EMA
EUROPEAN MEDICINES AGENCY

SPOR & XEVMPD Status Update

Recent & planned changes and impacts to users

9 April 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**.*

*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.*

For Questions: www.slido.com code: #STUP09425

Housekeeping notes – Q&A

You can ask questions or give your input via the audience interaction tool **Slido**.

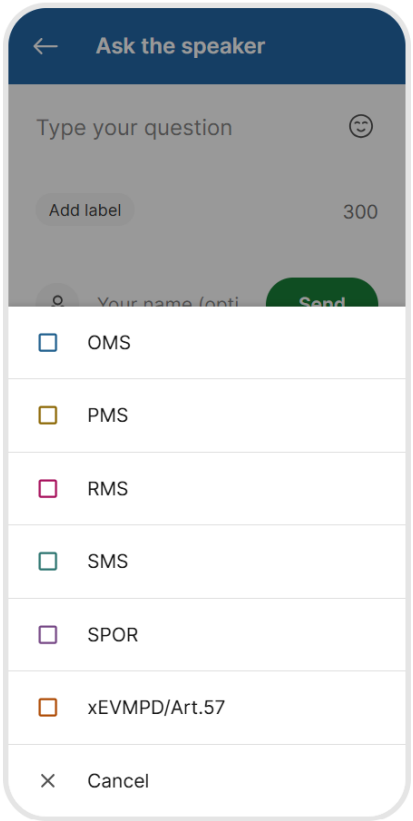
1. **Join at slido.com** with the code #STUP09425 or by scanning the QR code below.
2. **Send or upvote the questions** you want to hear answered
3. **Questions will be shown on the screen** and EMA colleagues will **verbally address top 5 voted questions** in the live Q&A sessions.

*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.*

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:

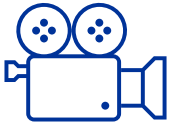
- *OMS*
- *PMS*
- *RMS*
- *SMS*
- *SPOR*
- *XEVMPD/ Art 57*



Housekeeping notes – Webinar materials

Presentation will be available at:

- SPOR Portal Documents section
- EMA Event Web Page



Recording will be available at:

- EMA YouTube Channel
- EMA Event Web Page

For Questions: www.slido.com code: #STUP09425

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.**

For Questions: www.slido.com code: #STUP09425

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 survey + 5 mins Q&A
   10:10 – 10:35
3. **SMS status update**
   10 mins presentation + 10 mins Q&A
   10:35 – 10:55
4. **OMS status update**
   10 mins presentation + 10 mins Q&A
   10:55 – 11:15
5. **RMS status update**
   10 mins presentation + 10 mins Q&A
   11:15 – 11:35
6. **XEVMPD status update**
   10 mins presentation + 10 mins Q&A
   11:35 – 11:55
7. **PMS status update**
   10 mins presentation + 10 mins Q&A
   11:55 – 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
   12:20 – 12:30

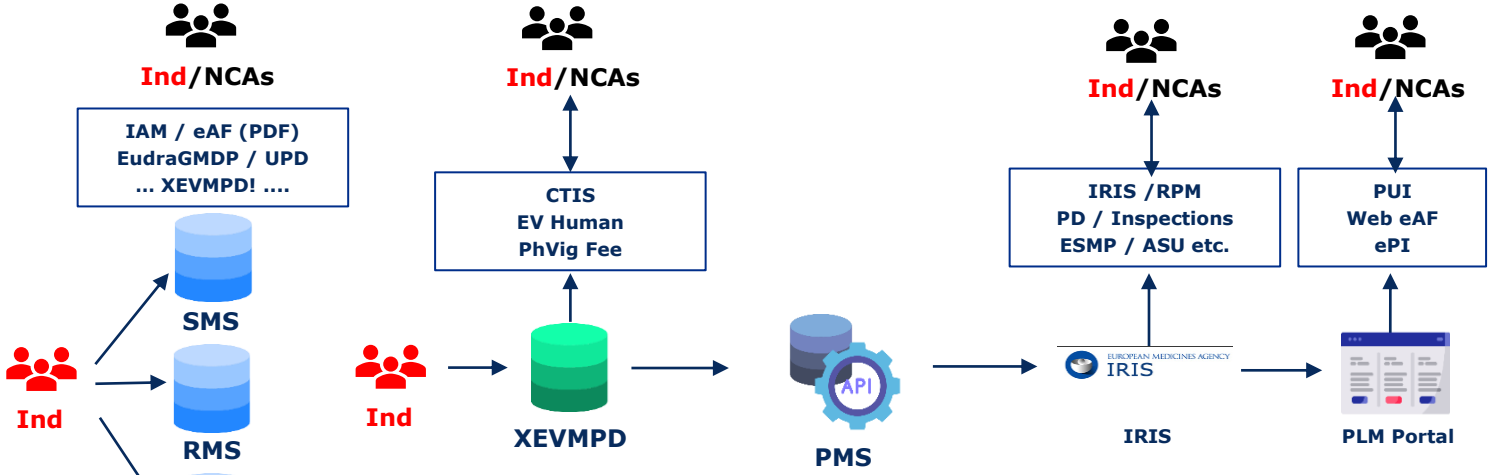
For Questions: www.slido.com code: #STUP09425

SPOR, XEVMPD/PMS and customer engagement

For Questions: www.slido.com code: #STUP09425

SPOR, XEVMPD/PMS and other processes

What is registered in **SMS, OMS and RMS** and **how data is mapped affects** what Industry will see in **XEVMPD, PMS and other solutions!**



- Industry should **request** Substances Terms and Organisations/locations **ahead of application**/ XEVMPD submissions
- Industry cannot update data in PMS or other solutions; **if update is required, product data must be updated in XEVMPD**
- Industry and NCAs interact with EU systems/applications where SPOR data is used, including product data

For Questions: www.slido.com code: #STUP09425

How to stay connected to work on SPOR & XEVMPD

SPOR engagement in 2025

S, P(XEVMPD), O & R Status update Webinars

- Achievements vs what is planned;
- Key highlights for SPOR users

1) 9 April 2025
2) 9 July 2025
3) 8 October 2025

Announced via EMA's Website Events Pages

S, P(XEVMPD), O & R week

NEW FORMAT TBC!

Give us your feedback!

TBC October 2025

Announced via EMA's Website Events Pages

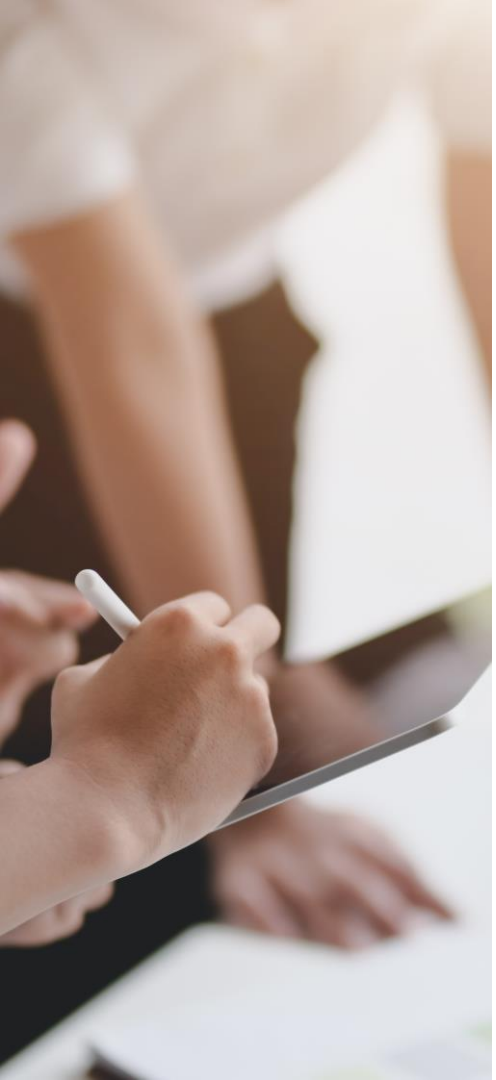
SPOR customer satisfaction survey

NEW FORMAT TBC!

Give us your feedback!

TBC Oct-Nov 2025

Announced via SPOR webinars & email

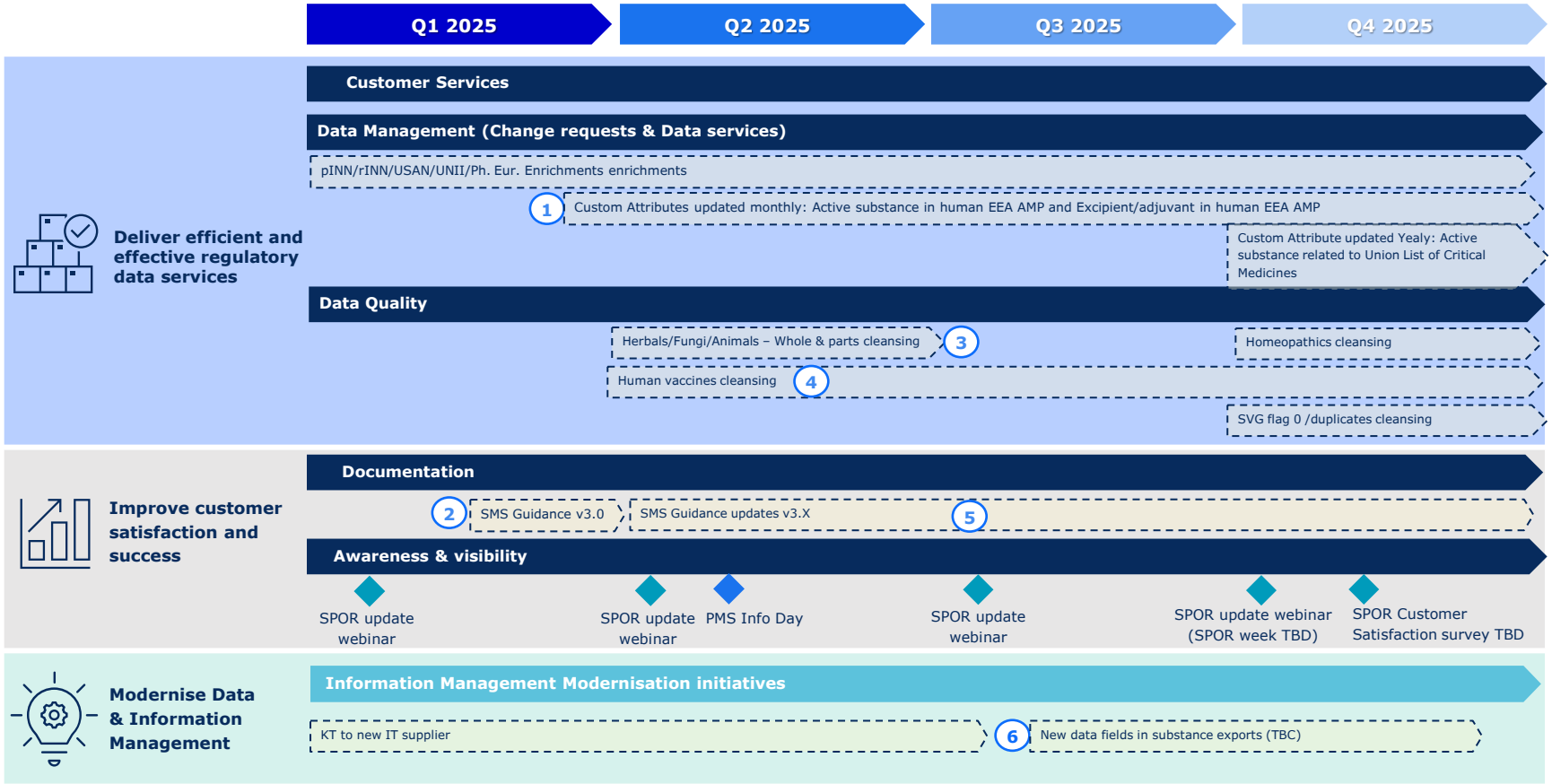


Your feedback matters

- Please spare a few minutes to **complete the survey** in Slido, sharing your feedback on **SPOR engagement activities** to help us tailor them to your needs.
- **Join Slido.com** using this code **#STUP09425** or scan this QR code

SMS status update

Planned SMS Activities



 For Questions: www.slido.com code: #STUP09425

Work completed – What has been done in Q1 2025

	Why	How & when	Impact/ benefits to users

1 Custom Attributes related to substance role in human AMP	• Addressing the request from stakeholders on better identification of substances used in human AMP	• Relevant substances have been updated with two Custom Attributes related to its role in human authorised medicinal products:
		  • Active substance in valid EEA human AMP (RMS ID 200000043379)
		  • Excipient/Adjuvant in valid EEA human AMP (RMS ID 200000045061)
		• These Custom Attributes will be updated on a **quarterly basis**.
		• Custom Attributes are only visible via the SMS API
			• **New data/attributes visible to API users!**
			• Supporting Health use case e.g. ePrescription
			• Supporting the generation of Global Substance IDs (GSIDs)
			• Better substance data cleansing prioritisation

2 SMS Guidance for External Users 3.0	• Reacting to feedback from customer satisfaction survey where customers demanded more/ better documentation	• Revised version describing new **Data Enrichments** and **Business Rules**	• **Enhanced supporting documentation** allowing improved awareness • Predictability of how substances will be registered and maintained

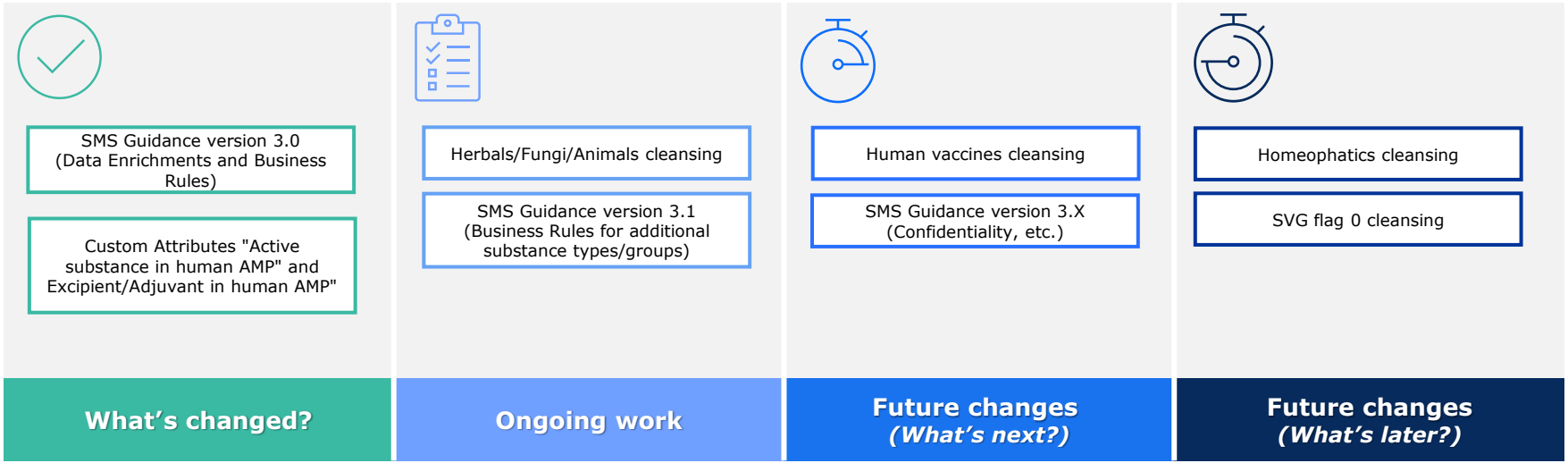
 For Questions: www.slido.com code: #STUP09425

What's next? – What will be done in Q2 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 Q2	• **Improved Data Quality** • New substance groups cleansed and business rules defined for new substance records
4 Human vaccines cleansing	• Complete the cleansing of substances used in Critical Medicines	• SVG cleansing is ongoing • **Priorisitation of human vaccines from Critical Medicines** • Afterwards, focus on human vaccines used in approved products	• **Improved Data Quality** • Reliable/stable list of active substances used in Union List of Critical Medicines • New substance groups cleansed and business rules defined for new substances
5 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 key sections at a time	• More frequent **documentation** updates • Enhanced supporting documentation allowing improved awareness • Predictability of how substances will be registered and maintained
6 Knowledge Transfer (KT) from existing IT supplier to new IT supplier	• Due to procurement cycles and new Framework Contract in place	• SMS IT development has been temporarily put on hold and focus is **in providing Knowledge Transfer (KT) from existing IT supplier to new IT supplier**	• Improvements in the SMS exports that were planned for Q1 are now delayed to later quarters

 For Questions: www.slido.com code: #STUP09425

Highlights to you



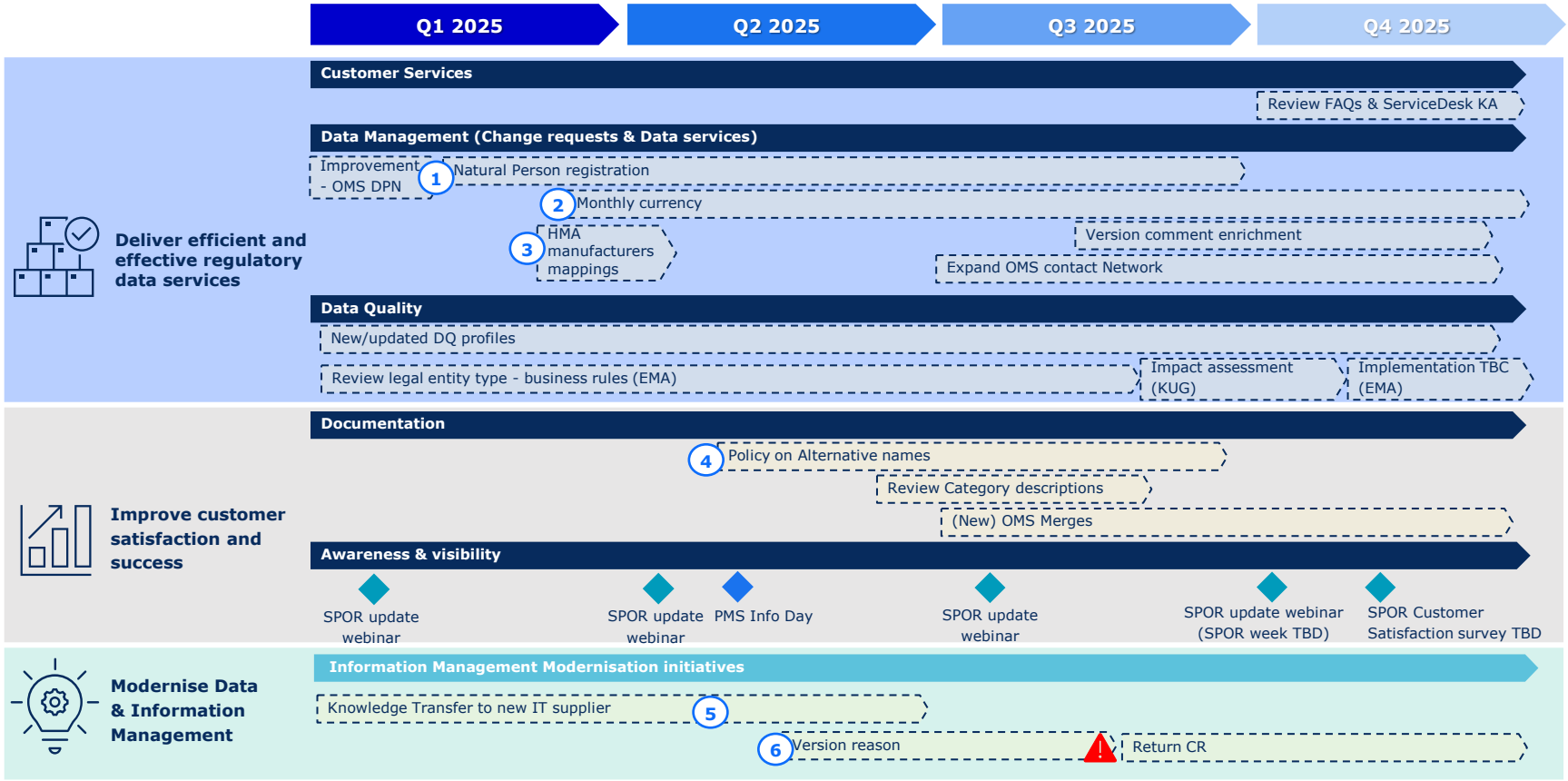
Acronyms

AMP: Authorised Medicinal Product

For Questions: www.slido.com code: #STUP09425

OMS status update

Planned OMS Activities



For Questions: www.slido.com code: #STUP09425

Work completed – What has been done in Q1 2025

	Why	How & when	Impact/ benefits to users
1 Natural Person registration	• Certain Individuals/Natural Persons are needed to **support veterinary procedures in UPD, EudraGMDP certificates and EV MAH obligations.**	• OMS now registers **Individuals/Natural Persons** for which there is a **legal justification** and are **not registered with National Business Registry** • **Resolution of 12 tickets** opened whilst the discussion/process was being developed • Further clarification on the process consult T - OMS Data Protection Notice	• **Service improvement -** We don't necessarily expect more/all Individuals/Natural persons to register in OMS – this however allows that **specific requests** for **can be resolved.**
2 Monthly currency	• Ensure information in OMS is **current** • Create **process efficiencies** and **prevent accumulation of "outdated" records**	• Streamlined currency check **from yearly to a monthly activity,** reviewing organisations that have **not been updated for more than 2 years** in that given month	• **Improved Data Quality –** prevent inactive Organisations of being incorrectly used in applications/regulatory processes • Currency check is a "back-up plan"- **Companies are still requested to inform OMS when an organisation ceases to operate**!
3 HMA Manufacturers mapping	• To **expedite communication of surveillance results** within Network, OMS Loc Identifier will be added to **HMA Post marketing risk assessment tool**	• OMS is mapping all manufacturers used in HMA **Post marketing risk assessment tool:** › mapping of finished product manufacturers is concluded › **mapping of API manufacturers** is ongoing	• **Improved Data Quality –** All API and finished product manufacturers are mapped across OMS and HMA database and available in OMS for use in regulatory procedures and for required PMS enrichments

For Questions: www.slido.com code: #STUP09425

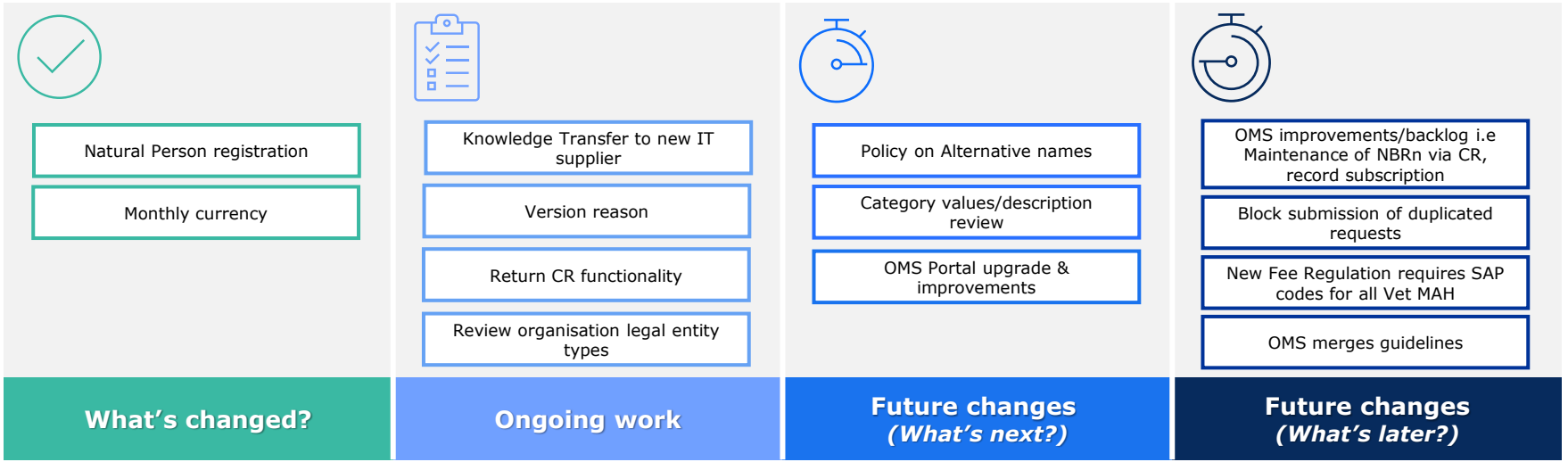
What's next? – What will be done in Q2 2025

	Why	How & when	Impact/ benefits to users
Policy on Alternative names 4	• 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 Q2 2025.	• **Guidance/documentation** with clear recommendations on the correct use of alternative names in regulatory procedures
Knowledge Transfer (KT) from existing IT supplier to new IT supplier 5	• Due to procurement cycles and new Framework Contract in place	• OMS IT maintenance and support has been temporarily put on hold and focus is in providing Knowledge Transfer (KT) from existing IT supplier to new IT supplier	• Some IT capabilities (see next slides) that were planned for Q1 are now delayed to Q2-Q3

Version reason 6	• **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 is **currently in UAT environment**
		• **Implementation is expected in PROD in Q2 2025** – OMS will notify to all registered API users **2 weeks in advance** of deployment
			⚠ **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: #STUP09425

Highlights to you



Acronyms

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

CR: Change Request

NBRn: National Business Registries number

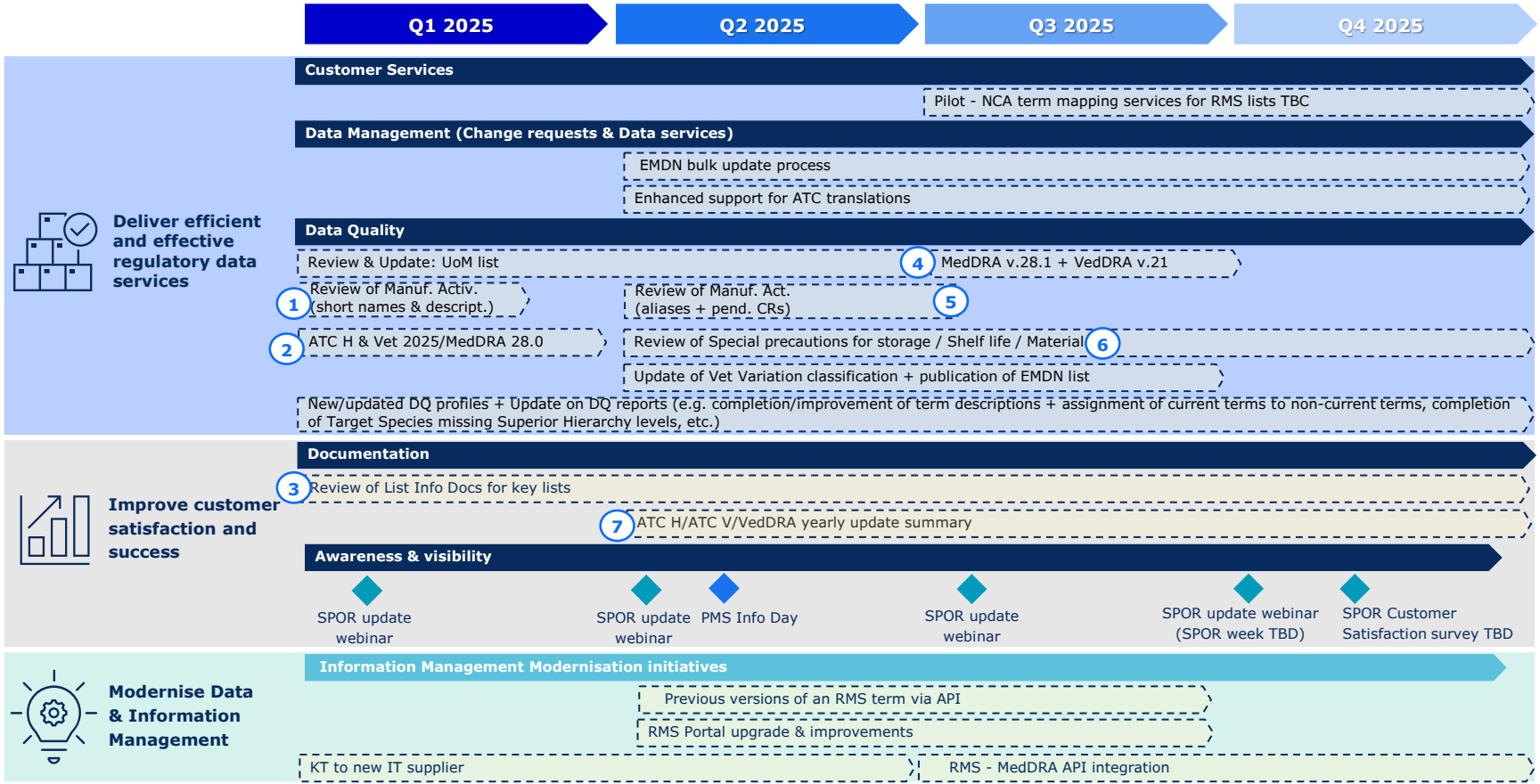
SAP: Statutory Accounting Principles

MAH: Marketing Authorisation Holder

For Questions: www.slido.com code: #STUP09425

RMS status update

Planned RMS Activities



For Questions: www.slido.com code: #STUP09425

Work completed – What has been done in Q1 2025

	Why	How & when	Impact/ benefits to users
1 Review of Manufacturing activities (short names & descriptions)	• **Absence of short names and descriptions** for several terms created **confusion** in consuming systems such as **eAF and PMS.**	• **Multidisciplinary group** (**IWG, QWP, BWP, QIG, CMDv** and **EMA**) **consulted** in **Dec 2024**. • **Changes** implemented in **Jan 2025.** • Only **short names** and **descriptions** were added or updated (**no terms added** or **nullified**)	• **Improved Data Quality/Clarity** › **Descriptions** will help understanding terms better. › **Short names** will improve readibility in consuming systems (e.g. PMS/eAF) and reduce the number of questions and/or submission errors.
2 ATC H & Vet 2025 MedDRA v. 28.0	• **WHO CC/MSSO** releases **yearly/6-monthly updates** and these need to be reflected in SPOR.	• **Bulk updates** done in RMS soon after updates are received from list owners.	• **Process efficiency -** Up to date lists should **reduce the number of change requests** to add new terms/codes.

Work completed – What has been done in Q1 2025

	Why	How & when	Impact/ benefits to users
Review of List Info Docs for key lists 3	• List information documents provide essential information but around 30% of RMS lists don´t have one.	• RMS plans to publish ~15 list information documents per quarter and complete all lists by the end of 2025. • List info docs published since 1 Jan 2025: › Conditions › Documentation › **National Classification list** › Medicinal Product Vocabulary › Referral Scopes › Data Classification › RMS NCA Translator Language › Shortages Root Cause • Next list info docs planned for publication: › Substance Type › Substance Name Type › OMS Request Type › Substance Authorisation Status › Official Name Type › Substance Relationship Role › Substance Relationship Combination › Substance Name Domain › Country Subdivisions	• **Improved Transparency and efficiency** • Increased awareness of RMS lists. • Reduction of list-related questions and submission errors.

What's next? – What will be done in Q2 2025

	Why	How & when	Impact/ benefits to users
4 UoM	• Some data fields/content was missing or was not correct.	• **Unit symbols** and **UCUM codes** were reviewed and changes will be implemented by Q2 2025. • A more detailed review is needed and will be planned in the next opportunity.	• **Improved data quality** and **reduction of technical issues** in consuming systems triggered by missing symbols or codes.
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 **Q2 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 **Q2 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.

7 ATC H/ATC V/ VedDRA yearly update summary	• There is **no easy way to identify within the SPOR portal what exactly has changed with the yearly updates.**	• Starting in Q2 2024, a **document showing the new terms inserted and the terms updated with the yearly review** will be published in the **Documentation area** of the **RMS portal.**	• Increased **transparency** and **awareness** of lists updates.

 For Questions: www.slido.com code: #STUP09425

Highlights to you

Review of Manuf. Activ. (short names & descriptions)

ATC H & Vet 2025 & MedDRA 28.0

What's changed?

Update of Vet. Variation classification

New/updated DQ profiles

Review of List Info Docs for key lists (see slide 26)

KT to new IT supplier

Ongoing work

Review of Manuf. Activ. (aliases+pending CRs)

Review of Special precautions for storage/Shelf life/Material

ATC H, ATC V & VedDRA yearly update summaries

Future changes *(What's next?)*

RMS – MedDRA API integration

Publication of EMDN list + EMDN bulk upload process

Future changes *(What's later?)*

Acronyms

MedDRA: Medical Dictionary for Drug Regulatory Activities

DQ: Data Quality

KT: Knowledge Transfer

CR: Change Request

API: Application Programming Interface

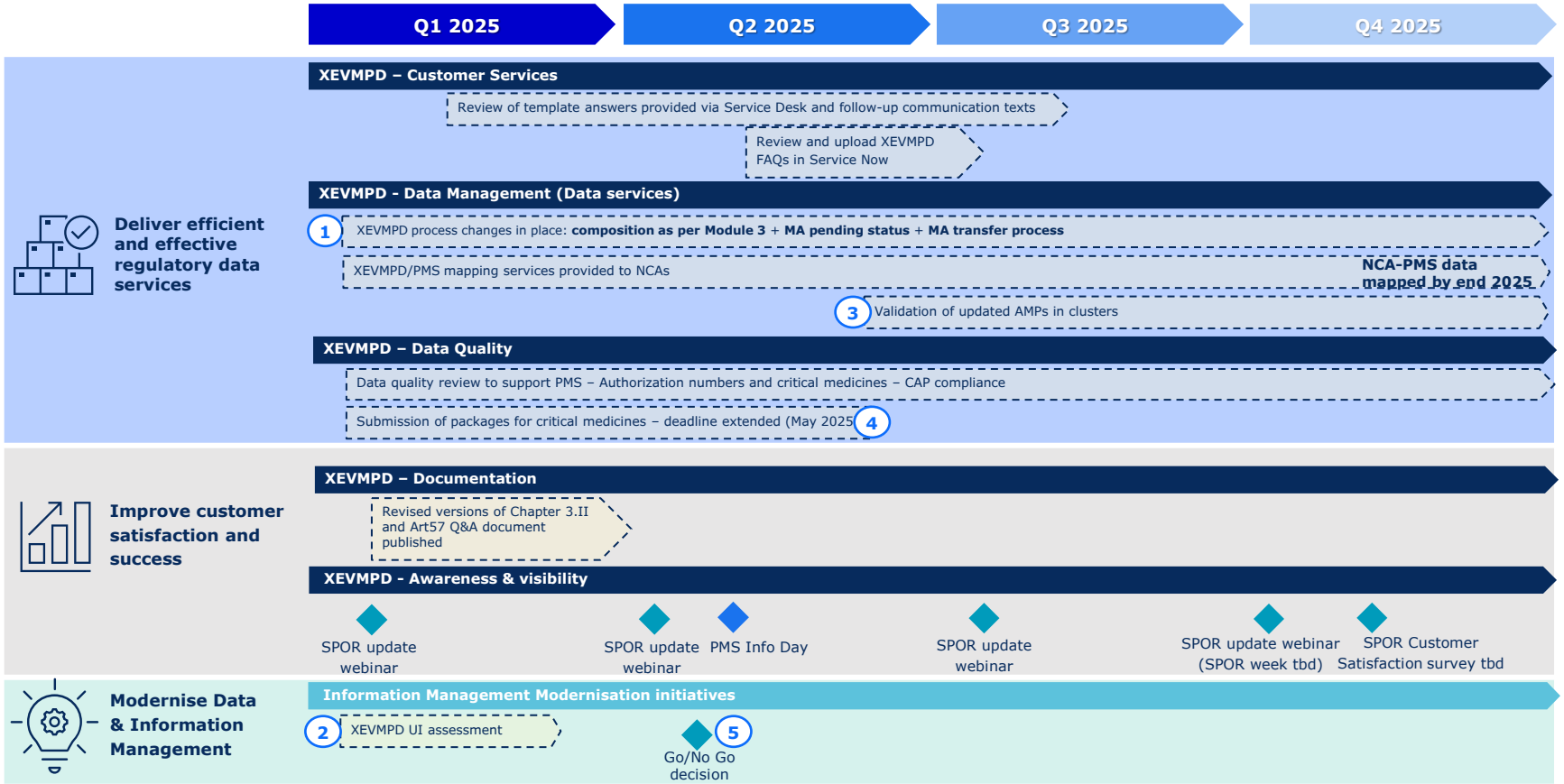
EMDN: European Medical Device Nomenclature

For Questions: www.slido.com code: #STUP09425

XEVMPD status update

For Questions: www.slido.com code: #STUP09425

Planned XEVMPD Activities



For Questions: www.slido.com code: #STUP09425

Work completed – What has been done in Q1 2025

	Why	How & when	Impact/ benefits to users
1 **Submission of AMP composition as per Module 3**	• To support MAHs that wish to provide **composition** within their AMP **as per Module 3 dossier**	▪ EMA accepts composition information provided as per Module 3 dossier (section 3.2.P.1) ▪ *From January 2025* ▪ No follow-up communication is raised with the MAH if the substance information is not aligned with information in the SmPC	• **Process efficiencies and alignment with Regulatory/submission requirements -** MAHs can use data submitted in XEVMPD/PMS to prepare web-based eAF variation form
1 **'Valid – pending national phase' MA status in Art57 database**	• To support submission of information for **MRPs and DCPs** approved in the Reference Member State but **still under evaluation in the Concerned Member State(s)** in the XEVMPD	▪ EMA made available a new authorisation status value ***'Valid – pending national phase'*** in Art57 database ▪ *From January 2025*	• **Process efficiencies and alignment with Regulatory/submission requirements -** MAHs can use the web-based eAF variation form to submit variations on products awaiting national approval
1 **MA transfer process change in Art57 database**	• To enable former MAHs to **transfer/delegate access to product information** in PMS	▪ EMA implemented a (minor) change in process for products where MA was transferred to another MAH ▪ **MAHs indicate the new MAH** in an AMP that was subject to transfer of MA ▪ *From January 2025*	• **Process change and increased access control -** MAHs control the data and access to their products in PMS • **Enriched data in PMS is kept** after the MAH is changed due to a transfer of MA.
2 **New XEVMPD UI - Assessment**	• To enable users **to access to XEVMPD UI without the need for ActiveX or IE Tab**	▪ EMA to identify new technical solution, without compromising security, and maintaining the same look & feel ▪ *By end of Q1/2025 - done*	• **Improved user experience** - Easier access for users, browser-based solution which can be used in other supported browsers and on MAC laptops

What's next? – What will be done in Q2 2025

	Why	How & when	Impact/ benefits to users
3 **Cluster validation of updated AMPs**	• To ensure consistent validation of **updated data for the same products**	• EMA is improving the validation process in XEVMPD so that product records belonging to the same medicinal product are validated together • *From end of Q2/2025*	• **Improved data quality -** Updated data for the same product is consistent • No delay in making updated product data available for Pharmacovigilance and other business processes
4 **Submission of packages for critical medicines - deadline extended**	• Proactive measure to **support management of shortages in the EU** and the ESMP project	• MAHs to submit information **packages** for approved products on the **ULCM** – (initially by 31 January 2025) **extended to 31 May 2025** • **EMA to validate** newly submitted records - *On weekly basis*	• **Deadline extension** - MAH to review the **updated Union list of critical medicines** (ULCM) and perform the required submissions for **any new/added products**
5 **New XEVMPD UI _ Go/No Go decision**	• To enable users **to access to XEVMPD UI without the need for ActiveX or IE Tab**	▪ XEVMPD team to **request management approval** *By end of Q2/2025* ▪ If approved, EMA to work on the development of the new UI *From Q3/2025*	• **Improved user experience** - Easier access for users, browser-based solution which can be used in other supported browsers and on MAC laptops

 For Questions: www.slido.com code: #STUP09425

Highlights to you

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

What's changed?

Improvement on **cluster validation process <u>for new AMPs</u>**

XEVMPD/PMS **mapping services** provided to NCAs

Assessment of new solution for XEVMPD User Interface

Ongoing work

Improvement on **cluster validation process <u>for updated AMPs</u>**

XEVMPD Q&As available as **'Articles' in ServiceNow**

For info: PhV fee advice notes generated & sent out in April 2025

Future changes *(What's next?)*

Integration of product validation with review of substances with SVG flag 0

Future changes *(What's later?)*

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

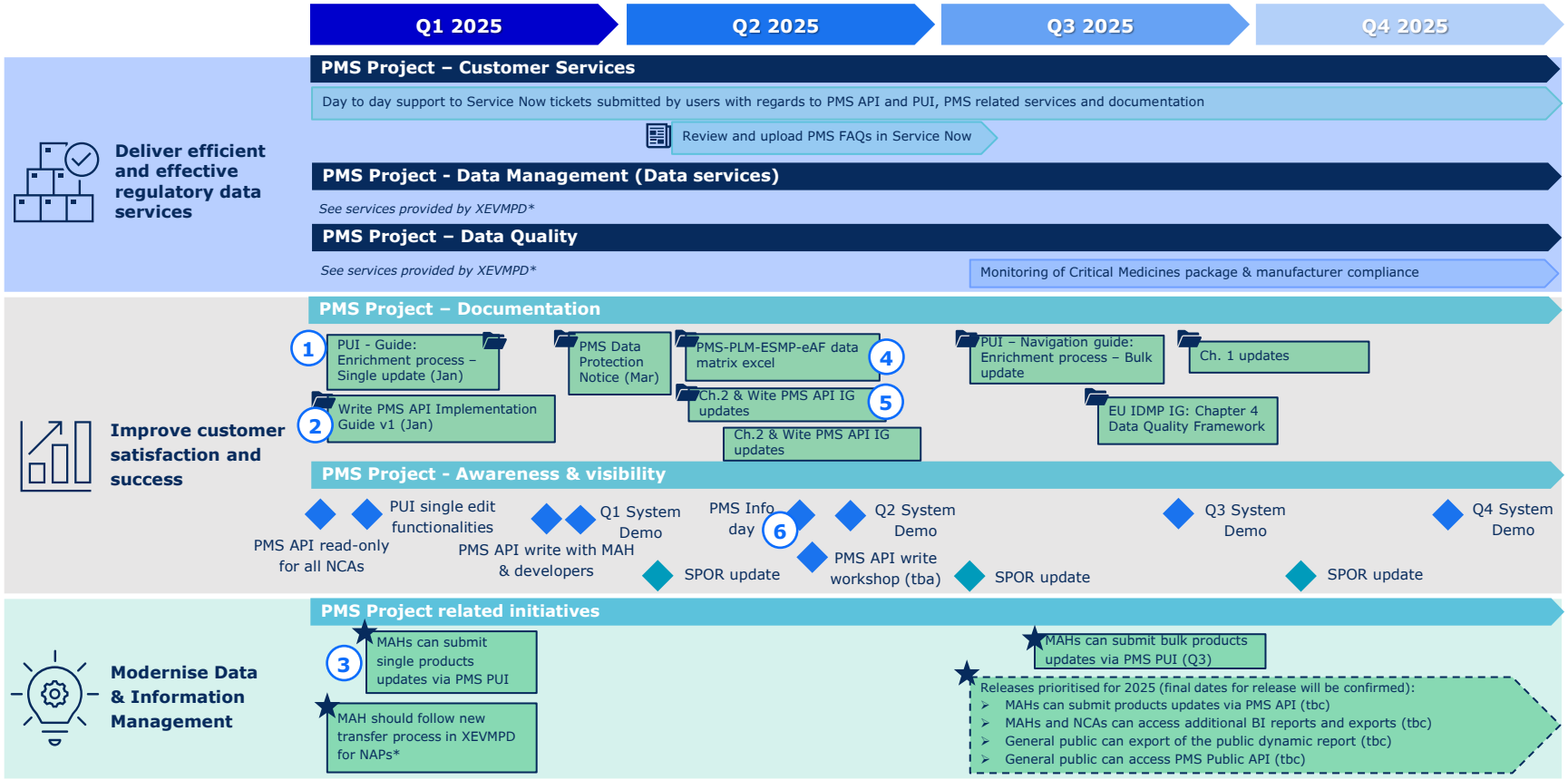
PMS: Product Management Service

SVG: Substance Validation Group

For Questions: www.slido.com code: #STUP09425

PMS status update

Planned PMS Activities



For Questions: www.slido.com code: #STUP09425

* Link with xEVMPD status update

Document release ★ Milestone ◆ SPOR update webinars ◆ PMS webinars

Work completed – What has been done in Q1 2025

	Why	How & when	Impact/ benefits to users
1 PUI - Guide: Enrichment process – Single update	• To provide support the PUI enrichment process	• On **20th January 2025**, the **PUI Navigation Guide** was updated to explain how the enrichment process for single updates works in the Product UI	• Updated **documentation** and **increased user support** enabling them to suceed with their enrichment submissions
2 Write PMS API Implementation Guide V1	• To support MAH or software developers **building machine-to-machine connections between RIM systems and the PMS API**.	• On **20th January 2025**, the relevant material/**technical specifications** have been published on the EMA PMS webpage.	• Updated **documentation** and **increased user support** enabling them to automate data submissions and improve operational efficiency.
3 PUI: Enrichment process – Single update	• To fulfil regulatory requirements and support ESMP.	• As of **end of January 2025**, MAH users can **submit authorized and structured product data** via PMS product User Interface, including **manufacturers and pack sizes.** • MAHs of non-CAPs from ULCM list are required to submit structured data to PMS. • MAHs of non-CAPs not mentioned in the ULCM list can also submit structured data to PMS.	• **Regulatory compliance -** *While other capabilities are still being developed/improved* MAH, particularly SMEs or companies with smaller portfolio of products can start to update their products via the user interface

 For Questions: www.slido.com code: #STUP09425

What's next? – What will be done in Q2 2025

	Why	How & when	Impact/ benefits to users
4 Chapter 2 & Write PMS API Implementation Guide updates	• To **address comments** from users and refine any applicable **business rule/specification** for the data submission of structured **manufacturers data and pack sizes.**	• In **April 2025**, **updated versions** of are expected to be released on PMS webpage and PLM portal • Chapter 2 (business rules and conformance on manufacturers and pack sizes) • Write PMS API IG (technical specifications).	• Updated **documentation** and **increased user support** enabling them to automate data submissions and improve operational efficiency.
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 PMS Info Day	• To enhance awareness and offer comprehensive insights into the implications of PMS for key stakeholders.	• **Wednesday, 21 May 2025, 09:00 - 17:30 Live broadcast Event page:** Link	• **Engagement & Insights :** Enables direct engagement with leaders, providing insights on PMS, its impacts, benefits, and EU implementation preparedness.

 For Questions: www.slido.com code: #STUP09425

Highlights to you

What's changed?

- PUI: Enrichment process – Single update (process and guideline)
- Implement the new transfer process for NAPs
- Write PMS API Implementation Guide
- PMS Data Protection Notice

Ongoing work

- Ch.2 update
- Write PMS API IG update
- PUI Enrichment process – Bulk update & Guide updates
- Public PMS API
- PMS data quality improvements & data fixes
- PMS-PLM-ESMP-eAF data matrix excel file

Future changes *(What's next?)*

- EU IDMP IG: Chapter 4 Data Quality Framework
- PUI Enrichment process – Bulk update – Production delivery

Future changes *(What's later?)*

- PMS FHIR R5 upgrade
- XEVMPD submissions decomissioned

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: #STUP09425

Conclusions

 For Questions: www.slido.com code: #STUP09425

SMS Guidance for External Users v3.0 published

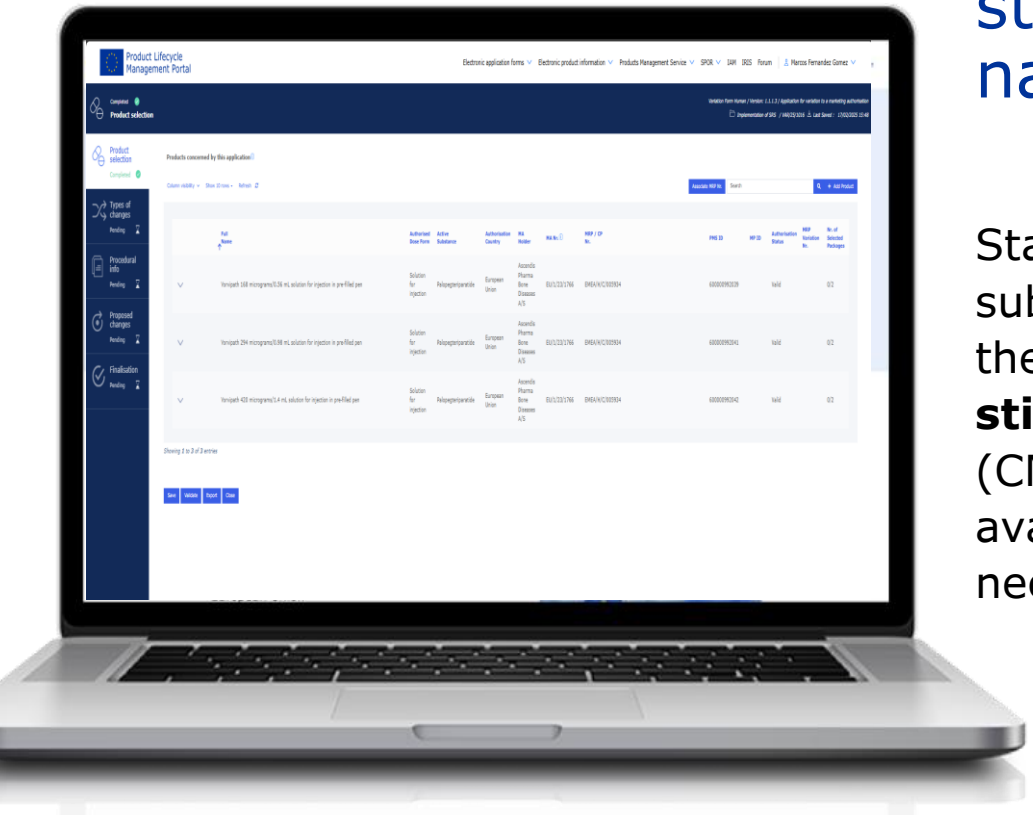
The revised version enhances clarity on **Data Enrichments** (INN, USAN, Custom Attributes, etc.) and **Business Rules** (for chemicals and veterinary vaccines) improving user awareness and predictability in substances registration and maintenance.

OMS Monthly currency

To keep OMS data current and prevent the use of inactive organisations in regulatory processes, OMS will conduct **monthly checks on organisations** not updated for over two years

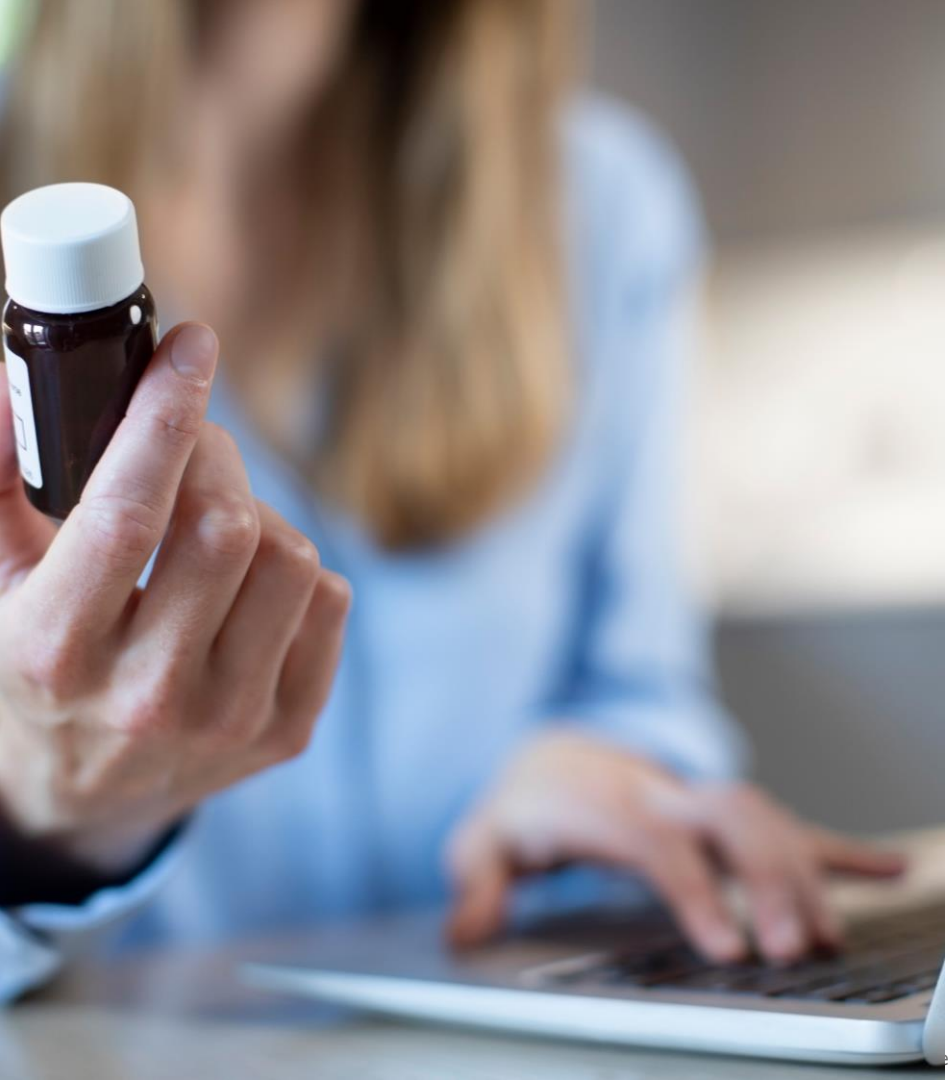
Update of Manufacturing Activity

RMS updates of short names and **descriptions** improve clarity of terms in the **Manufacturing Activity list**, enhancing PMS interface and reducing errors from unclear terminology.



XEVMPD new authorisation status: Valid – pending national phase

Starting **January 2025**, MAHs can submit MRP/DCP products authorised by the Reference Member State (RMS) but **still under Concerned Member State** (CMS) evaluation to XEVMPD, ensuring availability in the web-based eAF when needed.



Voluntary submission of composition as in M3 in XEVMPD

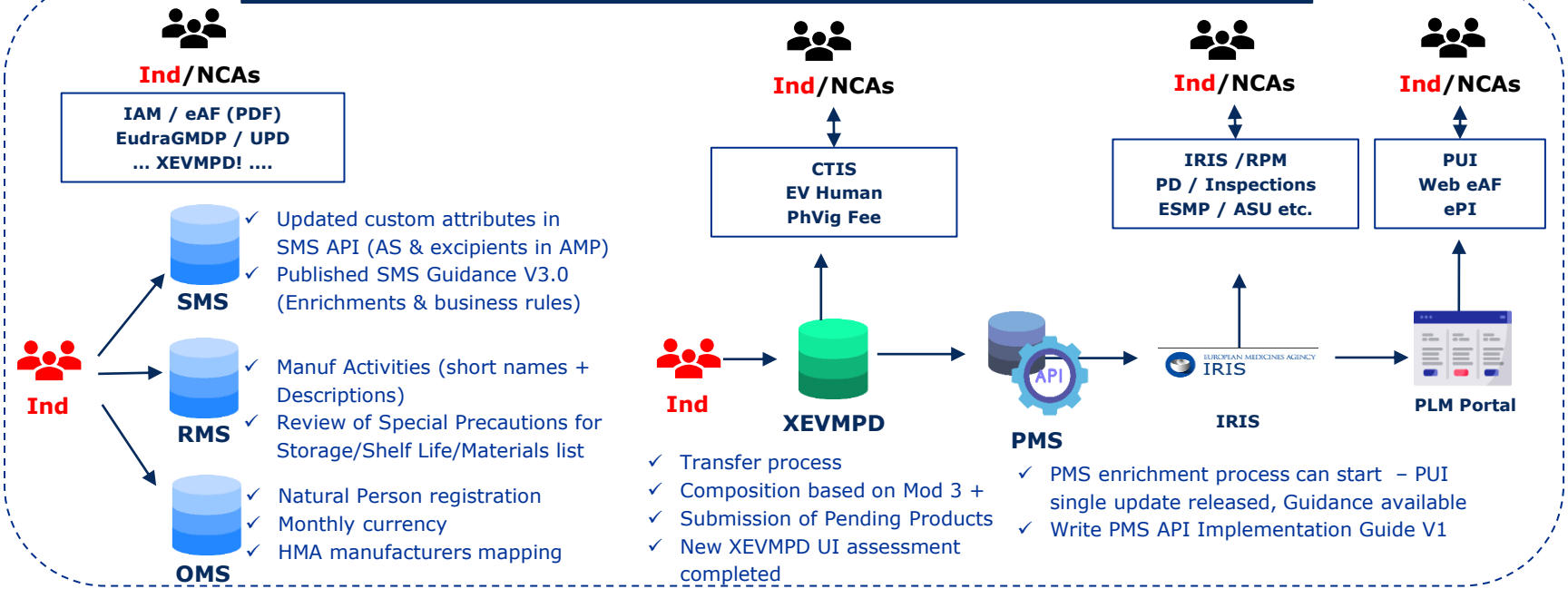
Starting **January 2025**, MAHs can **submit the medicinal product composition** as stated in **Module 3** instead of as stated in the SmPC on a voluntary basis.

PMS UI Enrichment Go-live

Starting **January 2025**, the PMS User Interface (PUI) enables MAHs to **submit structured pack sizes and manufacturer details for non-CAPs**, supporting the European Shortages Monitoring Platform (ESMP).

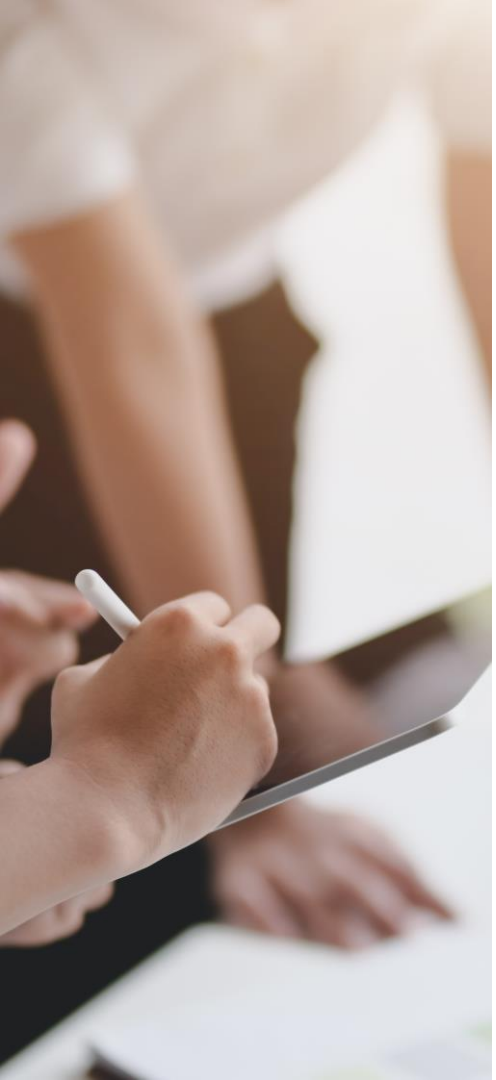
SPOR, XEVMPD/PMS and other processes

What is happening in **SMS, OMS, RMS** and **XEVMPD supports PMS and other solutions**



- Follow the instructions for **new Transfer of MA process** to avoid disruptions to access to Product data
- Optionally, align composition with Mod 3 - avoid using substances with SVG flag 0 or non-current terms where possible
- Submit **packages** for the Union List of Critical Medicinal Products (**ULCMP**) to **XEVMPD**
- Start completing **Manufacturers and structured pack sizes** for the Union List of Critical Medicinal Products (**ULCMP**) in **PUI**

For Questions: www.slido.com code: #STUP09425



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 **#STUP09425** or scan this QR code

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

More information: SPOR Web Page

Follow us