EMA
EUROPEAN MEDICINES AGENCY

SPOR & XEVMPD Status Update

Recent & planned changes and impacts to users

9 July 2025

Housekeeping notes – Personal Data Protection disclaimer

*Please note that **this session is being recorded** and **will be made available** through the **EMA Corporate Website and EMA YouTube Channel***

*At certain points throughout the meeting, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.*

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For Questions: www.slido.com code: #STUP09725

Housekeeping notes – Q&A

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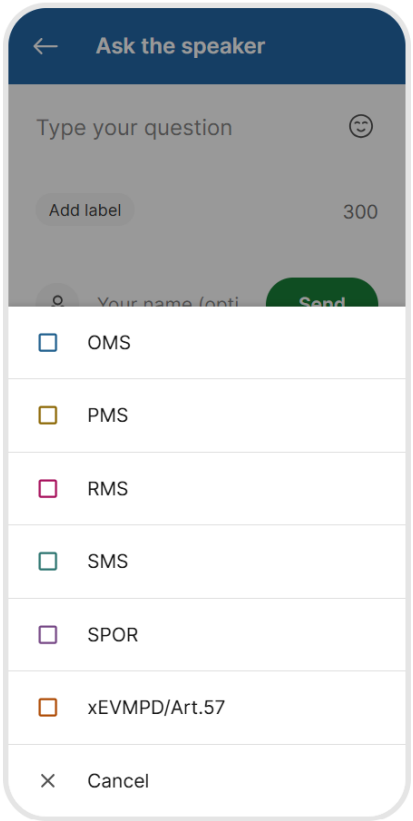
Housekeeping notes – Q&A labels

Before sending your question, please **use one of the following labels** to get your question answered in the relevant Q&A session:

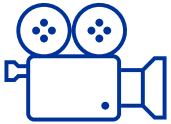
- *OMS*
- *PMS*
- *RMS*
- *SMS*
- *SPOR*
- *XEVMPD/ Art 57*



Housekeeping notes – Webinar materials

Presentation will be available at:

- SPOR Portal Documents section
- EMA Event Web Page



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Aim of this webinar

Today's webinar aims at sharing a short-term status update on **SMS, OMS, RMS, PMS and XEVMPD** focusing on **recent/ planned changes and impacts to users.**

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Agenda

1. **Welcome & Housekeeping notes**
   10 mins presentation (no Q&A)
   10:00 – 10:10
2. **SPOR, XEVMPD/PMS and customer engagement**
   10 mins presentation + 5 mins Q&A
   10:10 – 10:25
3. **SMS status update**
   10 mins presentation + 10 mins Q&A
   10:25 – 10:45
4. **OMS status update**
   10 mins presentation + 10 mins Q&A
   10:45 – 11:05
5. **RMS status update**
   10 mins presentation + 10 mins Q&A
   11:05 – 11:25
6. **XEVMPD status update**
   10 mins presentation + 10 mins Q&A
   11:25 – 11:45
7. **PMS status update**
   10 mins presentation + 10 mins Q&A
   11:45 – 12:05
8. **Conclusions – actions & further info**
   10 mins presentation (no Q&A)
   12:05 - 12:20
9. **Q&A Session**
   5 mins Q&A + 5 mins Slido survey
   12:20 – 12:30

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SPOR, XEVMPD/PMS and customer engagement

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Q3 objectives

Deliver efficient and effective regulatory data services

- Maintain the provision of S, O, R and XEVMPD/PMS data management services
- Prepare for Data Management Tender and/or Knowledge Transfer

Improve customer satisfaction and success

- Provide increased and targeted customer engagement

Modernise Data & Information Management

- Improve S, O, R and XEVMPD/PMS data management capabilities

How to stay connected to work on SPOR & XEVMPD

Looking for…

Latest updates

Join the quarterly S, P(XEVMPD), O & R status update webinars for latest information on past quarter progress and next quarter's plans → Next webinar: 8 Oct 2025

Subscribe to the Product Lifecycle Management Insights newsletter – featuring general SPOR news and public SPOR events

Live answers

New!

Join the S, O & R monthly Q&A clinics

Join the XEVMPD monthly Q&A clinics

*Both series are scheduled **from Sep to Dec 2025** - Based on participants' feedback, this period is **likely to be extended***

Training

New!

Consult the 2024 SPOR week webinars recordings in the dedicated EMA YouTube channel playlist for a deep-dive in each SPOR service

Feedback sharing

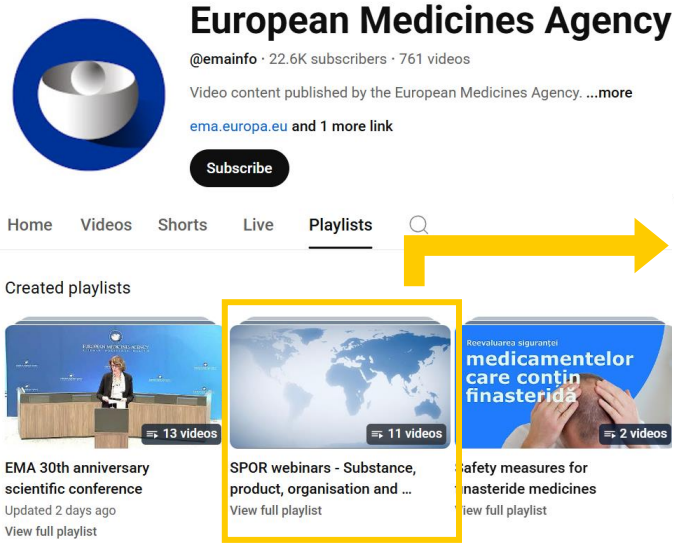
Fill in the **SPOR customer satisfaction survey**

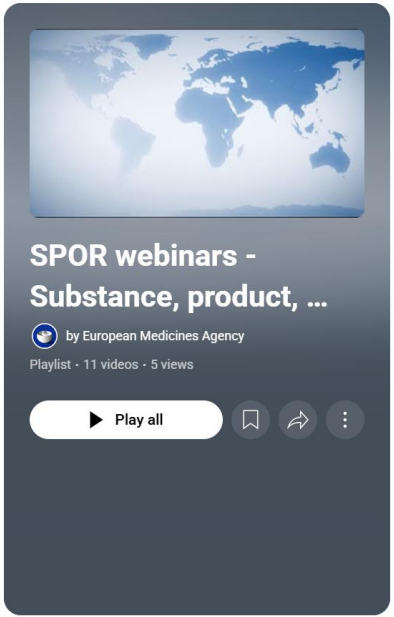
Next edition: Oct-Nov 2025

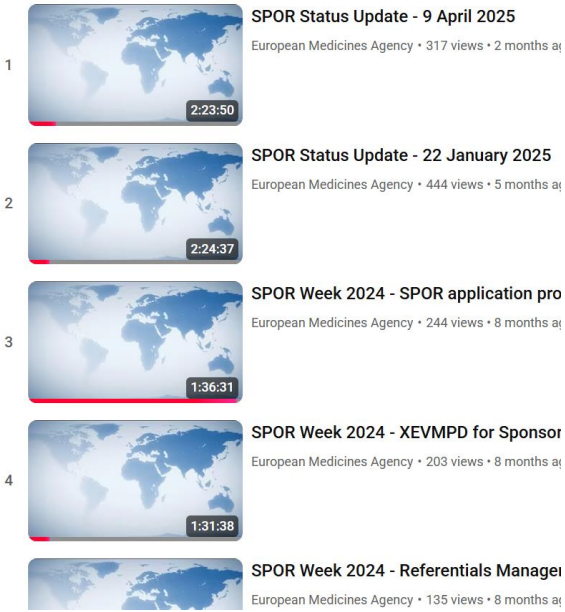
Focus on SPOR video library

Consult the SPOR video library on EMA's YouTube channel

New!







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Customer Satisfaction Survey 2025

The survey monitors:

- Performance
- Improvement Areas
- Trends

	Current process	Proposed process
Cadence	Conducted once a year	Conducted quarterly
Target audience	SPOR users	SPOR users
Distribution channel	EU survey individual email	Slido public link published on EMA website & SPOR portal
Question type	Same questions every year	Questions slightly adjusted every quarter

Q&A time

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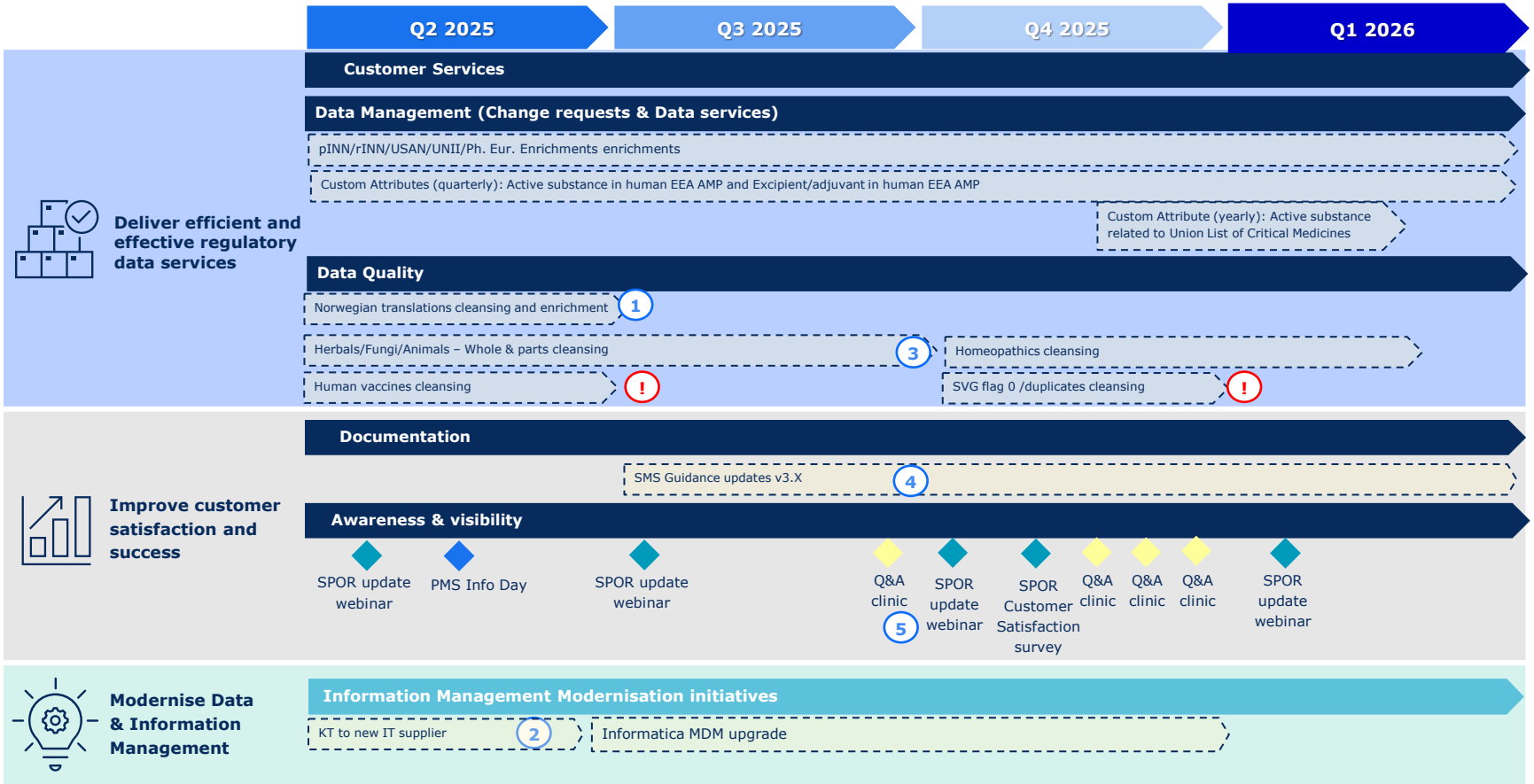
SMS status update

Planned SMS Activities



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Work completed – What has been done in Q2 2025

	Why	How & when	Impact/ benefits to users
Norwegian translations cleansing and enrichment 1	• **Cleansing/enrichment** initiative by the Norwegian Medical Products Agency (NOMA) to **address Norwegian translations** of substances in SMS	• Already registered Norwegian **translations reviewed** by NOMA with incorrect translations removed by SMS team • **Missing** Norwegian translations provided by NOMA and registered by SMS team • Maintenance process being defined with NOMA	• High quality of Norwegian translations in SMS
KT to new IT supplier 2	• Due to procurement cycles and new Framework Contract in place	• Knowledge transfer has now been completed • Repriositisation of SOR backlog ongoing	• Improvements in the **SMS exports** that were planned for Q1 are now **delayed** to later quarters

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What's next? – What will be done in Q3 2025

	Why	How & when	Impact/ benefits to users
3 **Herbals/fungi/animals cleansing**	• Quick win, easy to cleanse and outsource • Enable the future cleansing of homeopathic substances and herbal extracts	• SMS pre-cleansing completed • SVG discussions to start soon • Planned SVG cleansing completion in Q3	• **Improved Data Quality** • New substance groups cleansed and business rules defined for new substance records
4 **SMS Guidance V3.X**	• Reacting to feedback from customer satisfaction survey where customers demanded more and faster access to information	• **Iterative versions over the year** with updates in Business Rules for additional substance types/groups at a time	• More frequent **documentation** updates • Enhanced supporting documentation allowing improved awareness • Predictability of how substances will be registered and maintained
5 **SOR Q&A clinics**	• To provide users with an opportunity to ask questions related to substance, organisation and referential processes	▪ Q&A sessions organized on *monthly basis*, starting *in September* ▪ *08 September* ▪ *13 October* ▪ *10 November* ▪ *15 December*	• Live interaction between SPOR users and EMA's SMS, OMS and RMS business team

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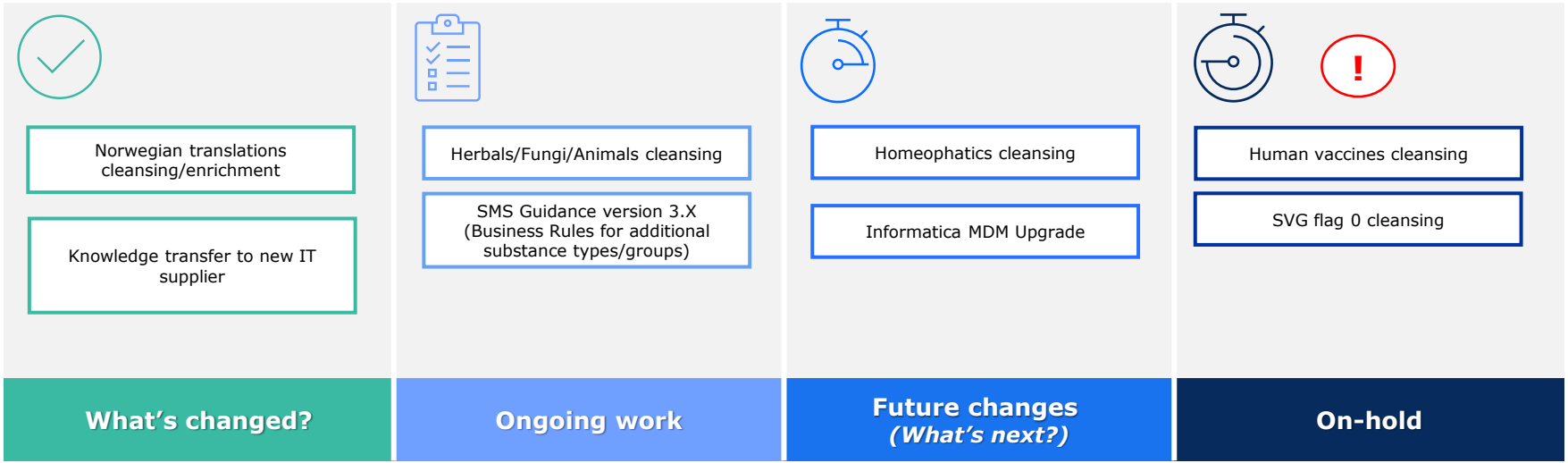
Highlights to you



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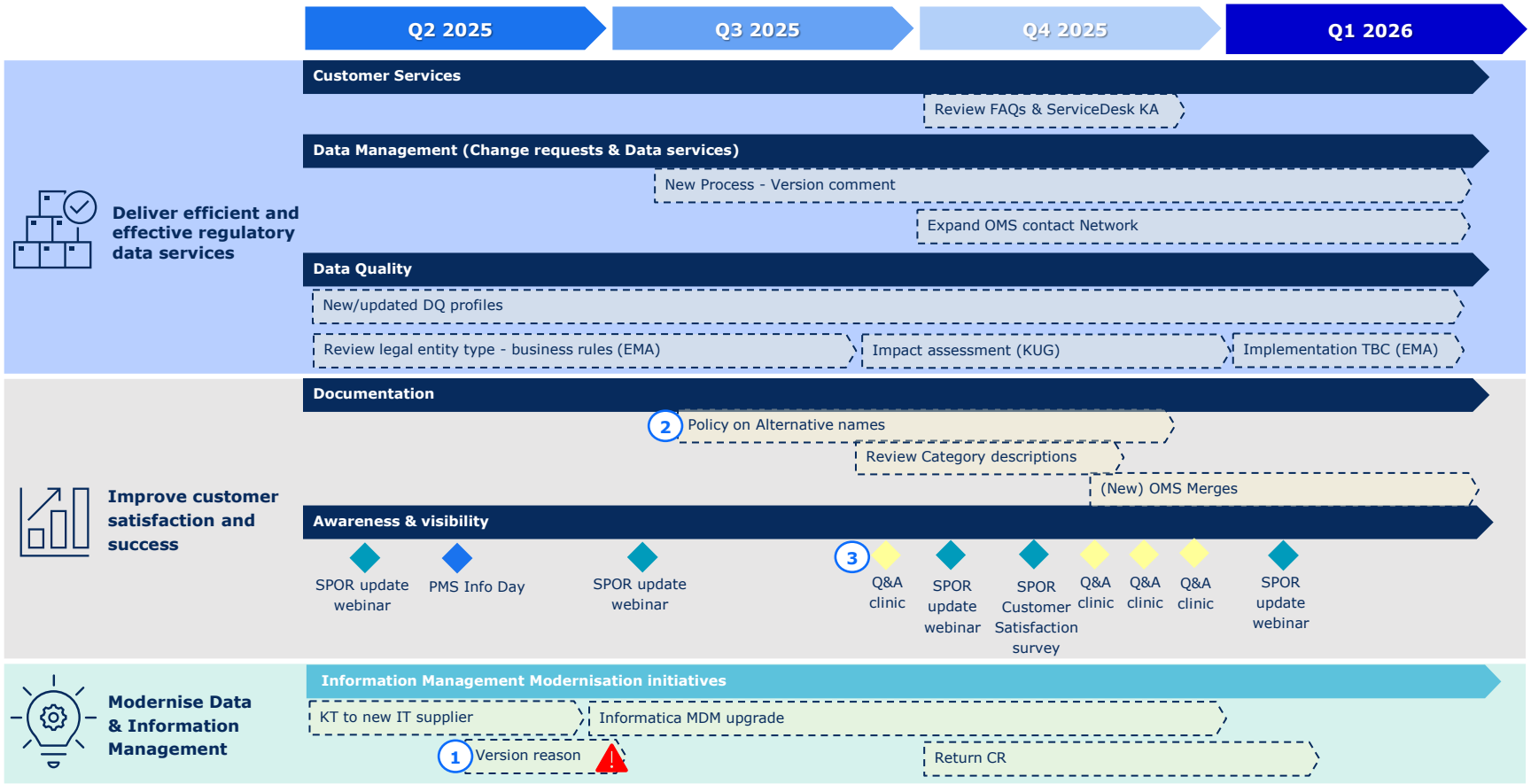
OMS status update

Planned OMS Activities



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Work completed – What has been done in Q2 2025

	Why	How & when	Impact/ benefits to users

Version reason 1	• **Transparency** on the reason to create a **new version** at organisation and location level	• For each new version OMS will maintain 2 fields:
		  • Version type – standard RMS terms
		  • Version comment – further details on reason/outcome
		• This feature has been **completed**, and is **currently in UAT environment,** allowing for Users activities
		• **2 Phased implementation**
		  • **Preparation** - OMS notified all registered API users on **July 1st 2025**
		  • **Phase 1 – OMS system and API** > expected in PROD on **July 16th 2025**
		  • **Phase 2 – OMS exports** > date TBC
			System Change - Prepare for future integration/planning by **using UAT environment**
			• **Improved transparency/traceability of changes -** Clearer reason for creation of new version, e.g.
			  • Version type: Location standardisation + Comment: what changed
			  • Version type: Business merge + Comments: which ID will become the master/prevail

For Questions: www.slido.com code: #STUP09725

What's next? – What will be done in Q3 2025

	Why	How & when	Impact/ benefits to users
2 **Policy on Alternative names**	• Unclear data management rules, and **inconsistent use of OMS alternative names** across processes creates confusion/questions	• KUG to define scope/focus of policy and next steps required in Q3 2025	• **Guidance/documentation** with clear recommendations on the correct use of alternative names in regulatory procedures
3 **SOR Q&A clinics**	• To provide users with an opportunity to ask questions related to substance, organisation and referential processes	▪ Q&A sessions organized on *monthly basis*, starting *in September* ▪ *08 September* ▪ *13 October* ▪ *10 November* ▪ *15 December*	• Live interaction between SPOR users and EMA's SMS, OMS and RMS business team

NEWS: As of 15 July the Spanish NCA (AEMPS) will make OMS mandatory for:

- applications for new registrations and MA variations for nationally registered medicines
- applications for national codes for centrally authorised medicines and their variations

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Highlights to you

Version reason

Knowledge Transfer to new IT supplier

What's changed?

Informatica MDM upgrade

Return CR functionality

Review organisation legal entity types

Ongoing work

Policy on Alternative names

Category values/description review

MDM upgrade

Future changes *(What's next?)*

OMS improvements/backlog i.e Maintenance of NBRn via CR, record subscription

Block submission of duplicated requests

OMS merges guidelines

Future changes *(What's later?)*

Acronyms

NFR: New Fee Regulation

MAH: Marketing Authorisation Holder

MDM/IDD: Master Data Management solution/Informatica Data Director (user interface)

CR: Change Request

NBRn: National Business Registries number

SAP: Statutory Accounting Principles

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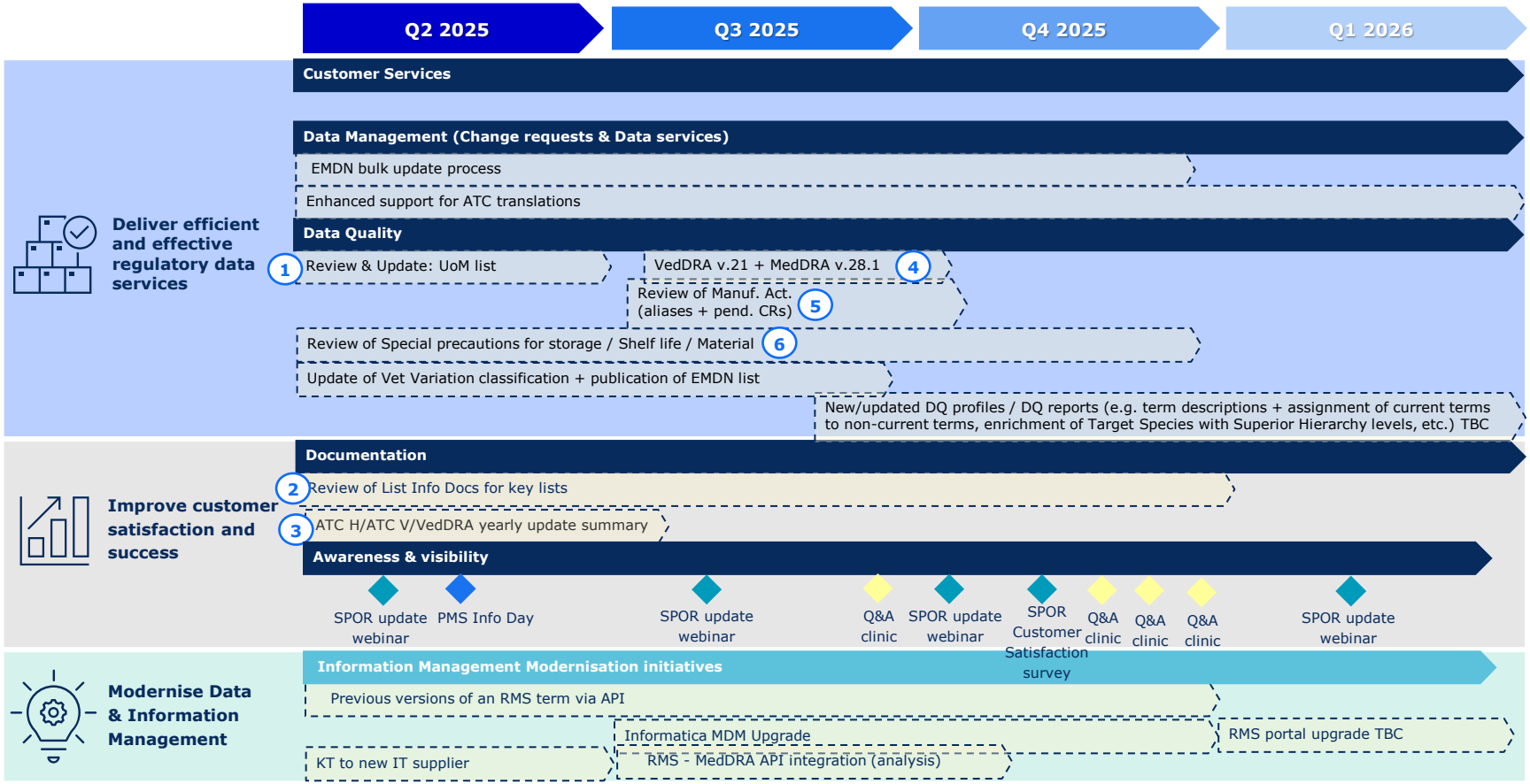
RMS status update

Planned RMS Activities



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Work completed – What has been done in Q2 2025

	Why	How & when	Impact/ benefits to users
Review & Update of Units of Measurement 1	• UoM list has data quality issues such as **missing unit symbols or other extended attributes** (e.g. UoM type or fraction position)**,** or **incorrect UCUM codes**	• Review and update of already populated fields & enrichment of empty fields.	• **Improved Data Quality/Clarity** • **Better understanding and usage of the list terms**, reducing any technical issues triggered by missing data in consuming systems such as PMS or eAF.
Review of List Info Docs for key lists 2	• At the beginning of 2025 around **30%** of RMS lists didn´t have list information document. This has to be addressed as this doc provides essential information on the RMS list. • RMS plans to publish ~15 list information documents per quarter and complete all lists by the end of 2025.	**10 List info docs published during Q2 2025**: Substance Type, Substance Name Type, OMS Request Type, Substance Authorisation Status, Substance Relationship Role, Substance Relationship Combination, Substance Name Domain, Substance Document Type, ASU Use Categories, ASU Antimicrobial Classification. Next list info docs planned for publication: Material, Official Name Type, Country Subdivisions, Document Type, Clinical Trial Mehodology Elements, Non-Clinical Development Areas, Clinical Trial Design Elements, Medical Device Classification, etc.	• **Percentage of lists missing the document is now 21% (June 2025)**. • **Improved Transparency and efficiency** • Increased awareness of RMS lists. • Reduction of list-related questions and submission errors.
ATC H/ATC V yearly update summary 3	• There is **no easy way to identify within the SPOR portal what exactly has changed with the yearly updates.**	• Starting in Q2 2025, a **document showing the new terms inserted and the terms updated with the yearly review** are published in the **Documentation area** of the **RMS portal.**	• Increased **transparency** and **awareness** of lists updates.

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What's next? – What will be done in Q3 2025

	Why	How & when	Impact/ benefits to users
4 VedDRA v. 21 + MedDRA v 28.1	• VedDRA is updated once yearly by EMA & MedDRA is updated twice yearly by MSSO. RMS publishes the updates as soon as possible after these updates are made available.	• Both lists are expected to be updated in Q3 2025 and therefore the changes are expected to be replicated within the same quarter (ideally within one month of publication by the maintenance organisation).	• Complete and up to date lists in RMS may increase usage of terms and should reduce the number of requests for new or updated terms.
5 Review of Manufacturing Activities (aliases + pending CRs)	• Only few terms contain aliases/other names, creating confusion/questions from users.	• **Consultation** with the multidisciplinary group planned for **Q3 2025**. • List will be updated afterwards and **minutes will be published in the RMS portal.**	• **Improved clarity and process efficiency** • Aliases will help improve understanding of the terms and reduce the number of questions to EMA or the number of CRs rejected due to lack of awareness of the list.

6 Review of Special Precautions for Storage/Shelf Life/Material	• **Increasing number of requests** and the need to have them ready for PMS implementation.	• **Subject matter experts** will be **identified** in **Q3 2025**.
		• Review planned to start in Q3 2025 and implementation by the end of Q4 2025.
			• **Improved clarity and process efficiency**
			  • Reassurance to users that lists are fit for purpose.
			  • Complete and up to date lists will ensure that the selection of referentials in regulatory applications is straightforward.

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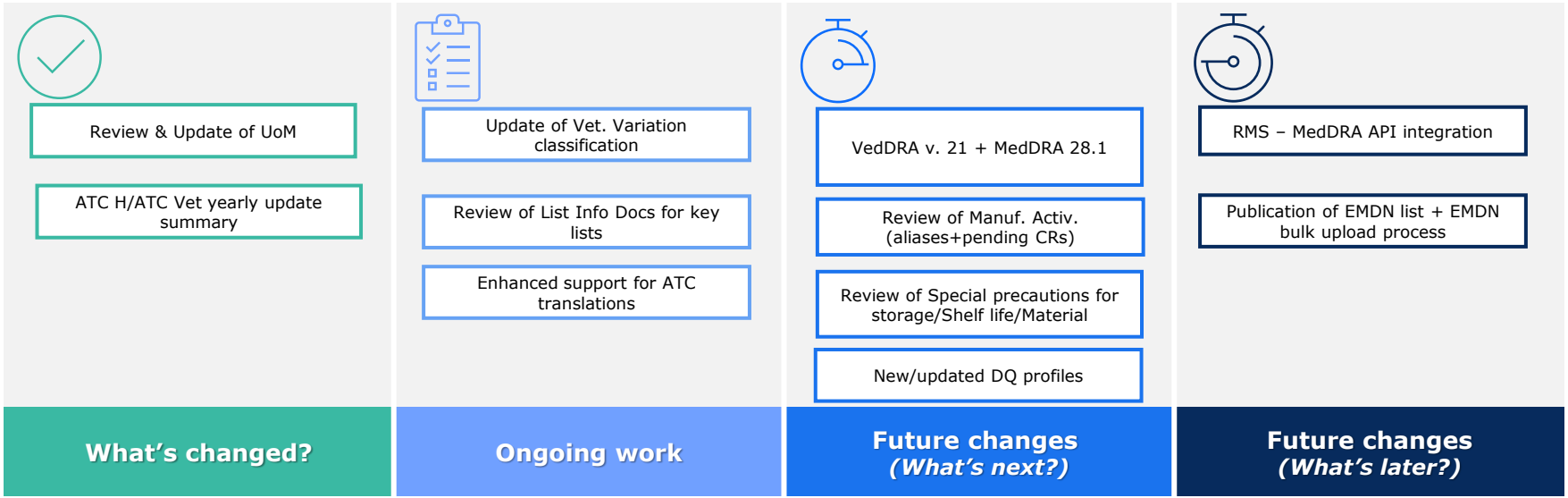
Highlights to you



Acronyms

MedDRA: Medical Dictionary for Drug Regulatory Activities

VedDRA: Veterinary Dictionary for Drug Regulatory Activities

DQ: Data Quality

CR: Change Request

API: Application Programming Interface

EMDN: European Medical Device Nomenclature

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XEVMPD status update

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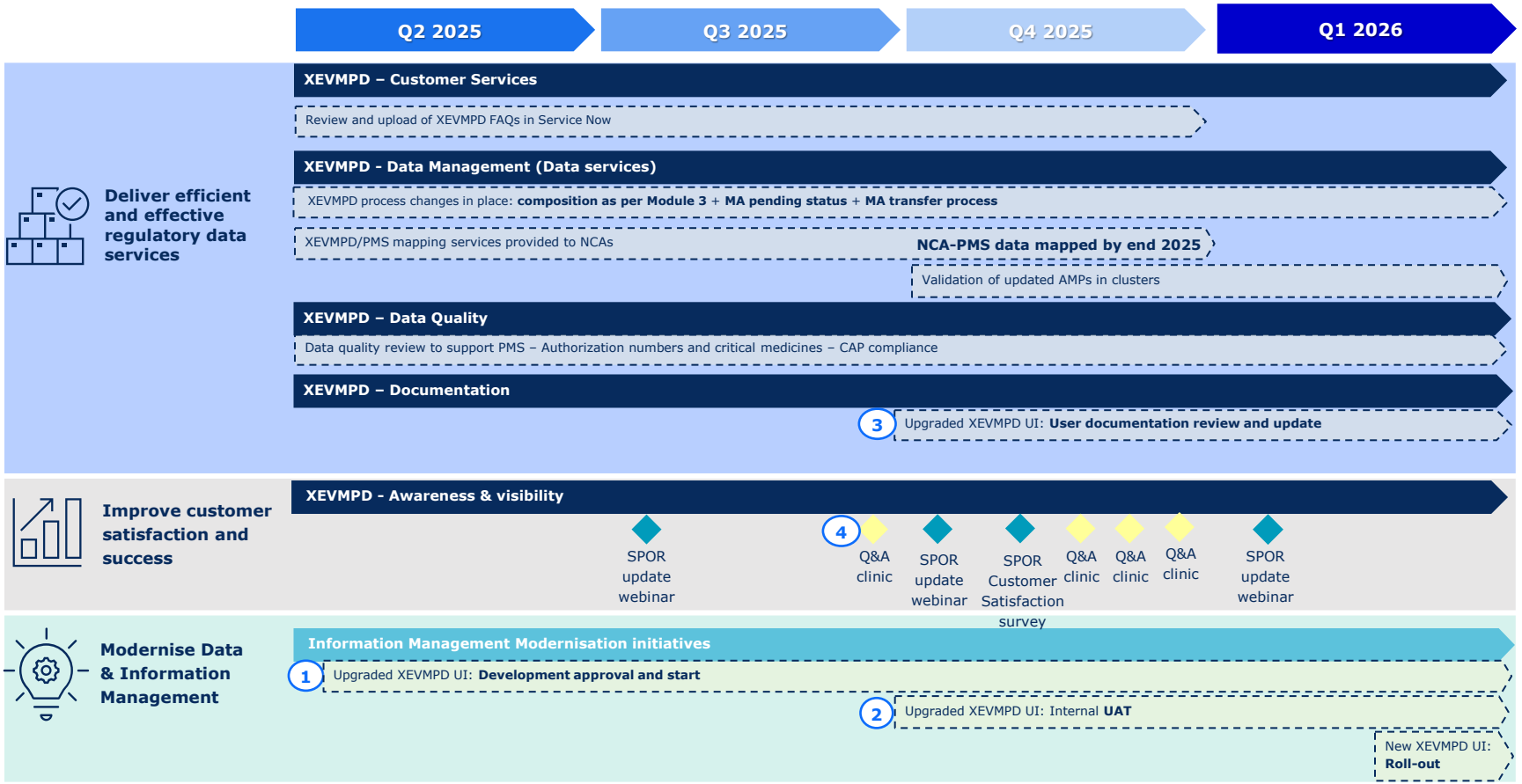
Planned XEVMPD Activities



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Work completed – What has been done in Q2 2025

	Why	How & when	Impact/ benefits to users
1 Upgraded XEVMPD UI: development approval and start	• To deliver upgraded version of the XEVMPD UI to users in Q1/2026	▪ Management **approval obtained** *in Q2/2025* ▪ **Development** of upgraded UI **started** ▪ Provisional **delivery plan defined**; -> updates on progress will be provided during status update webinars	• **Improved user experience**: easier access for users, browser-based solution which can be used in other supported browsers; • Upgraded UI has the **same/similar look and feel as the current UI**; • **No need for training** on how to use the upgraded solution; the application is similar and intuitive

What's next? – What will be done in Q3 2025

	Why	How & when	Impact/ benefits to users
2 Upgraded XEVMPD UI: UAT	• To ensure that all functionalities work as designed and support all business processes in use	• Internal UAT to be performed (by EMA and XEVMPD trainers), • **No external UAT planned/required**; • Phased testing: *-> UAT phase 1 planned for end of Q3*	• **Functionalities available to industry users are expected to remain similar to the ones in place**
3 Upgraded XEVMPD UI: User documentation review and update	• To ensure that updated documentation is available at the time of planned roll-out	• Update of the **User Manual** for the upgraded UI to start at the *end of Q3* • Other documentation (step by steps, training presentations etc.) to follow • Progress updates to be provided during status update webinars	• Updated documentation for the upgraded UI is available at the time of roll-out (foreseen for the end of Q1/2025)
4 New: XEVMPD Q&A Clinic	• To provide MAH and sponsor users with an opportunity to ask questions related to their XEVMPD submissions	▪ Q&A sessions organised on *monthly basis*, starting *in September* ▪ *18 September* ▪ *14 October* ▪ *18 November* ▪ *18 December*	• Live interaction between industry and EMA's XEVMPD business team

Highlights to you

What's changed?

- Amendment in process: notifications of **MA transfers** approved after 1 Jan 2025
- Submission of **AMP composition** as per **Module 3 dossier**
- '**Valid – pending national phase**' MA status in Art57 database
- **Windsor Framework** in force from 1 January 2025

Ongoing work

- Improvement on **cluster validation process <u>for new AMPs</u>**
- XEVMPD/PMS **mapping services** provided to NCAs
- **Development of new solution** for XEVMPD User Interface

Future changes *(What's next?)*

- XEVMPD Q&As available as '**Articles**' **in ServiceNow**
- **Review and update of documentation** for upgraded XEVMPD UI

Future changes *(What's later?)*

- Integration of product validation with review of substances with SVG flag 0
- Upgraded XEVMD UI available from Q1/2026
- Improvement on **cluster validation process <u>for updated AMPs</u>**

Acronyms

XEVMPD: Extended EudraVigilance medicinal product dictionary

AMPs: Authorised Medicinal Products

DCP: De-Centralised Procedure

MA: Marketing authorisation

MRP: Mutual Recognition Procedure

NCA: National Competent Authority

PMS: Product Management Service

SVG: Substance Validation Group

UAT: User Acceptance Testing

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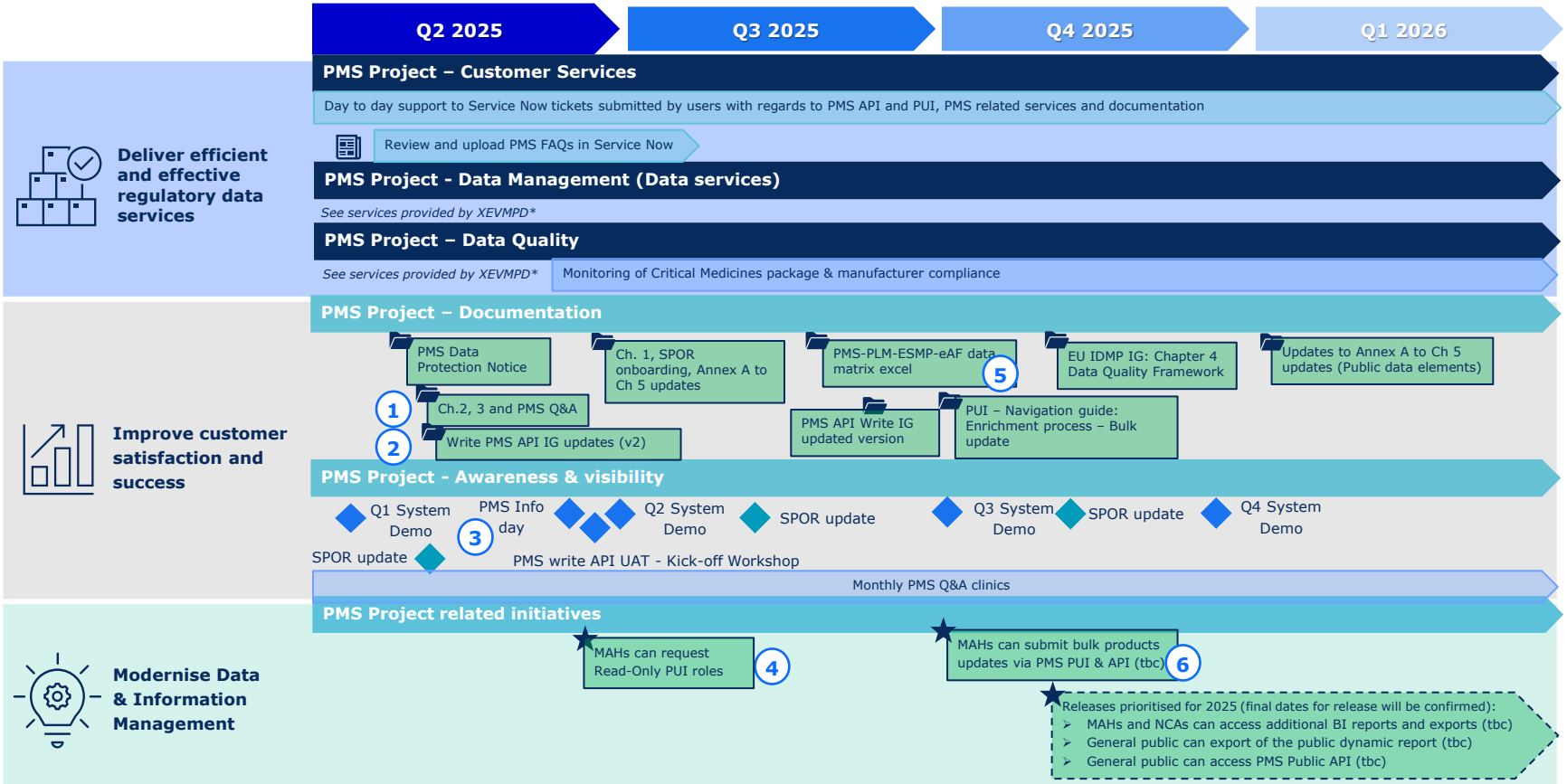
PMS status update

Planned PMS Activities



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* Link with xEVMPD status update

Document release | Milestone | SPOR update webinars | PMS webinars

Work completed – What has been done in Q2 2025

	Why	How & when	Impact/ benefits to users
1 **PMS documentation updates**	To incorporate **user feedback** and refine business rules and specifications for **structured manufacturer data** and **pack sizes**.	Updates published in **Q2 2025** on the **PMS webpage** and **PLM portal**, including: • Chapter 2: Business rules & conformance for manufacturers and pack sizes • Chapter 3: Clarifications on structured Manufacturer operations and pack size data submission • PMS Q&A: Bug clarifications on identified Data Quality issues and timelines for fixing	• Provides **clearer guidance** and improved support • Helps users **automate submissions** and boost **operational efficiency**
2 **Write PMS API IG v2**	To support MAH or software developers **building machine-to-machine connections between RIM systems and the PMS API.**	Updates released in **May 2025**, on PMS webpage providing to technical expert, software developers and vendors additional technical specs and clarifications to submit a limited set of products data in PMS API. Note: New updated version expected in Q3.	Updated **documentation** and **increased user support** enabling them to automate data submissions and improve operational efficiency.
3 **PMS Info Day**	Raise awareness and inform stakeholders on PMS impacts.	**PMS Info Day:** Wednesday, 21 May 2025, 09:00 - 17:30 Live broadcast Event page: Link	• **Engagement & Insights:** Gain direct access to PMS information and EU readiness updates. • **Reliable Release:** Prepares testers for effective API validation, supporting a stable production rollout.

What's next? – What will be done in Q3 2025

	Why	How & when	Impact/ benefits to users
4 PUI Industry Read vs Write roles	The role split clarifies permissions, reduces confusion, and ensures users access only what is relevant, improving efficiency.	**Starting July 2025**, users can request relevant **Read-Only (RO) roles** via the EMA Account Management portal: • PUI Industry Read user • PUI Industry Qualifier Read user	• Users can now be assigned either **Read-Only (R)** or **Read+Write (R+W)** access, providing more flexibility and security. • All **previously registered users retain their Read+Write capabilities.** • Admins can **review and redistribute role permissions** to fit the appropriate access level (R or R+W) for their team members.
5 PMS-PLM-ESMP-eAF data matrix excel file	To ensure better understanding of **product data elements** used/required by applications and **use cases**	A Data matrix/Excel file with **PMS data elements** and its use by **PMS/PUI, eAF, and ESMP** will be released in **mid-Q2 2025** on the **PMS webpage and the PMS PUI guidance portal.**	**Enhanced Clarity & Alignment -** Ensuring better understanding on how PMS data is consumed by different systems.
6 Release of Write PMS API & PUI Enrichment process – Bulk update & Guide updates	• To enable non-CAP MAHs to efficiently **submit high volumes** of product data **updates**. • To timely **comply with ESMP deadlines** while ensuring data quality and consistency across submissions.	• **Production** is planned for **September 2025**. • **UAT starts in July 2025**, with 1 month for Write PMS API testing and 2 weeks for PUI Bulk Upload testing before that.	• Enables **bulk data submission** at scale. • Ensures functionality is **validated and ready** for production use.

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Highlights to you

PMS Data Protection Notice

EU IG Chapters 2 & 3, and PMS Q&A

Write PMS API Implementation Guide v2

PMS Info Day and Write API UAT - Kick-off Workshop events

What's changed?

New PUI Industry roles release

Release of Write PMS API & PUI Enrichment process & Guides

PMS-PLM-ESMP-eAF data matrix excel file

PMS data quality improvements & data fixes

Ongoing work

Continuous PMS data quality improvements & data fixes

EU IDMP IG: Chapter 4 Data Quality Framework

Public PMS API

Future changes *(What's next?)*

PMS FHIR R5 upgrade

XEVMPD submissions decomissioned

Future changes *(What's later?)*

Acronyms

PMS: Product Management Service
PUI: Product User Interface
MAH: Marketing Authorisation Holder
NCA: National Competent Authority
EU IG: EU IDMP Implementation Guide
FAQ: Frequently Asked Questions
NAPs: Nationally Authorised Products
PMS API: PMS Application Programming Interface

For Questions: www.slido.com code: #STUP09725

Q&A time

You can ask questions via the audience interaction tool **Slido**.

1. **Join at slido.com** with the code #STUP09725 or by scanning the QR code here.

2. **Send or upvote the questions** you want to hear answered
3. **Questions will be shown on the screen** and EMA colleagues will **verbally address top 5 voted questions** in the live Q&A sessions.

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

Conclusions

 For Questions: www.slido.com code: #STUP09725

Q3 Highlights

Improve customer satisfaction and success

Provide increased and targeted customer engagement

- S, O, R and XEVMPD monthly clinics
- Organised SPOR information and Training material
- New Customer satisfaction survey
- Updated SMS, OMS and PMS Guidance

Deliver efficient and effective regulatory data services

- Maintain the provision of S, O, R and XEVMPD/PMS data management services
  - SMS: Norwegian translations
  - RMS: ATC H, ATC V yearly updates summary
- Prepare for Data Management Tender and/or Knowledge Transfer

Modernise Data & Information Management

Improve XEVMPD/PMS data management services (and capabilities)

- SPOR: IT Knowledge transfer completed
- ⚠ OMS version – **go-live 16 July 2025!**
- XEVMPD UI upgrade started
- PMS bulk product updates via PMS PUI & API (tbc)

EMA

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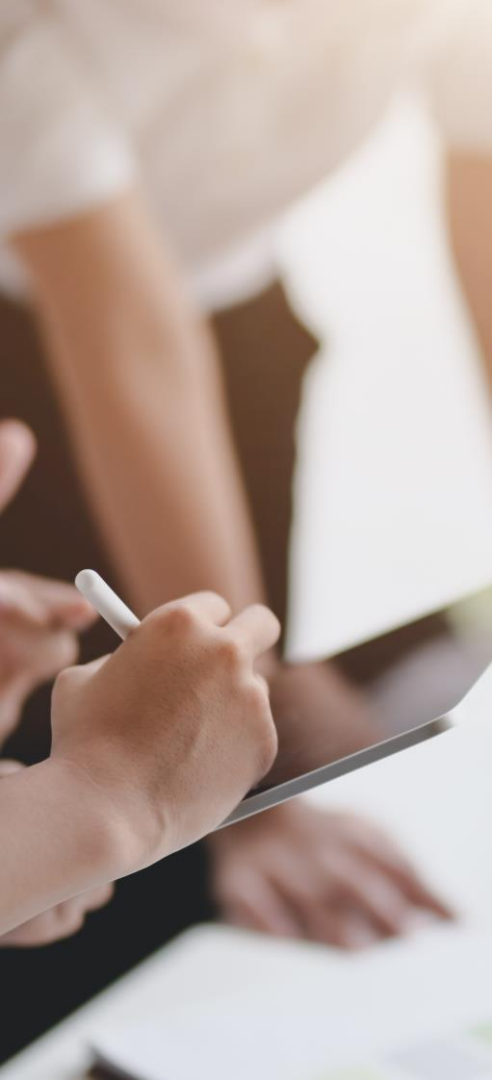

Your feedback matters

- Please spare a few minutes to **complete the survey** in Slido, sharing your feedback on **today's webinar**.
- **Join Slido.com** using this code **#STUP09725** or scan this QR code

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Thank you

More information: SPOR Web Page

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