



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on Agile governance key dates and Subject Matter Experts status

Industry Standing Group (ISG) meeting, 21 November 2024





Quarterly System Demo – Q4 2024

- Next system demo will take place on **Thursday 12 December** 9:00 – 12:15 CET
- **Draft agenda** (final agenda to be published a week in advance)
 - 09:05 CET: New Fee Regulation (NFR)
 - 09:25 CET: Product Management Service (PMS)
 - 09:45 CET: Product User Interface (PUI)
 - 10:15 CET: Electronic Product Information (ePI)
 - 10:55 CET: Regulatory Procedure Management (RPM) for Product Lifecycle Management on IRIS
 - 11:25 CET: Electronic Application Form (eAF)
 - 11:55 CET: Veterinary Union Product Database (UPD)
- Link to YouTube livestream on the event page
- <https://www.ema.europa.eu/en/events/quarterly-system-demo-q4-2024>



Key 2025 agile governance dates for industry

2025	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
SPR						3					25	
SD			26			25			17			16
ROG					15 (tbc)						20 (tbc)	

- SPR Strategic Portfolio Review (with invited industry representatives)
- SD Quarterly System Demo (livestream)
- ROG Regulatory Optimisation Group (with invited industry representatives)

Industry Subject Matter Experts (SME)

- Mandate duration extended for three product teams
 - Regulatory Procedure Management (RPM) post-authorisation procedure epic until 30 June 2025
 - Product Management Service (PMS) Human & Application Interfaces epic until 31 March 2026
 - eCTD implementation epic until 31 March 2026
- Three new calls for industry experts
 - Veterinary Union Product database (UPD) further development and improvements epic – deadline for nominations 10 January 2025 (V)
 - Regulatory Procedure Management (RPM) initial marketing authorization application epic – deadline for nominations 10 January 2025 (H+V)
 - Electronic Product Information (ePI) implementation epic – to be launched in December or January (H)
- [List of industry SMEs](#) is published on EMA corporate website



Any questions?

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