Housekeeping notes – Personal data protection notice

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

*Throughout the session, 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: SWOCT1124

Housekeeping notes – Q&A

Join at
slido.com
#SWOCT1124

- Join via **QR code** or **slido.com -** *please provide your questions and comments in Slido only*
- **Send or upvote the questions** you want to hear answered – *before raising a question check whether its has been raised already and vote for it*

Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will attempt to **address questions in writing throughout the session**
- EMA colleagues will **verbally address (unanswered) top voted questions** at the end in the live Q&A session

Unanswered questions

- This can be due to high volume of questions or assistance of a specific colleague not available today is required
- Unanswered questions will be reviewed, and the **most relevant ones may be addressed** in other webinars or in a FAQ document
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned

1 For Questions: www.slido.com code: SWOCT1124

Webinar materials sharing and technical recommendation

Presentations will be available at:

- SPOR Portal Documents section
- EMA Events Web Page

Recordings will be available at:

- EMA YouTube Channel
- EMA Events Web Page

For Questions: www.slido.com code: SWOCT1124

SPOR Webinars

EUROPEAN MEDICINES AGENCY

During **SPOR webinars,** EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

Webinar title	Date	Time
SPOR Data Governance	4 October 2024	10:00-12:00 CEST
Referentials Management Service (RMS)	7 October 2024	10:00-12:00 CEST
Substance Management Service (SMS)	8 October 2024	10:00-12:00 CEST
Organisation Management Service (OMS)	9 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for MAH	10 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for Sponsors	11 October 2024	10:00-12:00 CEST
Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API	14 October 2024	10:00-12:00 CEST

For Questions: www.slido.com code: SWOCT1124

Goals of the session

Re-cap of **XEVMPD submissions requirement** and **processes for DMPs**

Share an **XEVMPD status overview**

Provide information on the **relationship between XEVMPD and CTIS**

Remind sponsors of the **actions to be taken** on their XEVMPD data

For Questions: www.slido.com code: #SWOCT1124

Agenda

1. **Welcome**
   10:00 – 10:05
2. **Introduction to XEVMPD and pre-submission requirements**
3. **Mandatory reporting requirements and XEVMPD submission process**
4. **XEVMPD Statistics**
5. **XEVMPD Documentation & help**
6. **XEVMPD data in CTIS**

Coffee break
10 minutes

7. **XEVMPD status update** NEW
8. **Key Takeaways and Conclusions**
9. **Q&A Session**
   11:45 – 12:00
10.
11.

For Questions: www.slido.com code: SWOCT1124

Introduction to XEVMPD and pre-submission requirements

Presented by Veronika Baker

For Questions: www.slido.com code: SWOCT1124

XEVMPD introduction

XEVMPD
(aka 'Article 57 database')

Centralised source of information on authorised and un-authorised medicines

Authorised medicinal **product data** is submitted and maintained in the XEVMPD by **marketing authorisation holders (MAHs)**

as per Article 57(2) of Regulation 726/2004

Un-authorised (referred to in the XEVMPD as 'development') medicinal product data is **submitted and maintained** in the XEVMPD by **sponsors**

as per Article 81(3) of Regulation (EU) No 536/2014

Substance records are submitted and maintained in the XEVMPD by EMA's **Substance Management Service (SMS) data stewards**

MAH and **sponsor organisation** records are submitted and maintained in the XEVMPD by **MAHs** and **sponsors**

Referential terms are submitted and maintained in the XEVMPD by **EMA's Referentials Management Service (RMS) data stewards** and **sponsors (development terms only)**

For Questions: www.slido.com code: SWOCT1124

Pre-submission requirements (1/2)

EUROPEAN MEDICINES AGENCY

- XEVMPD can be used by all **organisations registered with EudraVigilance** for **medicinal product reporting**

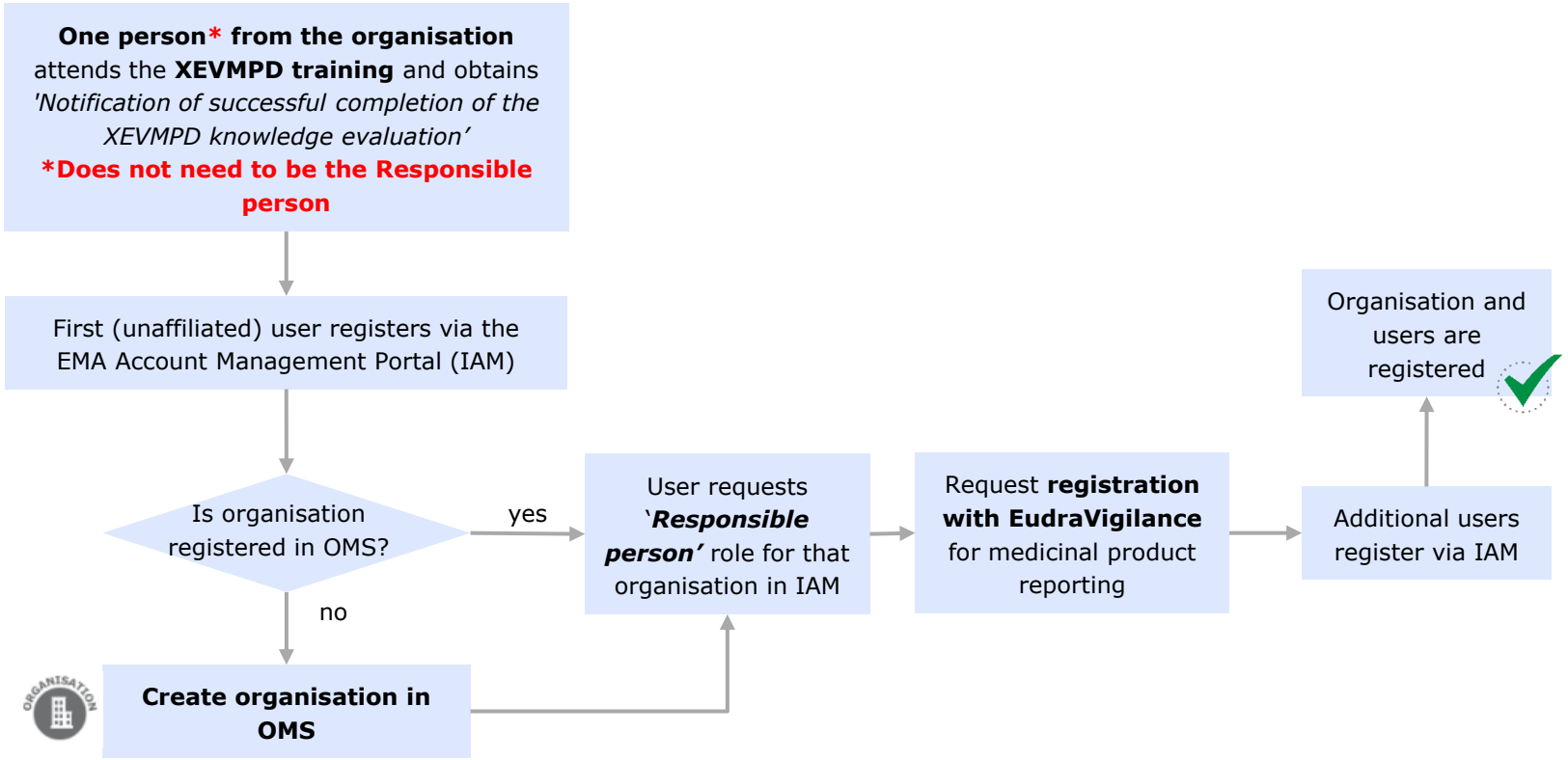
  i.e.: marketing authorisation applicants (MAA), marketing authorisation holders (MAHs), sponsors, national competent authorities (NCAs)

  - Clinical research organisations (CROs), IT vendors and third-party service providers registered in EV under MAH/sponsor organisation profiles
    - independent registration with their own EudraVigilance ID not possible
    - can only submit information on behalf of MAH/sponsors registered in EV, using the MAH's/sponsor's organisation ID
- **Organisations** must be registered in the Organisation Management System (OMS)

- **Individual users** must be registered in the EMA Account Management Portal

For Questions: www.slido.com code: SWOCT1124

Pre-submission requirements (2/2)



For Questions: www.slido.com code: #SWOCT1024

Available as:

- **Virtual** training course run by the Drug Information association (DIA)
  - Separate courses for MAHs and sponsors
  - **Paid** training course; **trainer led**, knowledge evaluation is performed by the trainers
  - No limit on the number of participants from one organisation

- **E-learning** training
  - Separate courses for MAHs and sponsors
  - **Free** training based on **self-study**; users register for knowledge evaluation via EMA Service Desk
  - Max 5 people from the same organisation
    - '*Notification of successful completion of the XEVMPD knowledge evaluation'* is requested from **one person** during the **organisation's initial registration in EV**

The holder of the notification **can train others** as part of internal knowledge transfer

Mandatory reporting requirements and XEVMPD submission process

 For Questions: www.slido.com code: SWOCT1124

Mandatory reporting requirements

Submission of medicinal product information in the XEVMPD **by sponsors** required as per:

- Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3')
- Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

Responsible person

The person responsible for maintaining commercial sponsor and non-commercial sponsor EudraVigilance (EV) profiles in the EV registration system

- Sponsors must have a **responsible person** registered in EV at the HQ level
  - There can only be one RP per HQ organisation
- **Trusty deputy** may also be registered
- Responsible person information is **not referenced in DMPs in the XEVMPD**

- If the **responsible person changes** within an organisation, the organisation must nominate a new RP within **10 calendar days**
  - **The new RP must self-register** for the relevant RP role in the EMA Account Management Portal); the existing RP cannot be removed from EudraVigilance until their replacement is fully registered

For Questions: www.slido.com code: SWOCT1124

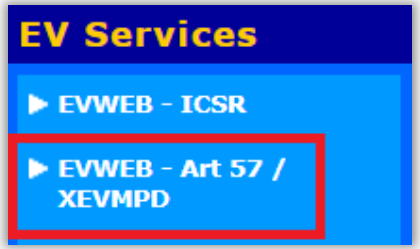
Sponsors must submit medicinal product information in the XEVMPD:

- If an **active substance is used** in a clinical trial in a **new pharmaceutical dose form** and/or in a **new strength**
- If a medicinal **product not authorised in the EU/EEA** is used in a **clinical trial in the EU/EEA**

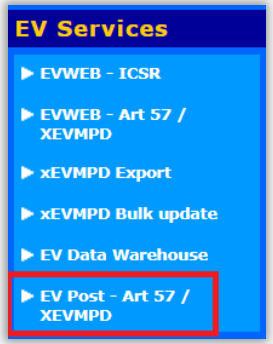
 For Questions: www.slido.com code: SWOCT1124

Submission methods

- Via **eXtended EudraVigilance Medicinal Product Report Messages (XEVPRMs)**
- XEVPRMs can be **generated** using:
  - **In-house tools**
  - The **XEVMPD data entry tool** *(EVWEB - Art 57/XEVMPD)* provided by the Agency



- XEVPRMs to be **submitted** to the EMA via the **EudraVigilance Gateway** via**:**
  - **In-house tools** (Gateway to Gateway connection)
  - The **XEVMPD data entry tool**
  - **EV-Post functionality** *(EV Post – Art 57/XEVMPD)*



 For Questions: www.slido.com code: SWOCT1124

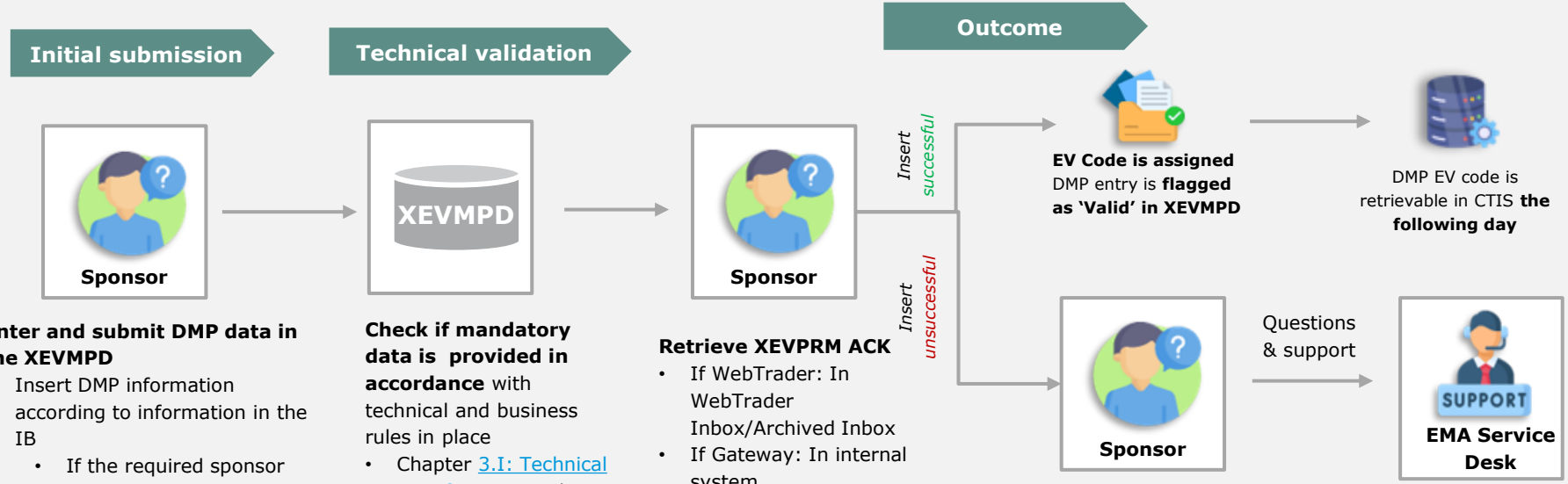
- Available to **registered users** only
- To access EVWEB, users are required to have:
  - set up a **multi-factor authentication (MFA)**;
  - **requested access** to the **XEVMPD production environment** via the EMA Account Management portal; and
  - **installed ActiveX** on their computer and access EVWEB using an **IE Tab extension**, as per instructions on the 'xEVMPD support' section of the EV restricted area for EV Registered users.

Confirmation of XEVPRM submissions

- Via **XEVPRMs Acknowledgements:**
  - **1st level ACK**: Generated automatically EMA's Gateway (MDN Acknowledgement)
  - **2nd level ACK**: Generated once an XEVPRM is processed by the EudraVigilance system; it is an XML message acknowledgement which contains:
    - the **results of the electronic submission of the XEVPRM** and
    - the **result of the operation type requested for each entity within that XEVPRM**
  - **3rd level ACK**: **validation related**, contains information related to the **validation of AMPs** in the XEVMPD; **not generated for DMPs**
- **WebTrader Users** find their XEVPRM ACKs in their **WebTrader Inbox/Archived Inbox**
- **Gateway users** should **check with their Gateway providers where these are stored**

For Questions: www.slido.com code: SWOCT1124

DMP: Initial submission process



Enter and submit DMP data in the XEVMPD

- Insert DMP information according to information in the IB
  - If the required sponsor organisation is not present in the XEVMPD -> insert it with the DMP
  - If the required active substance is not present in the XEVMPD -> request the insert of the substance information via 'Request SMS services' form in the EMA Service Desk

Check if mandatory data is provided in accordance with technical and business rules in place

- Chapter 3.I: Technical specifications and
- Business guidance on submission of IMPs

1st and 2nd XEVPRM ACK generated

Retrieve XEVPRM ACK

- If WebTrader: In WebTrader Inbox/Archived Inbox
- If Gateway: In internal system

Correct data as per XEVPRM ACK and re-submit

For Questions: www.slido.com code: SWOCT1124

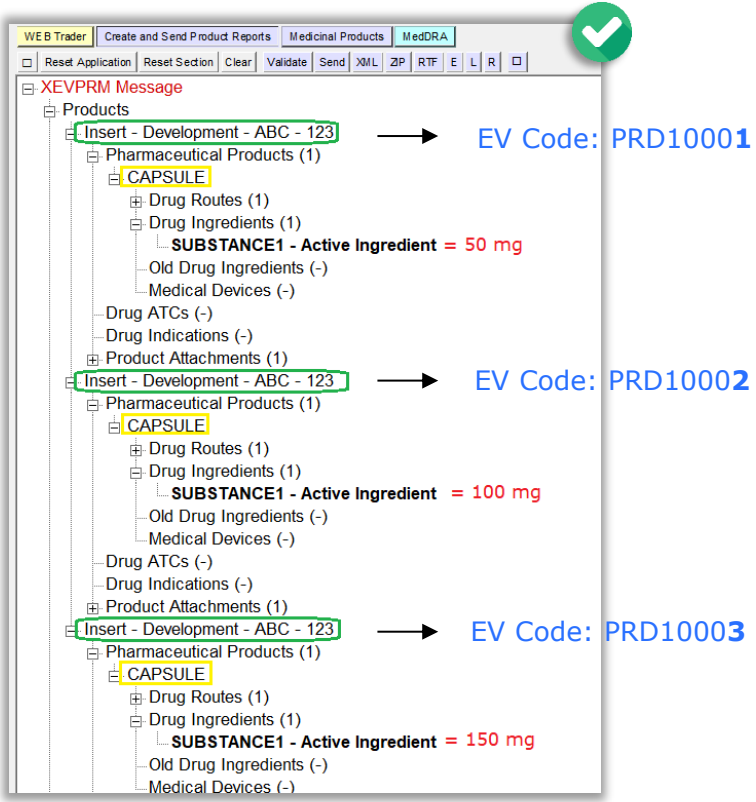
- If an active substance is studied in a clinical trial in the EU/EEA:
  - in a **new dose form** → the sponsor submits a DMP record in the XEVMPD
  - in a **new concentration** → the sponsor submits a DMP record in the XEVMPD

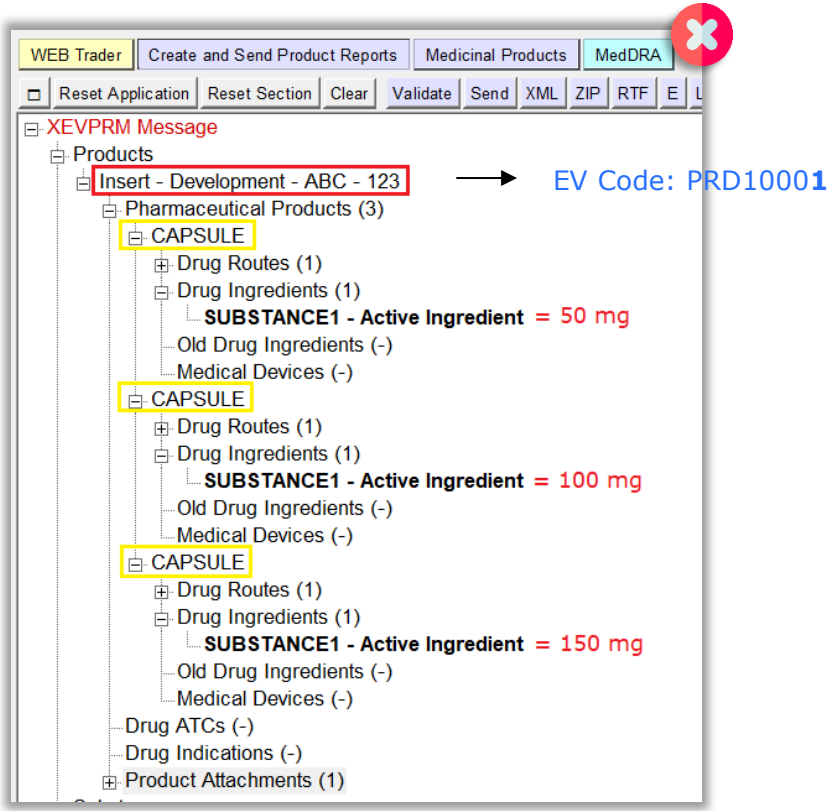
- If the **same medicinal product** is studied in clinical trials by **different sponsors** → **each sponsor** submits the DMP information in the XEVMPD

 For Questions: www.slido.com code: SWOCT1124

Practical example 1

An **active substance** is studied in a clinical trial in the **same pharmaceutical dose form** in **different strengths**

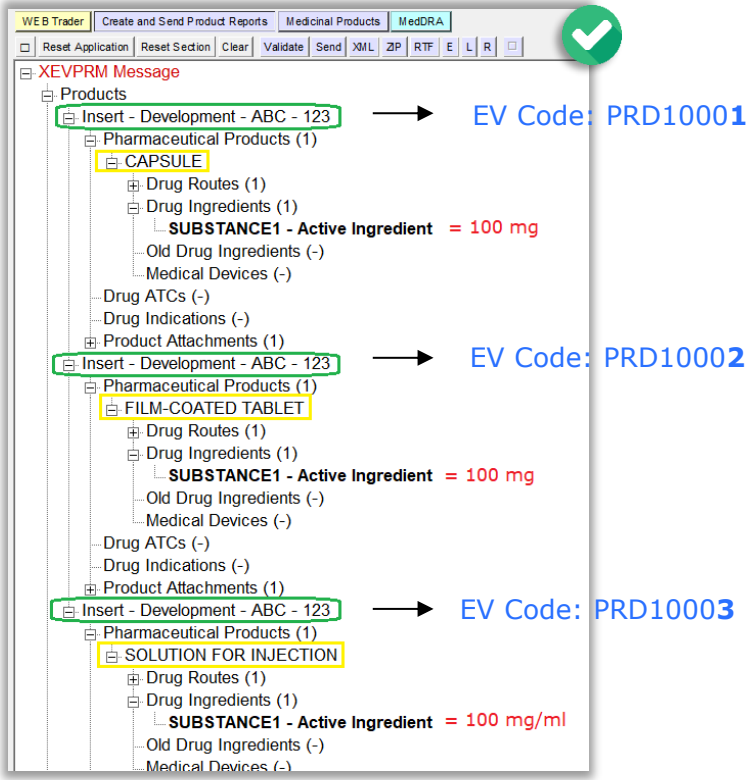


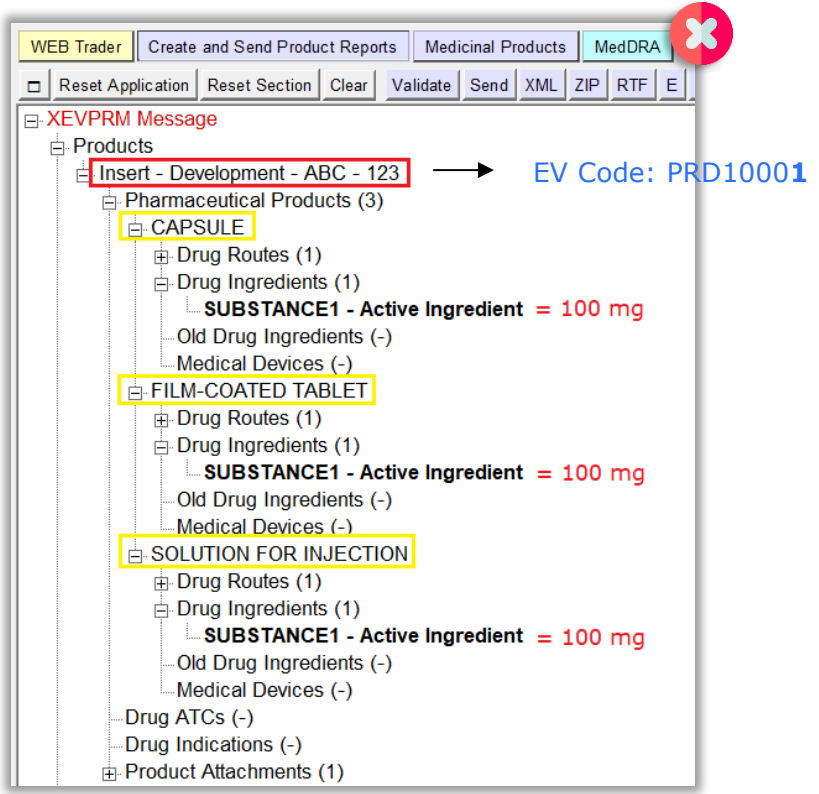


 For Questions: www.slido.com code: SWOCT1124

Practical example 2

An **active substance** is studied in a clinical trial **different pharmaceutical dose forms** in the **same strength**





 For Questions: www.slido.com code: SWOCT1124

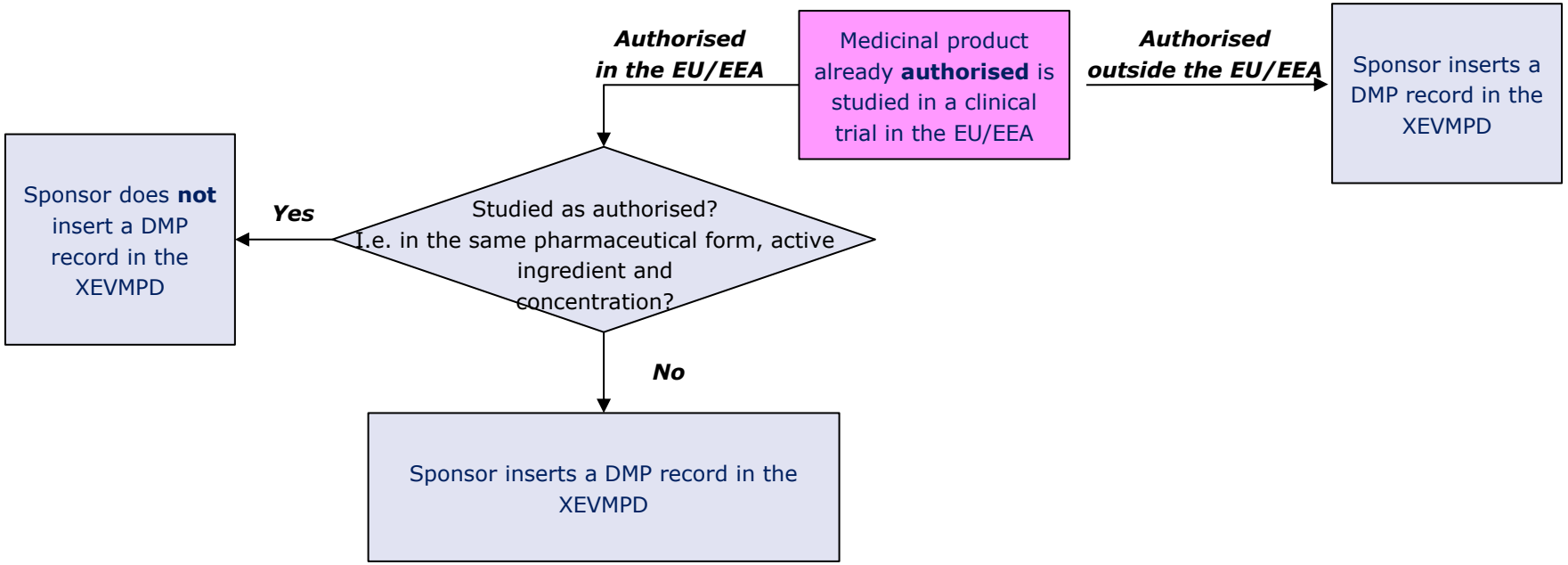
Practical example 3

The **same medicinal product** is studied in clinical trials by **different sponsors**

	active ingredient	*strength of active ingredient*	*pharma form*	*RoA*	*EV Code assigned*	*Visible in XEVMPD to*	*Can be maintained in XEVMPD by*
Sponsor A	Substance XYZ	100 mg	capsule	oral use	PRD11111	Sponsor A + EMA + NCAs	Sponsor A + EMA
Sponsor B	substance XYZ	100 mg	capsule	oral use	PRD22222	Sponsor B + EMA + NCAs	Sponsor B + EMA
Sponsor C	substance XYZ	100 mg	capsule	oral use	PRD33333	Sponsor C + EMA + NCAs	Sponsor C + EMA

 For Questions: www.slido.com code: SWOCT1124

Authorised medicinal products



Auxiliary medicinal product (AxMP) is defined by the regulation as *"a medicinal product **authorised** in accordance with Regulation (EC) No 726/2004, or in any Member State concerned…"*

 For Questions: www.slido.com code: SWOCT1124

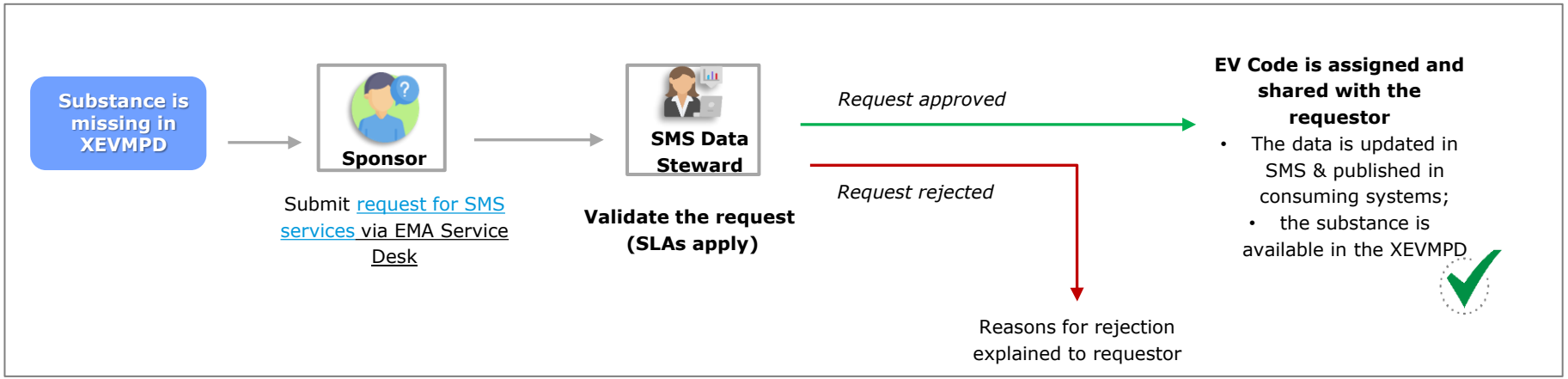
Submission of placebos

Submission of placebos: sponsors do not need to submit information on placebo to the XEVMPD. Only information on the active ingredient(s) of the investigational medicinal product is required

Substance submission process

If a **substance** information is missing in the XEVMPD
and it is not/cannot be **re-mapped to another existing approved substance**

- Request the addition of the substance information in the XEVMPD via EMA Service Desk request for SMS services



List of substances available in the XEVMPD:

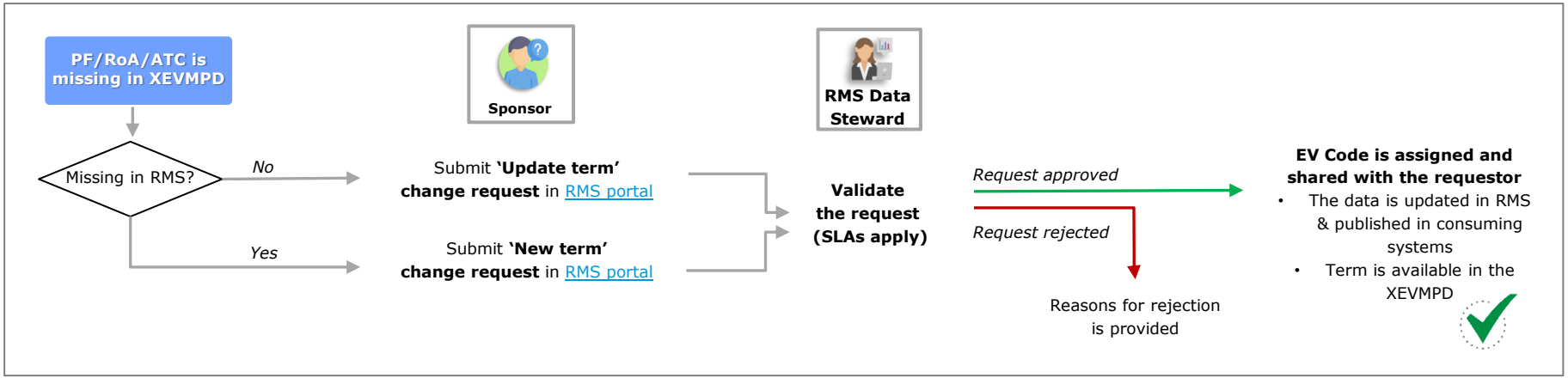
- XEVMPD 'Substances' look-up tables (Approved or Development)
- SMS substance extracts in the SMS portal

For Questions: www.slido.com code: SWOCT1124

Term submission process

If **pharmaceutical form**, **route of administration** or **an ATC Code** are missing in the XEVMPD and the terms are not/cannot be **re-mapped to another existing term**

- request the addition of the term in the XEVMPD via a **change request** in the Referentials Management System (RMS) portal



Lists of PFs/RoA/ATC Codes are available in the XEVMPD can be retrieved from:

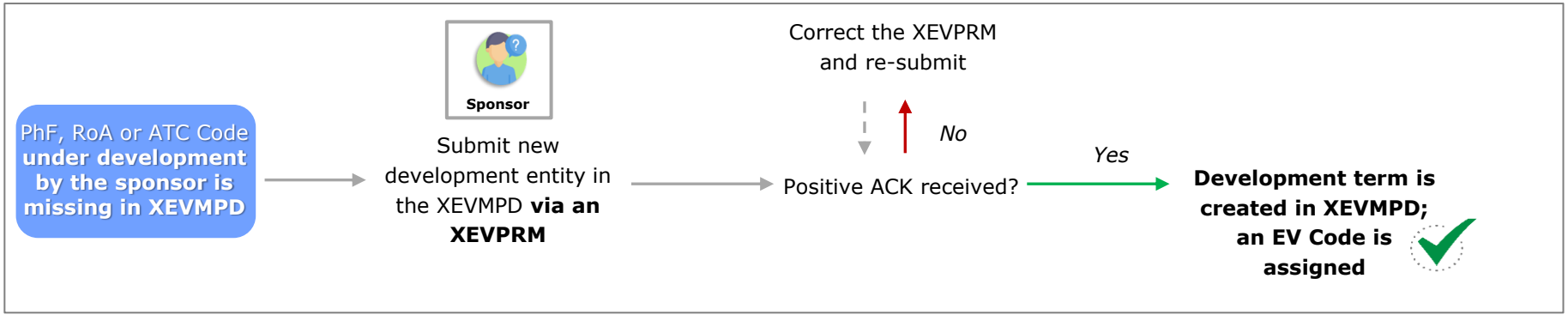
- XEVMPD 'Pharmaceutical Forms', 'Routes of Administration', ATC Codes look-up tables
- RMS lists in the RMS portal
- List of proposed terms that can be mapped to standard terms is available in the 'Documents' section of the RMS portal

For Questions: www.slido.com code: SWOCT1124

Development terms submission process

Sponsor can also submit in the XEVMPD '**development terms**' for a pharmaceutical form, route of administration and an ATC Code:

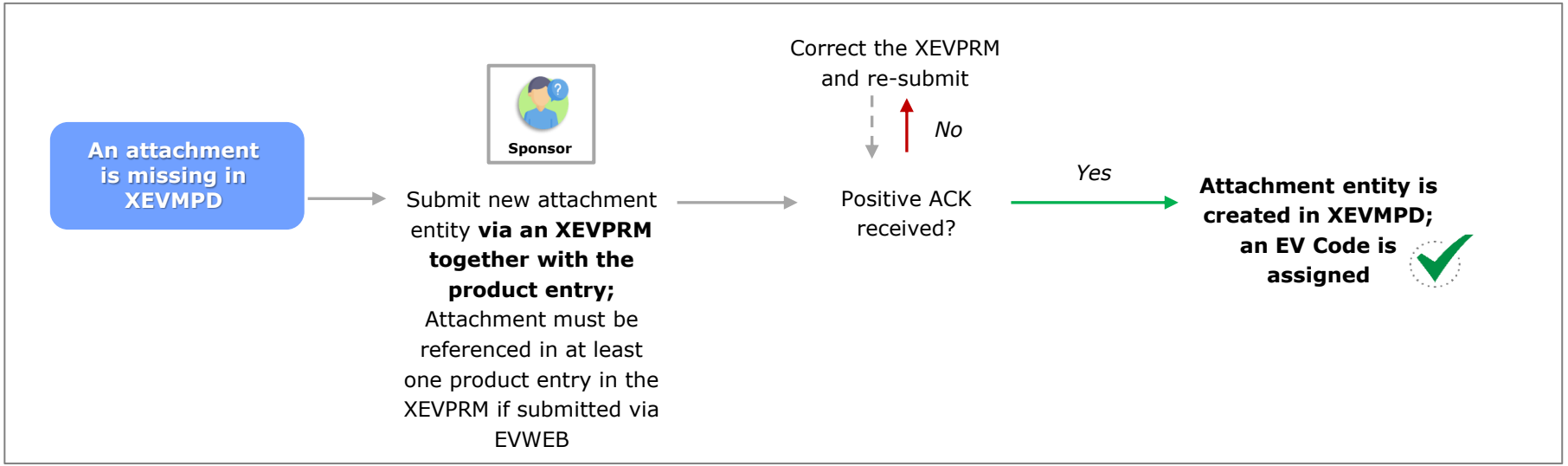
- **terms that are still under development** and the **information about such terms is considered confidential;**
- **can only be referenced in development product entries;**
- sponsor-specific; only the owner organisation can reference such terms in their DMPs;
- **must not match any current standard or proposed term already present in the XEVMPD**.



 For Questions: www.slido.com code: SWOCT1124

Attachment submission process

If the required **attachment** entity is missing in the XEVMPD
- submit the attachment entity in the XEVPRM via an XEVPRM



- Optional to reference attachments in DMPs
- Can be retrieved from XEVMPD 'Attachments' look-up table

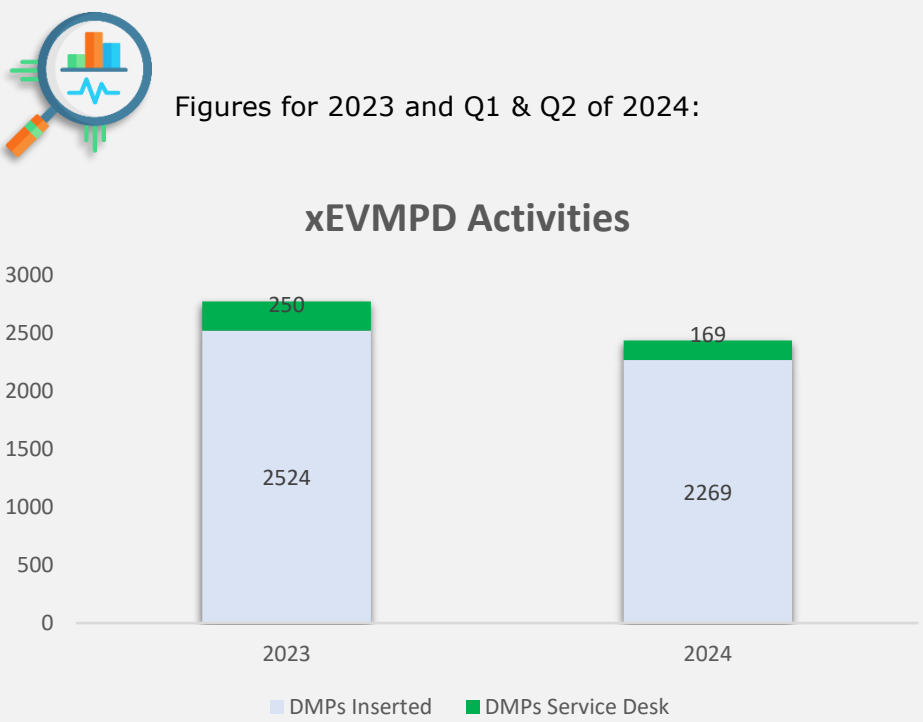
 For Questions: www.slido.com code: SWOCT1124

XEVMPD Statistics

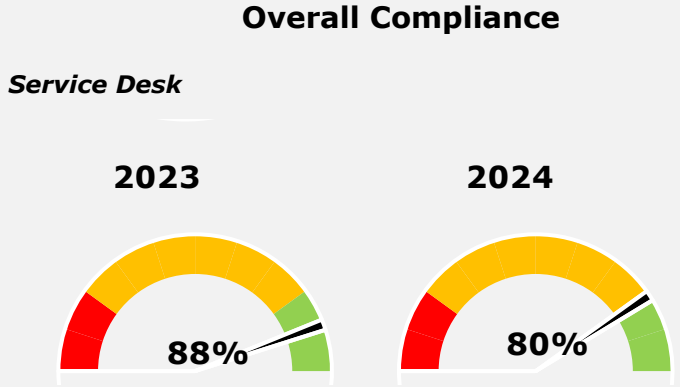
 For Questions: www.slido.com code: SWOCT1124

XEVMPD Statistics

Figures for 2023 and Q1 & Q2 of 2024:



- 97% of requests for information met the SLAs
- 80% of request for services met the SLAs
- 78% of incidents met the SLAs
- **SLA overall compliance is within the target score**



Documentation overview & help

 For Questions: www.slido.com code: SWOCT1124

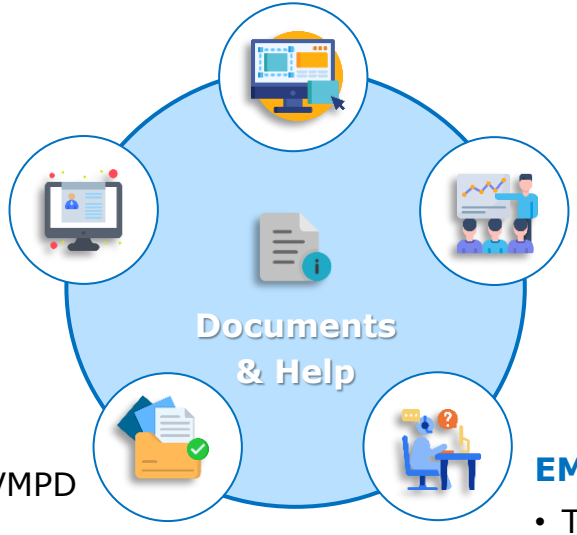
EUROPEAN MEDICINES AGENCY

EMA corporate website

- Overview of submission requirements for **sponsors** and link to guidance document
- Information on how to register with EV for product reporting

EMA Account Management Portal

- Guidance on to obtain access to EMA systems (including SPOR & XEVMPD)
- Create a new EMA account and request SPOR user role



Training opportunities

- @emainfo channel contains Videos of SPOR webinars with tips/tricks and questions raised from users
- XEVMPD Training webpage contains overview of available training courses, training documents & step-by-step guides

EV Restricted Area

- Access to EV Services (EVWEB, XEVMPD Export and Bulk update tools etc.)
- User Support section– technical documentation

EMA Service Desk

- To request information, support with XEVMPD data management, report technical issues
- Managed through the ServiceNow Portal

XEVMPD support via EMA Service Desk

Request *(for)* XEVMPD/Art.57 Services

To request:

- **XEVMPD data** (e.g., EV Code of an AMP/DMP, substance EV Code, copy of the XEVPRM ACK if not received by the sponsor etc.)
- **Support with XEVMPD data management** (e.g., nullification of validated entries, data amendment in XEVMPD on behalf of the organisation etc.)
- **Registration for XEVMPD e-learning training** (initial registration, assessment evaluation)

SLAs:

- 5 working days

Request for information

Service: **SPOR**

Service Offering: **XEVMPD/Art.57**

To request information or ask a question related to:

- **XEVMPD processes in use**
- **Guidance on how to submit data in XEVMPD**
- **Where to find XEVMPD related information**
- **How to use XEVMPD Data entry tool**
- **XEVMPD e-learning training process** (initial registration, assessment evaluation)

SLAs:

- 22 working days

Report a technical issue with XEVMPD/Art.57

To report a technical issue with:

- **XEVMPD (production or XCOMP)**
- **XEVMPD additional tools** (e.g., XEVMPD Data Export tool, XEVMPD Bulk update tool)
- **Gateway submissions to XEVMPD**

SLAs:

- 5 working days

For Questions: www.slido.com code: SWOCT1124

Points to consider when submitting tickets

EUROPEAN MEDICINES AGENCY

DOs

- **Submit tickets using the correct forms**

  If incorrect → the triage team cancels/closes the existing ticket, and new ticket is opened on behalf of the customer

- **Reference** the **correct 'Service'** and **'Service Offering'**

  If incorrect → ticket assigned to the incorrect support team

- **Provide as much information as possible**

  E.g.: if reporting a technical issue, include step by step description, screenshots, organisation ID, any XML files submitted etc.

  If not provided → customer is asked for that information

DON'Ts

- Submit tickets using **incorrect form hoping for a faster response**

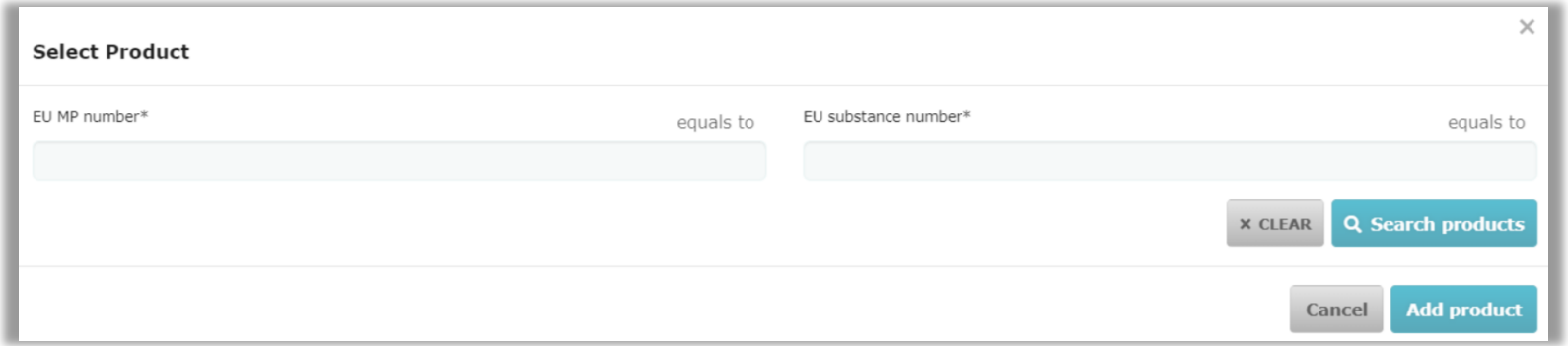
  -> the existing ticket is cancelled/closed by the triage team & new ticket is opened on behalf of the customer:

- **Submit the same issue/request/question via multiple tickets or channels**

XEVMPD data in CTIS

EU MP number and EU substance number (1/2)

- **EU MP (medicinal product) number** and **EU substance number** must be available in CTIS to register the clinical trial
  - The search in CTIS must be performed for the EU MP number **together** with the EU substance number
  - It is required to maintain the information up to date in CTIS



For Questions: www.slido.com code: SWOCT1124

EU MP number and EU substance number (2/2)

- **EU MP number = Product EV Code in the XEVMPD** (a code assigned to a specific product record in the XEVMPD)
  - **Authorised** medicinal products: **inserted by MAHs**
  - **Un-authorised** (aka 'development') medicinal products: **inserted by sponsors**

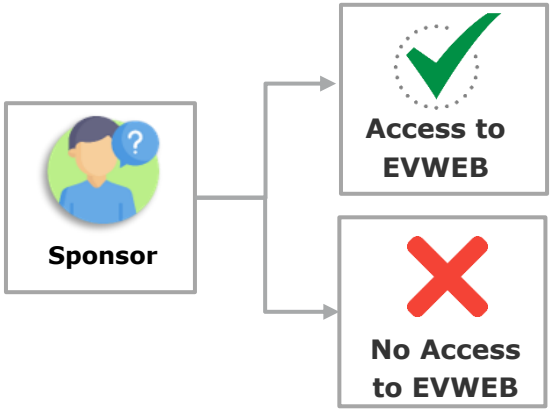
- **EU substance number = Substance EV Code in the XEVMPD** (a code assigned to a specific substance record in the XEVMPD)
  - the EV Code of the **substance referenced in the product** in the XEVMPD **as the active substance**

For Questions: www.slido.com code: SWOCT1124

How to obtain **EU MP number** for CTIS: **Authorised medicinal product**

EUROPEAN MEDICINES AGENCY

Product EV Code of an authorised medicinal product record in the XEVMPD



Search in the XEVMPD using simple or advanced queries

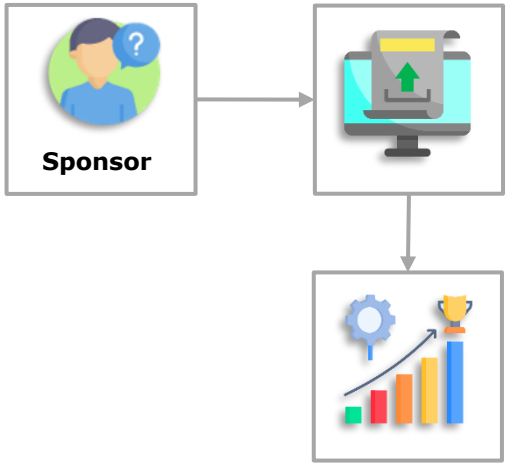
Submit a new EMA Service Desk request for XEVMPD/Art.57 Services

Specify:

- name of the medicinal product (as stated in section 1 of the SmPC)
- authorisation number
- authorisation country
- name of the MAH

For Questions: www.slido.com code: SWOCT1124

Product EV Code of a development medicinal product record in the XEVMPD



- Sponsor submits the medicinal product information in the XEVMPD
- EV Code assigned to the DMP is retrieved from the XEVPRM Acknowledgement
- '*Owned Development Products*' advanced query is also available in EVWEB

How to obtain **EU substance number** for CTIS

EUROPEAN MEDICINES AGENCY

Substance available

- **Sponsors with access to EVWEB:** search in the XEVMPD substance look-up tables using simple or advance queries
- **Sponsors without access to EVWEB:** download the current/non-current substance lists from the SMS portal

Substance missing

- **Request addition of substance information** via request for SMS services in EMA Service Desk

For Questions: www.slido.com code: SWOCT1124

Actions for sponsors to take

- **Avoid referencing substances with SVG flag 0 in any new or existing owned product records in the XEVMPD**
  - Refer to slide 20 of the Substance Management Service (SMS) webinar presentation for details/actions

- **Avoid referencing terms to be nullified in new product record submissions or updates in the XEVMPD**
  - Refer to slide 44 of the Referentials Management Service (RMS) webinar presentation for details/actions

- **Enter sponsor details in XEVMPD as per OMS**
  - Include the LOC ID in the 'Comment' field of the sponsor entity

Break (10 minutes)

EUROPEAN MEDICINES AGENCY

Let's have a short break!

XEVMPD status update

 For Questions: www.slido.com code: SWOCT1124

Planned XEVMPD Activities

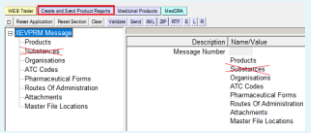
EUROPEAN MEDICINES AGENCY

	Q3 2024	Q4 2024	Q1 2025	Q2 2025
Deliver efficient and effective regulatory data services	**XEVMPD – Customer Services**			
		Revision of published documentation and processes in use		
	XEVMPD - Data Management (Data services)			
	XEVMPD – Data Quality			
Improve customer satisfaction and success	**XEVMPD – Documentation**			
		1 Revision and update of published guidance for sponsors		
	XEVMPD - Awareness & visibility			
	SPOR update webinars	SPOR week; SPOR Customer Satisfaction survey	SPOR update webinars	SPOR update webinars
Modernise Data & Information Management	Information Management Modernisation initiatives			
		2 Review of current XEVMPD User Interface and assessment of possible technical upgrade		

For Questions: www.slido.com code: #SWOCT1024

Work completed – Highlights of what was done in past quarters

EUROPEAN MEDICINES AGENCY

	WHY	HOW & WHEN	IMPACT/ BENEFITS to users
Technical restriction on submission of proposed terms	• To prevent industry from submitting duplicated or incorrect proposed terms in XEVMPD	• Submission of proposed terms via an XEVPRM blocked from *end of January 2024* • Industry should request the addition of standard and proposed terms via RMS change request	• Industry to check XEVPRM ACKs to confirm product submissions • Industry to update internal processes • Gateway users to update internal database
'Substances' section removed from the 'Create and Send product reports' section of XEVMPD data entry tool	• To prevent sponsors from attempting to insert substance information via an XEVPRM	• By removing the **'Substances' section** from the 'Create and Send product reports' section in **EVWEB - Art 57/XEVMPD** *From end of June 2024*	The 'Substances' section is no longer available in the 'Create and Send Product Reports' section 

For Questions: www.slido.com code: SWOCT1124

What's next? – Highlights of what will be done in the next quarter

EUROPEAN MEDICINES AGENCY

	WHY	HOW & WHEN	IMPACT/ BENEFITS to users
1 **Revision and update of published guidance for sponsors** 2	• To provide up to date information to sponsors, no need to submit questions via EMA Service Desk	• By reviewing and updating information in the Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD) document • *By end of Q4/2024*	• Information is available in one document • Sponsors do no need to submit tickets via EMA Service Desk to request the required information
Review of current XEVMPD data entry tool and assessment of possible technical upgrade	• To determine if XEVMPD UI could be accessed without the need for ActiveX and IE Tab extension and used in other supported web browsers	• EMA is **assessing** if/how XEVMPD UI can be improved whilst there is no major impact on current users (no need to re-train users, no loss in functionality, same secure access, look and feel etc.) • *From Q4/2024, no defined timeline*	• Easier access for users, browser-based solution • XEVMPD new UI could be used without ActiveX, IE Tab, in other supported browsers

For Questions: www.slido.com code: SWOCT1124

Highlights to you

Q1 2024 - Technical restriction on submission of proposed terms implemented

Q1 2024 - Change in process for the submission of standard and proposed terms to XEVMPD

Q2 2024 - 'Substances' section removed from the 'Create and Send product reports' section in XEVMPD data entry tool

What has changed?

Review of Guidance document for sponsors

Ongoing work

New version of Guidance document for sponsors will be published in Q4 2024

Review of current XEVMPD data entry tool and assessment of possible technical upgrade

Future changes *(What's next?)*

Consistency review of DMP information in XEVMPD

Development terms cleansing exercise

Future changes *(What's later?)*

Acronyms

XEVMPD: Extended EudraVigilance medicinal product dictionary
MFA: Multi-factor authentication
XCOMP: XEVMPD test environment
QPPV: Qualified person responsible for Pharmacovigilance
RP: Responsible person
AMPs: Authorised Medicinal Products
PhV: Pharmacovigilance
CAP: Centrally Authorised Product
FUP: Follow-Up
MRP: Mutual Recognition Procedure
DCP: De-Centralised Procedure
DMP: Development Medicinal Product

Key Takeaways and Conclusions

 For Questions: www.slido.com code: SWOCT1124

Conclusions

- Sponsors were reminded of their **submission requirements** and an overview of **how development medicinal product data should be submitted in the XEVMPD** was provided
- Information on the **relationship between XEVMPD data and CTIS** was provided
- XEVMPD status update related to DMP submissions was provided
- Sponsors were reminded of the actions to take; these included:
  - *Avoid referencing substances with SVG flag 0 and terms to be nullified in any new or existing owned product records in the XEVMPD*
  - *Enter sponsor information in XEVMPD as per OMS, reference LOC ID*

 For Questions: www.slido.com code: SWOCT1124

Quiz Time

 For Questions: www.slido.com code: SWOCT1124

Any questions on the webinar?

 For Questions: www.slido.com code: SWOCT1124

SPOR Webinars

During **SPOR webinars,** EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

Webinar title	Date	Time
SPOR Data Governance	4 October 2024	10:00-12:00 CEST
Referentials Management Service (RMS)	7 October 2024	10:00-12:00 CEST
Substance Management Service (SMS)	8 October 2024	10:00-12:00 CEST
Organisation Management Service (OMS)	9 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for MAH	10 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for Sponsors	11 October 2024	10:00-12:00 CEST
Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API	14 October 2024	10:00-12:00 CEST

 For Questions: www.slido.com code: SWOCT1124

Further information

Contact us through ServiceNow @ https://support.ema.europa.eu/

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Follow us on **@EMA_News**

Glossary

Glossary (1/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
API	Application Programming Interface
Art. 57	Article 57 of Regulation (EU) 726/2004, which requires marketing authorisation holders to electronically submit to the Agency information on all medicinal products for human use authorised in the EU
CAP	Centrally Authorised Product
CR	Change request
CTIS	Clinical Trials Information System
DADI	Digital Application Dataset Integration
DMP	Development Medicinal Product
DCP	De-centralised Procedure
DQ	Data Quality
eAF	Electronic Application Form
ePI	Electronic Product Information
eCTD	Common Technical Document in electronic format
EMA DB	European Medicines Agency Data Board
EMRN	European Medicines Regulatory Network
Epic	An epic is a container with one common objective, for a development initiative large enough to require analysis, definition of a minimal viable product (MVP) and financial approval before implementation. An epic usually takes more than one Programme Increment to complete and is broken into multiple Features. Business epics are large initiatives that deliver Solutions needed by the business/customers Enabler epics are pieces of work that extend the architectural infrastructure of the solution under development or improve the performance of the value stream

For Questions: www.slido.com code: SWOCT1124

Glossary (2/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
ESMP	European Medicines Shortages Monitoring Platform
ESMDP	European Medicinal Devices Shortages Monitoring Platform
EURS	European Review System for eCTDs
EU-SRS	European Substance Reference System
EUTCT	European Union Telematics Controlled Terms
FHIR	Fast Healthcare Interoperability Resources
HMA	Heads of Medicines Agencies
IAM	Identity and Access Management
ICSR	Individual Case Safety Report
IDMP	The ISO IDMP standards specify the use of standardised definitions for the identification and description of medicinal products for human use
INN	International Nonproprietary Names
IRIS	A secure online platform for handling product-related scientific and regulatory procedures with EMA (iris.ema.europa.eu)
KUG	Key User Group
KPI	Key Performance Indicator
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
Mon	Monitoring Value Stream

Glossary (3/4)

EUROPEAN MEDICINES AGENCY

Acronym	Name
MRP	Mutual Recognition Procedure
NAP	Nationally Authorised Product
NCA	National Competent Authority
NDB	Network Data Board
NICTAC	Network ICT Advisory Committee represents the network IT community
NPAG	Network Portfolio Advisory Group represents the Management Board and HMAs
OD	Orphan Designation
OMS	Organisation Management Service
PB	Portfolio Board
PI	Programme Increment, a three month period of work
PI Planning ceremony	A quarterly event to plan work for the entire Value Stream in the next quarter, ensuring that teams and stakeholders have a shared mission and vision
PIP	Paediatric Investigation Plan
PLM	Product Lifecycle Management Value Stream
PMS	Product (Data) Management Service
PO	Product Owner (PO) is the Agile team member primarily responsible for maximizing the value delivered by the team by ensuring that the team backlog is aligned with customer and stakeholder needs.
RMS	Referential Management Service
R&D	Research and Development Value Stream

For Questions: www.slido.com code: SWOCT1124

Glossary (4/4)

Acronym	Name
SAFe	Scaled Agile Framework
SIAMED	An Information System for the management of regulatory procedure for centrally authorised products
SLA	Service Level Agreement
SPOR	Substance, Product, Organisation and Referential
SmPC	Summary of product characteristics
SMS	Substance Management Service
SQI	Service Quality Indicator (metric)
SVG	Substance Validation Group
UNII	Unique Ingredient Identifier
USAN	United States Adopted Names
Value Stream	Value Streams represent the series of steps that an organization uses to implement Solutions that provide a continuous flow of value to the Business/Customer
VSM	EMA Value Stream Manager (VSM) is a "Servant Leader and Coach" for the Value Stream teams
VSO	EMA Value Stream Owner (VSO) has the primary responsibility for the business outcomes, including the delivery of business outcomes, in their Value Stream
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary