UPD) Beyhan Mustafov Product Owner for UPD, EMA Saskia Schiemann Network Product Owner for UPD, BVL Q&A and feedback session	10 min 09:05 – 09:15
3.	Regulatory Procedure Management (RPM) for Product Lifecycle Management on IRIS Madalina Duta-Mare Product Owner for RPM for PLM, EMA Q&A and feedback session	30 min 09:15 – 09:45
4.	Electronic product information (ePI) Elizabeth Scanlan Epic Owner and Product Owner for ePI, EMA Evin Drusys Network Product Owner for ePI, AEMPS Q&A and feedback session	15 min 09:45 – 10:00
5.	Electronic Common Technical Document version 4 (eCTD v4.0) Kristiina Puusaari Epic Owner and Product Owner for eCTD v4.0, EMA Q&A and feedback session	15 min 10:00 – 10:15



6.	Electronic application forms (eAF) – Human variations Kristiina Puusaari Epic Owner for eAF, EMA Q&A and feedback session	15 min 10:15 – 10:30
Break		10 min
7.	Product Management Service (PMS) Marcos Fernandez Gomez Co-Product Owner for PMS, EMA Q&A and feedback session	15 min 10:40 – 10:55
8.	Product user interface (PUI) Marcos Fernandez Gomez Co-Product Owner for PUI, EMA Q&A and feedback session	20 min 10:55 – 11:15
Monitoring value stream (MON VS)		11:15 – 11:40
9.	EudraGMDP Ivana Radic Product Owner for EudraGMDP, EMA Q&A and feedback session	25 min 11:15 – 11:40
Research & Development value stream (R&D VS)		11:40 – 12:20
10.	Clinical Trials Information System (CTIS) modernisation – Annual safety report (ASR) assessment / Request for information (RFI) and response Ana Rodriguez Product Owner for CTIS, EMA Q&A and feedback session	40 min 11:40 – 12:20
Technology Lifecycle Management value stream (TLM VS)		12:20 – 12:35
11.	EMA Account Management – improved user interface (UI) to request access on behalf of an organisation Carlo De Vittoria Product Owner for Identity and Access Management (IAM), EMA Jhonny Oliveira Platform Manager for IAM, EMA Q&A and feedback session	15 min 12:20 – 12:35
Closing of the demo		12:35