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**.*

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For Questions: www.slido.com code: #3713705

Housekeeping notes – Q&A

Join at
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- 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: #3713705

Webinar materials sharing and technical recommendation

EUROPEAN MEDICINES AGENCY

Presentations are available at:

- EMA Events Web Page
  - *Find event based on date/name*
  - *The presentation is available in the 'Documents' section of the event page*

*1st version of presentation already published, to be updated with final version (if necessary)

Recordings
will be available in due course on:

- EMA YouTube Channel
- EMA Events Web Page

*If you would like to **receive recordings and presentations via email**, please register your e-mail address in Slido (www.slido.com) using the **event code #5864645.***

For best **broadcast picture quality**, adjust your settings by selecting **HD Resolution** at the bottom right-hand corner of the screen

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Product Management Service (XEVMPD)

10 October 2023, 14:00 – 16:00 Central European Summer Time (CEST)

Presented by Marcos Fernandez Gomez and Veronika Baker

SPOR Webinar Series – 2-12 October 2023

H2 2023 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 and XEVMPD Data Governance	2 October 2023	10:00-12:00 CEST
Referentials Management Service (RMS)	3 October 2023	10:00-12:00 CEST
Organisation Management Service (OMS)	4 October 2023	10:00-12:00 CEST
Substance Management Service (SMS)	5 October 2023	10:00-12:00 CEST
Service Desk for SPOR and XEVMPD	**10 October 2023**	**10:00-12:00 CEST**
Product Management Service (XEVMPD)	10 October 2023	14:00-16:00 CEST
EMA Account Management	11 October 2023	10:00-12:00 CEST
SPOR application programming interface (API) - SPOR API	12 October 2023	10:00-12:00 CEST

For Questions: www.slido.com code: #3713705

Goals of the session

- Re-cap of **XEVMPD submissions requirement** and **processes for AMPs and DMPs**
- Provide an update on the **planned improvements**
- Give an overview of **XEVMPD statistics**
- Provide more information on the **relationship between XEVMPD and PMS**

For Questions: www.slido.com code: #3713705

Agenda

1. **Welcome**
   14:00 – 14:05
2. **Introduction to XEVMPD**
3. **XEVMPD process**
4. **Authorised medicinal products (AMPs) in the XEVMPD**
5. **Development medicinal products (DMPs) in the XEVMPD**
6. **XEVMPD statistics**
7. **XEVMPD Documentation & help**
8. **XEVMPD and its relationship with PMS and eAF**
9. **XEVMPD recent & planned activities**
10. **Key Takeaways and Conclusions**
11. **Q&A Session**
    15:45 – 16:00

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Introduction to XEVMPD

Presented by Marcos Fernandez Gomez

XEVMPD introduction

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XEVMPD is a **central source of medicinal product data** (authorised and un-authorised) that supports different processes in the Network

XEVMPD

- Medicinal Product data is **submitted and maintained** in XEVMPD by **MAHs and sponsors**.
- Authorised Medicinal Product data is checked by the EMA to ensure data is **standardised**
- **Customer support** is provided **via EMA Service Desk**

XEVMPD database can be **accessible** through a **user interface** (EVWEB) or through a **gateway** (API)

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Pre-submission requirements

Sponsor and **MAH** organisations must be registered with:

Organisation Management Service (OMS)

EudraVigilance for medicinal product reporting

- Responsible person (RP) and/or Qualified Person for Pharmacovigilance (QPPV) must be registered under the **HQ profile of the organisation**
- **User roles** are managed in the **EMA Account Management portal**
- At least one user from the organisation must follow the **XEVMPD training course** to be in possession of the **'Notification of successful completion of the XEVMPD training course'** -> required as part of the **organisation's** registration process with EV
- **Training is available as:**
    - E-learning training course and
    - Face-to-face training course (currently held virtually)

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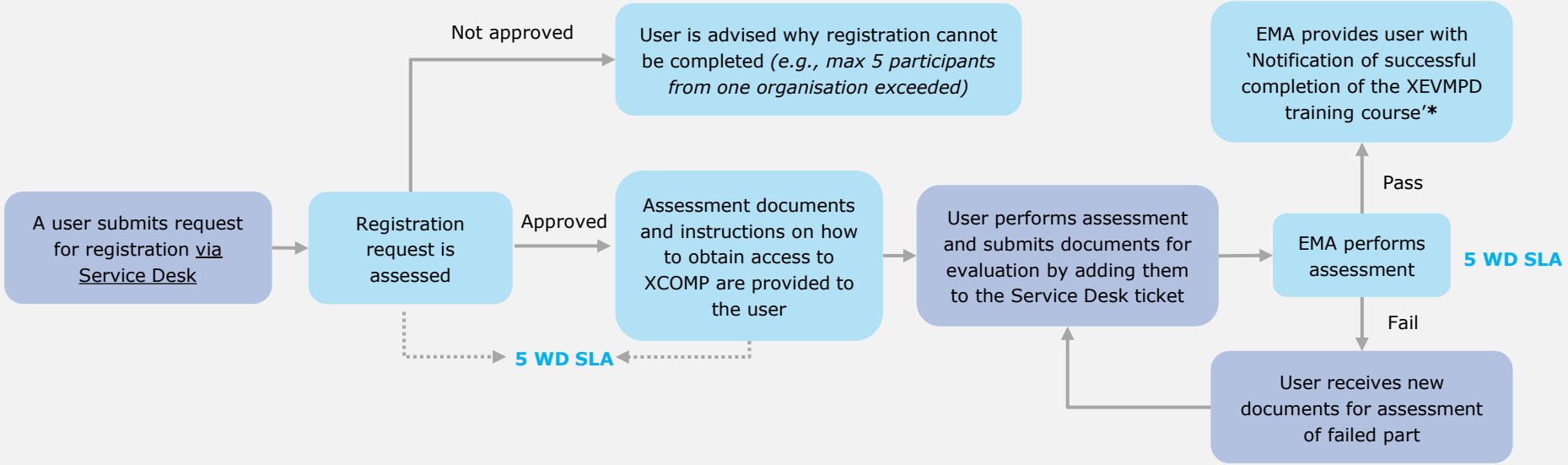
XEVMPD e-learning training process



* The 'Notification' is required from **one person** during **the initial registration of an organisation in EudraVigilance**; trained users can train others in their company

3 attempts for each failed part
If user fails all 3 attempts, they are advised to follow the face-to-face training course

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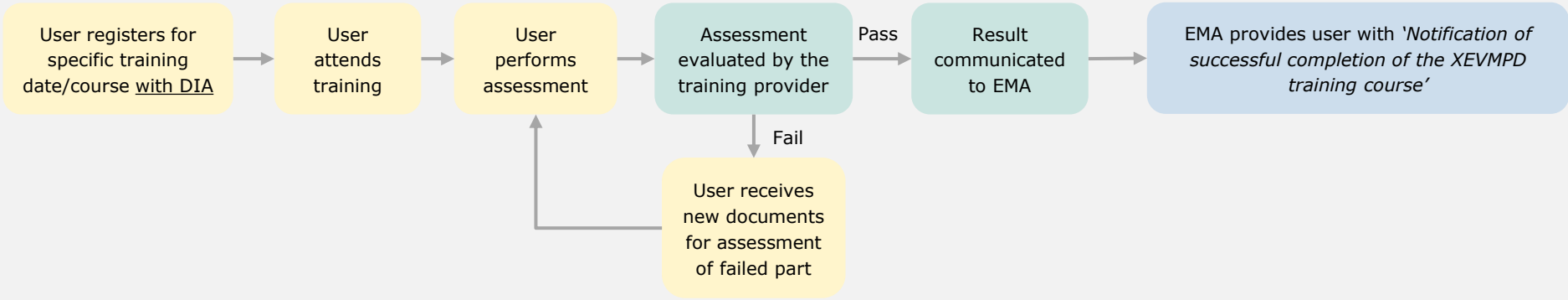
XEVMPD face-to-face training process



3 attempts for each failed part

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Submission methods

Medicinal product data must be submitted to XEVMPD electronically in an **eXtended EudraVigilance Medicinal Product Report Message** (XEVPRM) via:

WebTrader submission mode using the XEVMPD data entry tool ('EVWEB')

Gateway transmission mode

XEVPRM ACK will be provided to the sender organisation after each submission

Overview of EV registration process (MAHs and sponsors)

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Registration with EV for product reporting

One user from the organisation attends the **XEVMPD training** and obtains *'Notification of successful completion of the XEVMPD knowledge evaluation'*

First user registers with the EMA Account Management Portal

Is organisation registered in OMS?

yes

no

Create organisation in OMS

Request 'Responsible Person' or 'QPPV' role in the EMA Account Management Portal

Submit ticket via EMA Service Desk with

- Reference 'role request' ID (generated by the EMA Account Management Portal)
- Provide supporting documents
- Provide Gateway connection details, if applicable

In EV restricted area **complete/update information in the *'Manage your profile'*** section

Receive confirmation about submission mode set-up (Webtrader or Gateway)

Approve users' roles in the EMA Account Management Portal

Organisation and users are registered

The EV Registration team provides additional support for **non-commercial sponsors**.
See section *8. Non-Commercial Sponsors Additional Organisation & User management support* of EV Registration Manual

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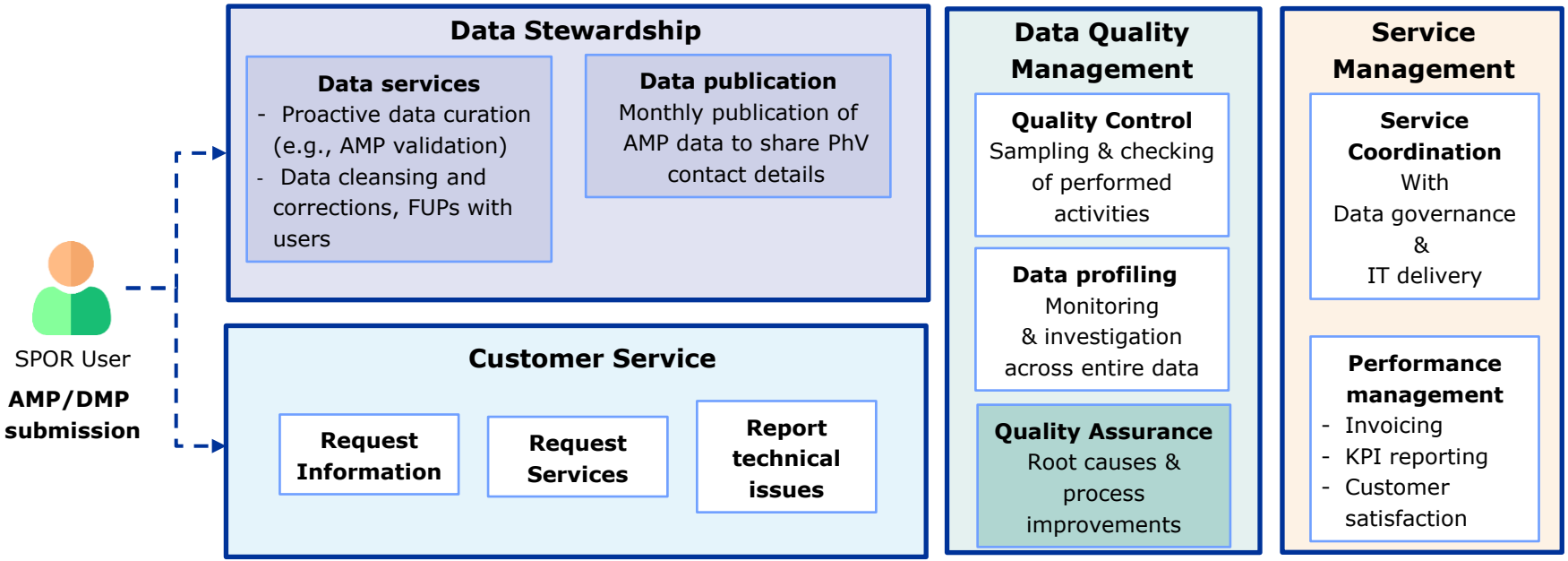
XEVMPD Process

Presented by Marcos Fernandez Gomez

XEVMPD Data management processes

EMA Data Steward

Business lead/ Product Owner



Data management processes are defined, operational and are monitored

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Authorised medicinal products (AMPs) in the XEVMPD

Presented by Marcos Fernandez Gomez

Mandatory reporting requirements for MAHs

Legal obligation from Article 57(2) of Regulation (EC) No 726/2004, the EEA Agreement and the Protocol on Ireland/Northern Ireland

MAHs **must submit** to the XEVMPD information on **medicinal products for human use authorised** under a *national, mutual-recognition, decentralised* and/or *centralised authorisation procedure in the EU*, *EEA countries and the Northern Ireland.*

- **New authorised medicinal products** must be submitted as soon as possible and no later than **15 calendar days** from the date of authorisation
- **Amendments to the terms of the marketing authorisations** following variation, transfer, renewal, suspension, revocation or withdrawal of the marketing authorisation must be submitted no later than **30 calendar days** from the date of which the amendments have been authorised

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Voluntary reporting requirements for MAHs

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MAHs **may submit** to the XEVMPD **information on:**

Herbal medicinal products - Art. 16a Dir No 2001/83/EC (traditional use registration application)

Homeopathic medicinal products - Art 14 Dir No 2001/83/EC (simplified registration application)

'Named patient use' and 'EU Distribution Procedure' - Art 5(1) and Art 5(2) Dir 2001/83/EC

Parallel Distributed/Imported medicinal products - Art 76(3) and (4) Dir No 2001/83/EC]

Medicinal products authorised **outside the EEA** or following a non-EU procedure

Products **without a marketing authorisation in the EU/EEA**, which are **approved under emergency use, compassionate use or other national schemes**

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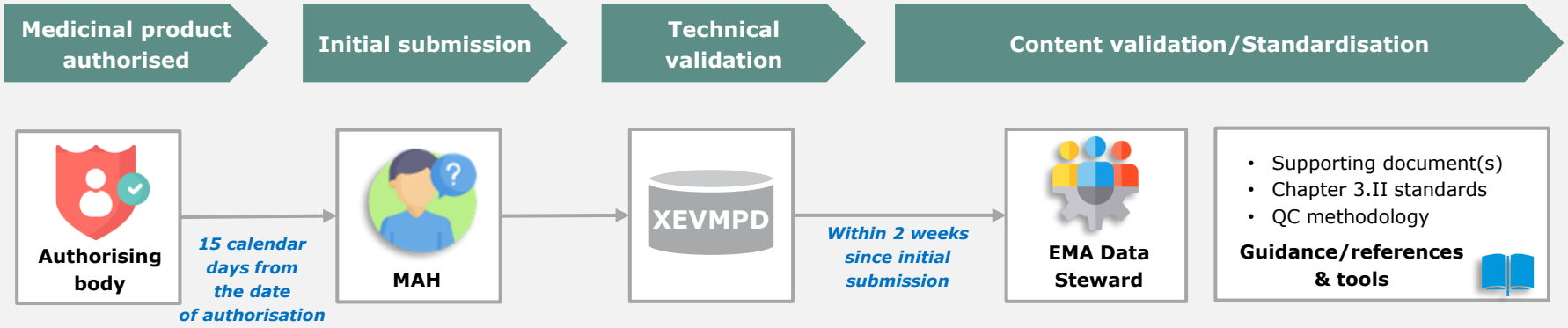
AMP: Initial submission process



Submit AMP data in XEVMPD:

- **Insert AMP information**, including MAH/PSMFL/QPPV information reference
- Insert and reference in the AMP record(s) **supporting document(s)** (e.g. SmPC/PIL)

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

- Chapter 3.I: Technical specifications
- Chapter 3.II: business guidance

1st and 2nd XEVPRM ACK generated

Perform validation based on

- Information provided in documents
- Chapter 3.II describing the business rules/approach for entering AMP data
- Data quality control methodology
- Rational assessment of the submitted information

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AMP: Validation process

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Content validation outcome - AMP validated/flagged for FUP

Product **entry is validated** (with or without changes made as part of the validation)

AMP record data (except for MFL and QPPV details) **become visible** to other users in EVWEB, not just the owner organisation and EMA. AMP record is used to support PhV activities

If MAH disagrees with the changes made as part of the validation/in case of additional questions, submit a ticket via the EMA Service Desk portal

MAH receives validation related XEVPRM ACK

(3rd XEVPRM ACK)

Product **entry not assessed**, FUP communication triggered

MAH receives FUP communication

FUP emails are sent on weekly basis

MAH amends product entry as required/provides additional documents

As per the timelines specified in the FUP communication (i.e.; 15 or 30 calendar days)

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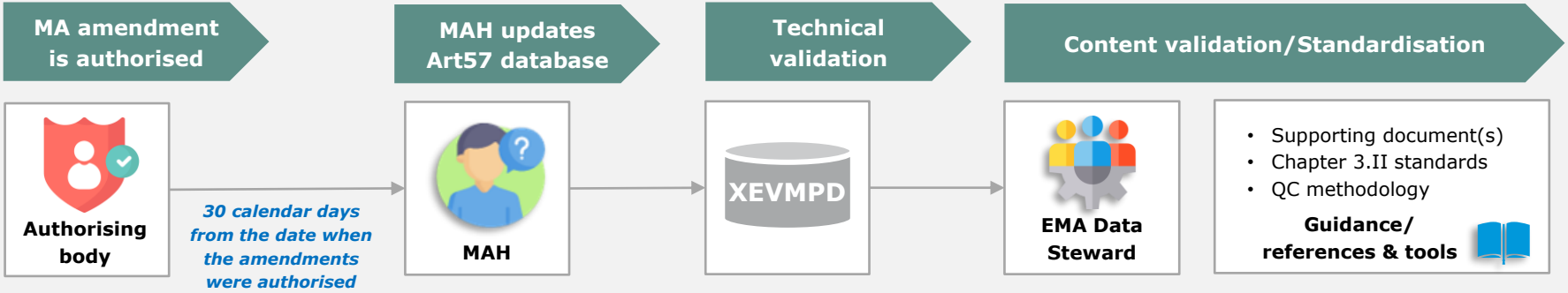
AMP: Amendments following regulatory procedure process



Insert/update/invalidate AMP data in XEVMPD as applicable

- Based on processes described in Chapter 3.II: business guidance
- Insert and reference in the AMP record(s) **supporting document(s)**

1st and 2nd XEVPRM ACK generated within 24 hours since submission

Perform follow-up validation

- *Re-validation is performed as needed and max within 2 years since last validation*

AMP CAP submission compliance check

Regular check performed by the EMA

New CAPs

- **Number of presentations** in EMA DB (SIAMED) is **compared** with XEVMPD entries
- **Product information** is entered in:
  - EMA's scientific group table
  - European Pharmacovigilance Issues Tracking Tool (EPITT)
- *If CAP data is not inserted in XEVMPD by the MAH within 15 calendar days since authorisation -> the QPPV is contacted*

Transferred CAPs

- **XEVMPD entry check** is performed:
  - Did the former MAH invalidate their AMP record?
  - Did the new MAH submit a new record?
- *If transfer of MA is not performed correctly by the MAH within 30 calendar days since MA amendment authorisation -> the QPPV is contacted*

Data Publication

Monthly

List of medicinal products authorised in the EU/EEA published on EMA web page: Public data from Article 57 database | EMA (europa.eu) **to share MAH's pharmacovigilance contact details (phone number and e-mail)**

Quarterly

XEVMPD controlled vocabulary lists published on: Guidance documents | European Medicines Agency (europa.eu)

This publication has been discontinued in 2023; information is available in the relevant SPOR services

Ad-hoc

Updates of documentation (Guidance docs, Q&A docs, other) as required

Development medicinal products (DMPs) in the XEVMPD

Presented by Veronika Baker

Mandatory reporting requirements for Sponsors

Regulation (EU) No 536/2014

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'):

section 104: "… the Sponsor should provide, before completing the clinical trials application form, information on the IMP in the EudraVigilance Medicinal Product Dictionary ('EVMPD' 1)…"

Sponsors to submit in the XEVMPD information on the investigational medicinal product (IMP) **before completing the clinical trials application (CTA) form in CTIS**

- '**EU substance number**' and '**EU product number**' must be available in CTIS to register the trial
- The search in CTIS must be performed for the EU MP number together with the EU substance number (i.e.: the number of the substance referenced in the product in the XEVMPD as the active substance)

The legislation (CT-3) does not cover the product information update in the XEVMPD however, it is required to maintain the information up to date in CTIS

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

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EU substance number = Substance EV Code in the XEVMPD (a code assigned to a specific substance record in the XEVMPD)

Substance records are **inserted** in the XEVMPD **by the** EMA's **Substance Management Service (SMS) data stewards on request from marketing authorisation holders and/or sponsors of clinical trials**

Substance available

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

Substance missing

Sponsor

Request addition/ update of substance in the XEVMPD via EMA Service Desk request for SMS services*

* Include:
- brief description of the substance;
- substance request form;
- supporting documentation

EMA Data Steward

Validate the request (SLAs apply)

Request approved

Request rejected

Reasons for rejection explained to requestor

EV Code is assigned and shared with the requestor
- Data updated in SMS & published in consuming systems
- Substance is available in the XEVMPD

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

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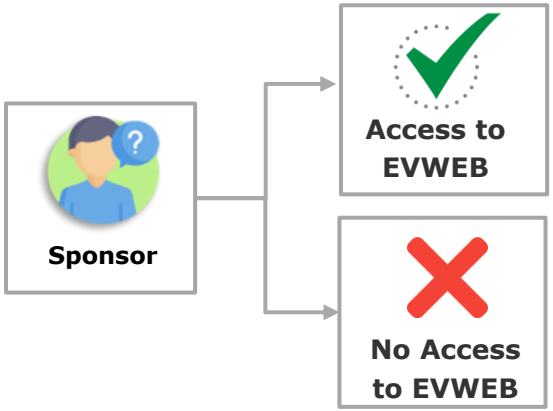
EU product number = Product EV Code (a code assigned to a specific product record in the XEVMPD)

- **Authorised** medicinal product information is **inserted in the XEVMPD by MAHs**
- **Un-authorised** (aka 'development') medicinal product information is **inserted in the XEVMPD by sponsors**
- EMA does not enter information about authorised and/or un-authorised medicinal products in the XEVMPD on behalf of MAHs/sponsors

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



Search in the XEVMPD

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

The XEVMPD/Article 57 business team performs the search based on the specified criteria and, if the product record is found, provide you with the EV Code(s) **> 5 w/d SLA**

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

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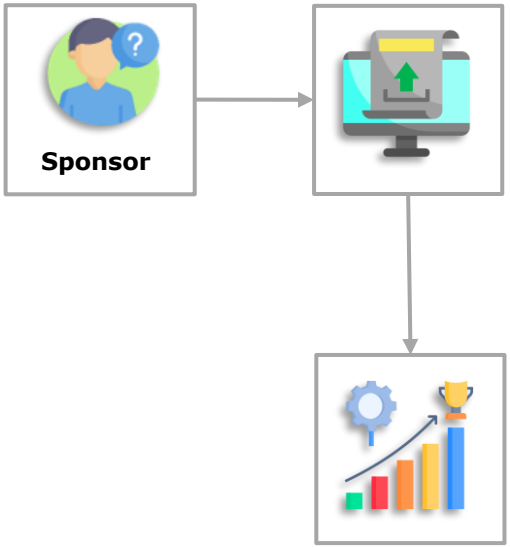
Product EV Code of a development medicinal product record in the XEVMPD



Sponsors must submit the 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**

  → *submit a new DMP in the XEVMPD*

- If a medicinal **product not authorised in the EU/EEA** is used in a **clinical trial in the EU/EEA**

  → *submit a new DMP in the XEVMPD*

If the **submission was successful**, the DMP EV Code will be shared with the sponsor organisation that submitted the information via an XEVPRM acknowledgement

- XEVPRM ACKs are sent within 24 hours
- The product EV code will be retrievable in CTIS the next day

DMP: Initial submission process

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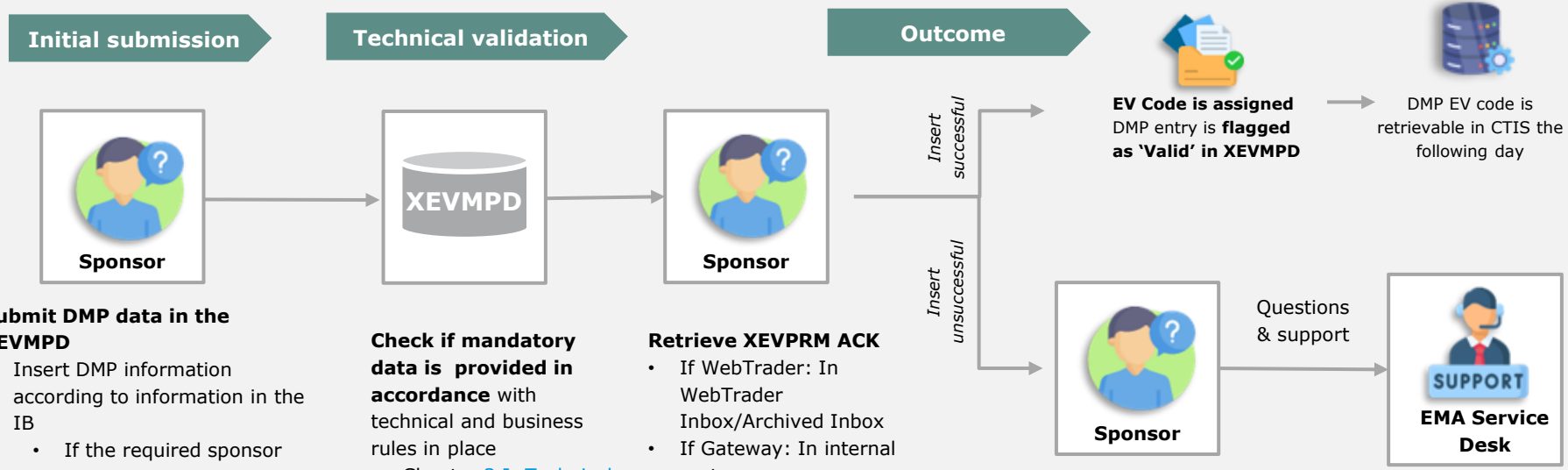


Submit DMP data in the XEVMPD

- 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

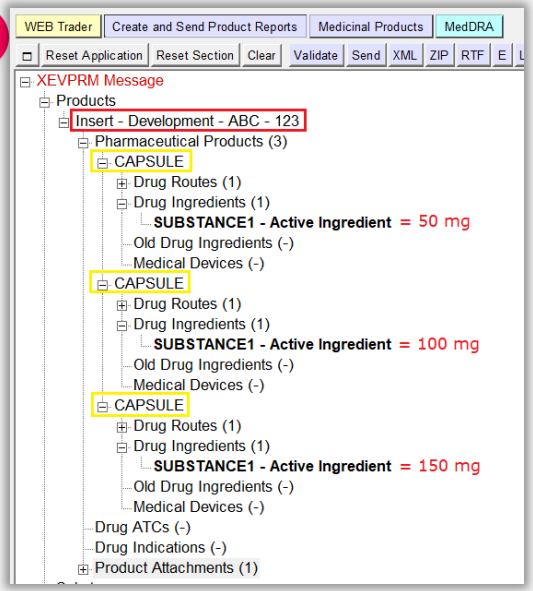
Correct data as per XEVPRM ACK and re-submit

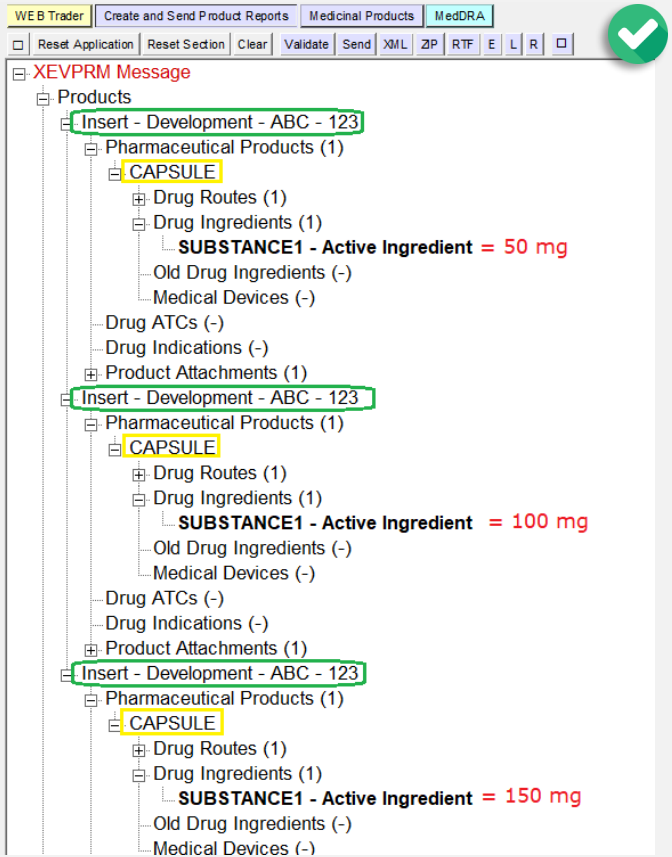
Points to consider for submissions (1/4)

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

→ **separate development medicinal products** must be submitted to the XEVMPD for each pharmaceutical product

An EV Code will be assigned to each development medicinal product





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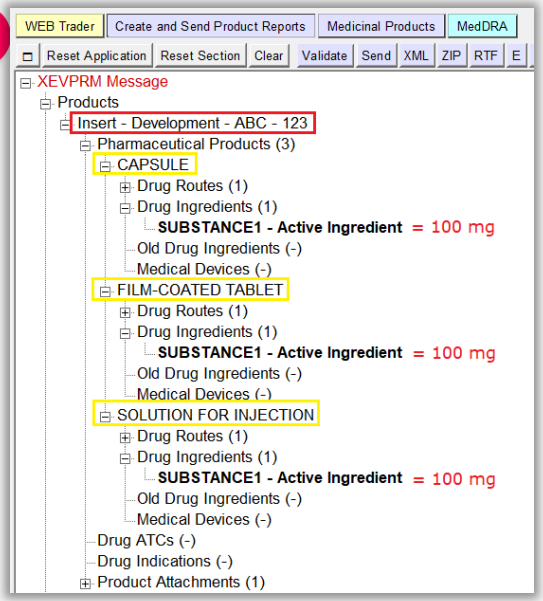
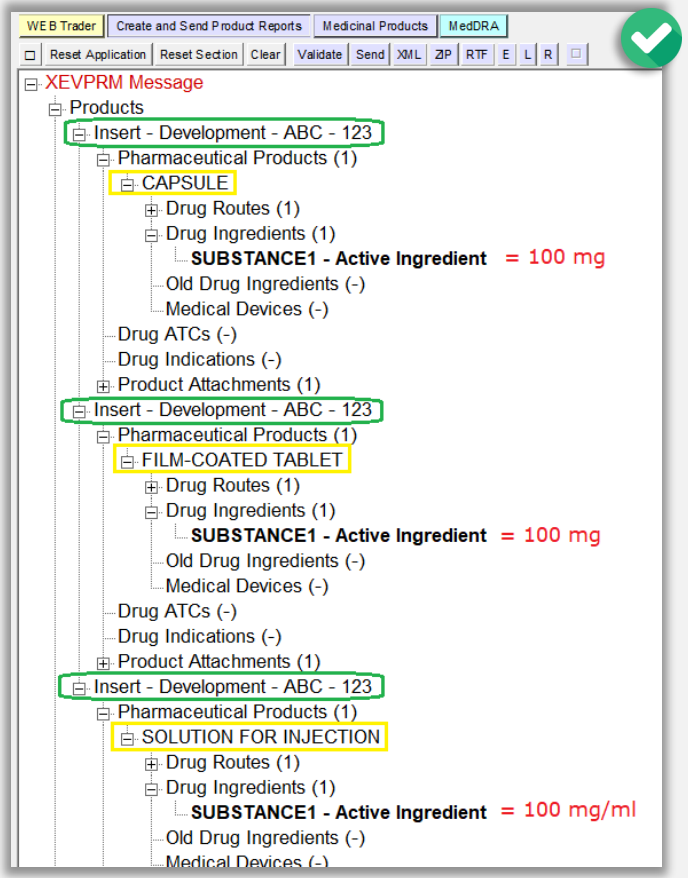
Points to consider for submissions (2/4)

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

→ **separate development medicinal products** must be submitted in the XEVMPD for each pharmaceutical product

An EV Code will be assigned to each development medicinal product





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Points to consider for submissions (3/4)

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

→ **each sponsor submits the DMP information in the XEVMPD**

An EV Code will be assigned to each development medicinal product

- *Each DMP in a clinical trial needs to be uniquely identifiable and is sponsor-specific*
- *Data entered in the XEVMPD as 'development' are strictly confidential and visible to the sponsor organisation that 'owns' this product data in the XEVMPD*
- *Updates of this data can only be performed in the XEVMPD by the owner organisation*

	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

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Points to consider for submissions (4/3)

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…"*

Valid marketing authorisation (MA) in the EU/EEA

Medicinal product exists with a **valid marketing authorisation (MA) in the EU/EEA** -> the product is submitted in the XEVMPD as an AMP by the MAH.

- If **studied** in a clinical trial **in its authorised form** (same pharmaceutical dose form, active ingredient and its concentration)

  → *in the CTA form, the sponsor makes a reference to the AMP entered in the XEVMPD by the MAH*

- If **studied** in a clinical trial **in different pharmaceutical dose form and/or composition** (active ingredient and concentration):

  → *the sponsor enters a DMP entry in the XEVMPD and*

  → *makes a reference to the DMP in the CTA form*

Valid MA outside the EU/EEA

Medicinal product exists with a **valid MA outside the EU/EEA** and is used in a clinical trial in the EU/EEA:

- If studied **in its authorised form** (same pharmaceutical dose form, active ingredient and its concentration):

  → *the sponsor enters a DMP entry in the XEVMPD*

  → *The sponsor makes a reference to the DMP in the CTA form*

- If **studied in different pharmaceutical dose form and/or composition** (active ingredient and concentration):

  → *the sponsor enters a DMP entry in the XEVMPD and*

  → *makes a reference to the DMP in the CTA form*

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XEVMPD Statistics

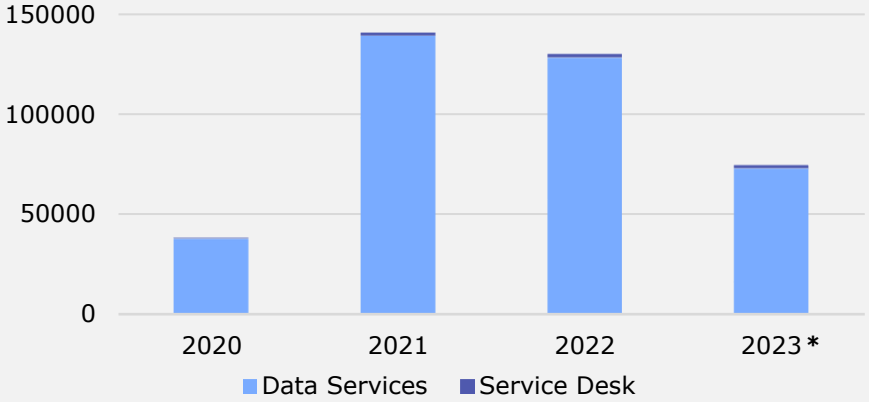
Presented by Marcos Fernandez Gomez

XEVMPD Statistics

- Based on H1 2023 figures, **number of tickets is increasing every year**. An increase on requests and operational questions has been noticed.
- **Data Service numbers are consistent** with other years

- 100% of requests for information met the SLAs
- 82% of request for services met the SLAs
- 90% of incidents met the SLAs
- **SLA overall compliance is within the target score**

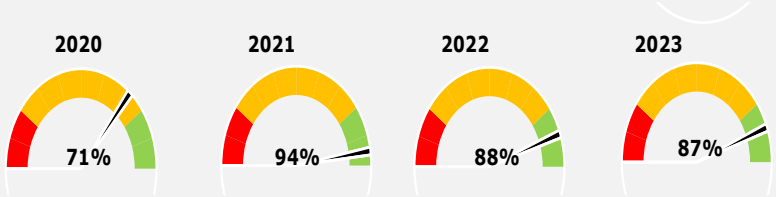
XEVMPD Activities



**2023 up to Q2 cumulative*

Overall Compliance

Service Desk



For Questions: www.slido.com code: #3713705

Documentation overview & help

Presented by Veronika Baker

 For Questions: www.slido.com code: #3713705

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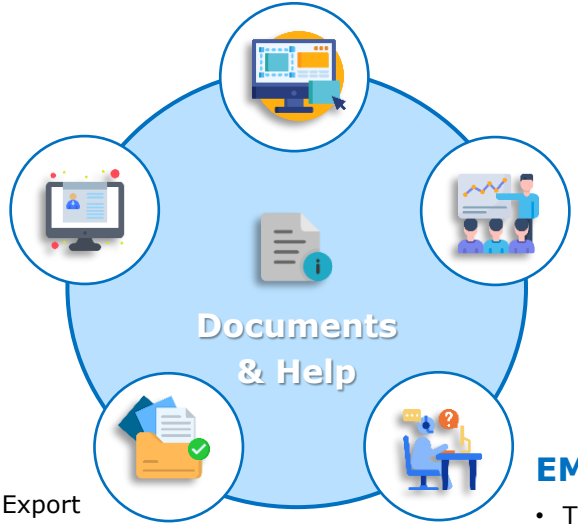
EMA corporate website

- Overview of reporting requirements **for MAHs**, links to guidance documents
- 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

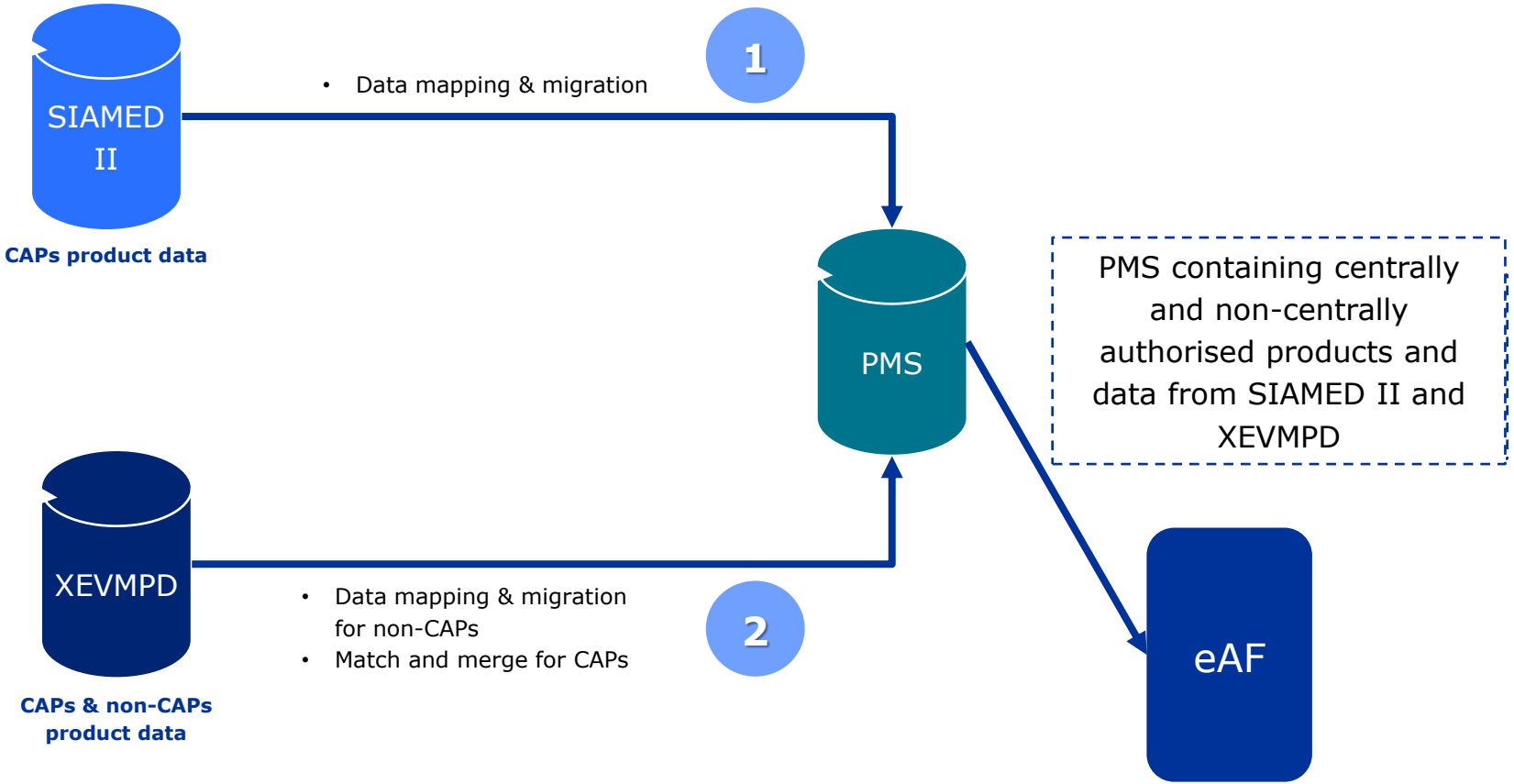
EMA Service Desk

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

XEVMPD and its relationship with PMS and eAF

Presented by Marcos Fernandez Gomez

Origin of existing product data in PMS: Initial data load



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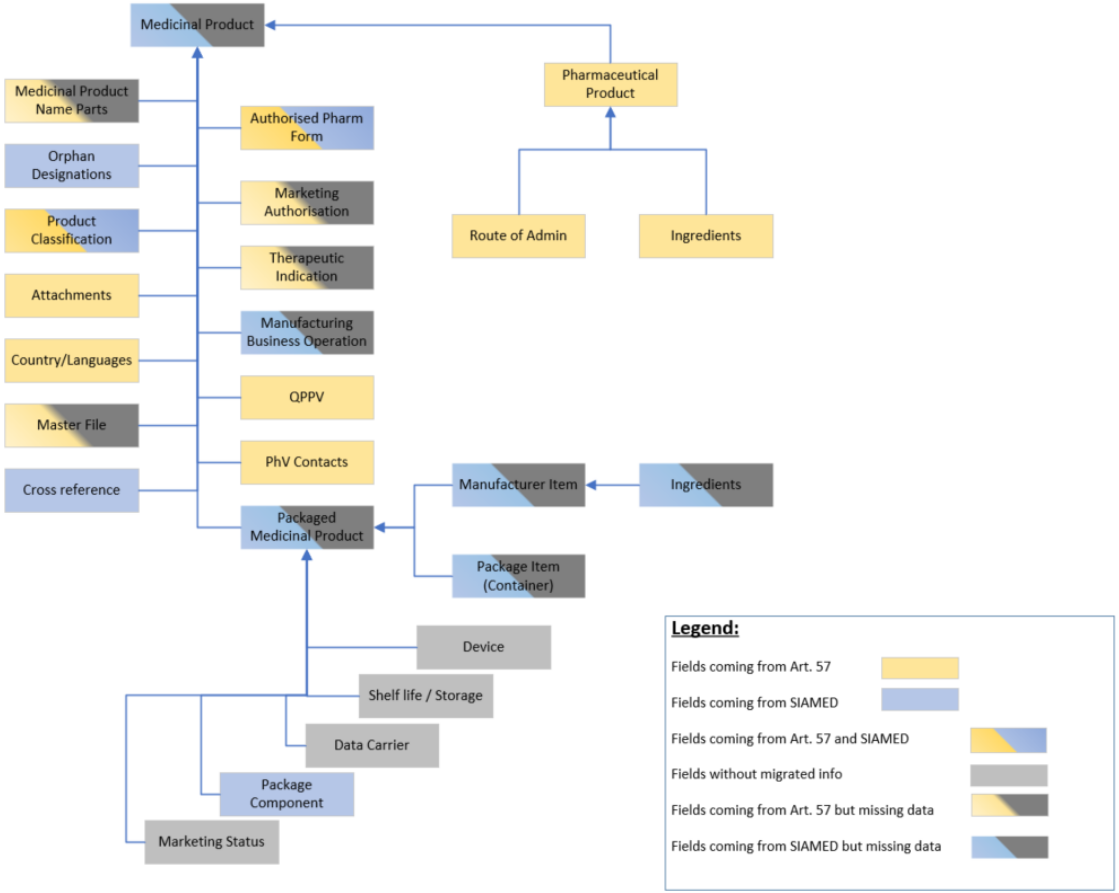
XEVMPD data used in PMS

- Only XEVMPD records with data in the following fields are migrated:
  - Auth Ph dose form
  - Legal Basis
  - Medicinal product type
  - Authorisation status different from:
    - Not Valid - Superseded by Marketing Authorisation Transfer
    - Not Valid - Superseded by Marketing Authorisation Renewal/Variation
- Last version of non-nullified records in XEVMPD is migrated to PMS.



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Migration of XEVMPD data into PMS

XEVMPD contains **non-CAPs** product data:

- At presentation level (i.e., one EV code per presentation)
- At medicinal product level (i.e., no presentations are submitted to XEVMPD)
- BE, FI and LU authorised products are submitted in each official language

EV codes with the same data in the following **XEVMPD fields** are grouped under the same PMS Medicinal Product

Marketing Authorisation Holder	Authorisation Country	Active Substance(s)	Strength of active substance(s)
Authorised pharmaceutical dose form	Product full name*	Authorisation number**	MRP/DCP number and Authorisation Procedure***

*All countries except BE, FI and LU
**FI and LU
*** BE

Please, review **Chapter 7** of the EU IG for more information

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Examples

Example 1

Owner HQ ID	Authorisation Country	Substance names	Pharmaceutical For	Full Presentation Nam	Authorisation Number
CHIESI	Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/03
CHIESI	Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/01
CHIESI	Romania	CROSPOVIDONE, LACTOSE MONOHYDRATE, MAGNESIUM STEARATE, SILICA, CO	TABLET	Flamexin, 20 mg, comprimate	7146/2006/02

3 EV codes in XEVMPD
(1 per presentation)

1 Medicinal product with
3 Package medicinal products

Example 2

Owner HQ	Authorisation Country	Substance names	Pharmaceutical Form	Full Presentation Name	Authorisation Numbe
ESTEVE	Spain	HYDROGENATED VEGETABLE OIL, HYDROXYPROPYL DISTARCH PHOSPHAT PROLONGED-RELEASE TABLET		DOLPAR 300 mg comprimidos de liberación prolongada	67.587
ESTEVE	Spain	HYDROGENATED VEGETABLE OIL, HYDROXYPROPYL DISTARCH PHOSPHAT PROLONGED-RELEASE TABLET		DOLPAR 100 mg comprimidos de liberación prolongada	67.585
ESTEVE	Spain	HYDROGENATED VEGETABLE OIL, HYDROXYPROPYL DISTARCH PHOSPHAT PROLONGED-RELEASE TABLET		DOLPAR 200 mg comprimidos de liberación prolongada	67.586

3 EV codes in XEVMPD
(1 per product)

3 Medicinal product with
1 Package medicinal product each

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Data quality issues

- There might be **data quality issues** in XEVMPD (visible via the PLM portal)
  - Applicants can update their product data directly in XEVMPD and it will be synchronised with PMS
- Any data quality issue present in XEVMPD can result in an **incorrect migration of product data or generation of products into PMS**
- **More information** can be found in EU IG Chapter 7

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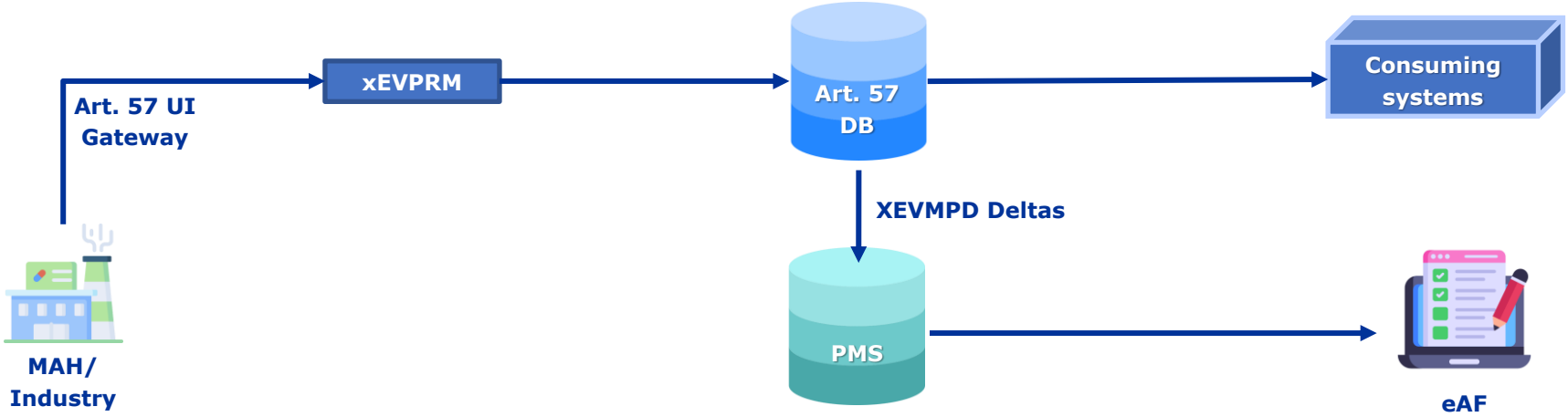
XEVMPD Deltas to PMS



- Chapter 9 will be released in Q4 2023 with all the information related to the XEVMPD Deltas
- Deltas can be used to correct data quality issues in XEVMPD
- Deltas will submit new records from XEVMPD to PMS (therefore will be seen in eAF)

Gateway users are advised to review 3rd AcK to avoid submitting incorrect data amended by EMA with every new XEVPRM

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My product is out of scope of Art57 requirements. How will it be available in the PLM portal?

- If your product is out of scope of Art. 57 but you want to use it in the eAF variation form, then, a **voluntary submission** to XEVMPD is needed. This way, it will be migrated to PMS and will be available in the PLM portal.
- Additional information is already available and will be extended to address the details of specific homeopathic medicinal products.

I cannot find my product in the PLM portal. What can I do?

- Check that your product:
  - is in XEVMPD *(if not, check question above)*
  - is not nullified in XEVMPD
  - has the correct MAH (MAH name, address and EV code)
- Check OMS to confirm that the EV code - OMS ID mapping is correct
- Check that you are logged in the PLM portal within the same MAH/Organisation
- If all the above is correct, please raise a ticket with relevant information so we can investigate the issue (technical issue or data quality issue).

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XEVMPD - PMS - eAF: FAQs

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The data that I see for my product coming from XEVMPD is wrong. How can I correct it?

- Once the data is visible in the PLM portal, XEVMPD, PMS and eAF will be synchronised. Any change done to XEVMPD will be propagated to PMS – eAF. You can therefore submit an update to XEVMPD and it will be reflected in PMS – eAF.
- If the data is correct in XEVMPD, but incorrect in the PLM portal, please raise a ticket with relevant information so we can investigate the issue (mappings).

I have performed an update in XEVMPD. When can I expect to see it in the PLM portal?

- XEVMPD, PMS and eAF are synchronised. Any change done to XEVMPD will be propagated to PMS – eAF. Time to see the update in PMS and PLM portal will depend on the amount of messages to be processed. Our goal is to increase the performance of these updates to achieve an almost real-time synchronisation.

I need to use the eAF variation form for a medicinal product that has not been authorised yet (e.g., the national phase for an MRP or DCP has not concluded yet). Can I submit this product to XEVMPD?

- The XEVMPD is discussing a process to include those products that, temporarily have not been authorised yet without disrupting any ongoing process (e.g., won't be included in the PV fees, ICSRs are not disrupted, etc).
- This is foreseen to be in place by Q1 2024.
- In the meantime, please use the PDF eAF for these products and do not submit them to XEVMPD until further notice

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What does this mean for you and XEVMPD?

DMP submissions should be done in XEVMPD for the foreseeable future

Pending AMPs submissions in XEVMPD

- Needed if specific variations for pending products should happen with eAF var form (due to need to select the product)
- Notification on when submissions of pending NAP products can start will be sent – Q1 2024

New voluntary AMP submissions in XEVMPD

- Needed if eAF var form should be used with those products (due to need to select the product)
- can start submitting voluntary AMPs to XEVMPD today – functionality exists

AMP submissions

- XEVMPD submissions are still mandatory and are the only way to keep PMS updated.

Data enrichment to PMS

- Not possible for the moment until other enablers are in place (Product UI and API submission for example)
- Roll-out plan of capabilities to enrich and re-use data will be provided in advance
- Transition period is also expected

Same long-term goal

- Replace XEVMPD submissions with direct submissions to PMS for CAPS and NAPS

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XEVMPD recent & planned activities

Presented by Veronika Baker

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XEVMPD recent changes

New process for requesting **access to XCOMP <u>for training purposes</u>**

from mid Sep 2023

Validation of newly submitted products increased from once a week to twice a week

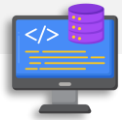
from Sep 2023

Submission of MAH information in XEVMPD as per OMS guidance

from July 2023

Requesting **inserts of XEVMPD terms via change requests in RMS and/or Service Desk request**

from July 2023



Development substance cleaning activity

from July 2023

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Planned XEVMPD activities

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Activities for 2024 to be adjusted based on Customer Satisfaction Survey's results

	Q3 2023	Q4 2023	Q1 2024	Q2 2024
Deliver efficient and effective regulatory data services	**XEVMPD – Customer Services** Knowledge base articles to be created in EMA Service Desk **XEVMPD - Data Management (Data services)** 1 Submission of MAH information in the XEVMPD as per information submitted to OMS 2 Process improvement: Request creation of proposed terms via RMS **XEVMPD – Data Quality** 3 Development substance data cleansing exercise in XEVMPD NEW QPPVs/RPs to review and confirm users registered in EMA Account Management portal for their organisation 4 Restriction of submission of proposed terms by sponsors and MAHs NEW 5 Review of DMP information in XEVMPD NEW 6 Review of AMPs as part of pre-advice note checks NEW 7 MRPs/DCPs under the national phase to be submitted as pending products, new Authorisation Status value available in XEVMPD NEW			
Improve customer satisfaction and success	**XEVMPD – Documentation** Chapter 3.II update Review & condense of XEVMPD docs & Review & update of information on XEVMPD related webpages **XEVMPD – Awareness & visibility**		SPOR week SPOR Customer Satisfaction survey	SPOR webinars
Modernise Data & Information Management	8 MFA deployment in XCOMP NEW			

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XEVMPD Data Management (Data services)

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1. MAH organisation details submission according to OMS rules/standards

WHY

To support successful PMS & eAF implementation and synchronisation of information in XEVMPD and OMS

HOW & WHEN

From July 2023 - MAHs to insert Org/Loc details in the XEVMPD as they were submitted to OMS

- **LOC ID** to be referenced in the 'Comment ' field (0.18) of the MAH organisation entity in XEVMPD (existing and/or new) if organisation info provided as in OMS

IMPACT on users:

Impact: Change in process, update of MAH data in the XEVMPD

Benefit: Improved data quality, less likely to have issues with PMS migration and data being used by eAF

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2. Submission of proposed terms

WHY

To support successful PMS & eAF implementation and synchronisation of information in XEVMPD and RMS

HOW & WHEN

From July 2023 - Proposed and/or standard terms are requested via RMS:

- Term not available in RMS and XEVMPD -> to be requested via a **'New term'** change request
- Term available in RMS but not in XEVMPD -> to be requested via **'Update term'** change request

IMPACT on users:

Impact: Change in process, users become familiar with requesting data via RMS

Benefit: Improved data quality less likely to have issues with PMS migration and data being used by eAF

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3. Re-map of development substances in DMPs to approved substances

and

Nullification of obsolete development substance records

WHY

To increase data quality and ensure that the same substance ID is used across the product lifecycle

HOW & WHEN

between 1 July and 1 October 2023- Sponsors to update DMP records to reference a replacement approved substance instead and/or to provide supporting documentation to request an insert of a new approved substance

- **On 4 October 2023 -** EMA to perform re-liking of development substances to approved substances in DMPs
- **Q4 2023 -** EMA to perform nullifications of obsolete development substance records in the XEVMPD

IMPACT on users:

Impact:

- *A*pproved substance EV Codes to be referenced in DMPs in the XEVMPD instead of development substance EV Codes
- Sponsors/EMA to update DMP information
- Sponsors might need to update the structured data in the CTA in CTIS to reflect the update of substance data in their DMP in XEVMPD

Benefit: Improved data quality

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	WHY	HOW & WHEN	IMPACT on users:
4. Restriction on submission of proposed terms	To support successful PMS & eAF implementation and synchronisation of information in XEVMPD and RMS	**From Q1 2024 -** Creation of proposed terms in XEVMPD by sponsors and MAHs to be blocked, new terms/update of terms to be requested via RMS	*Impact:* Change in process *Benefit:* Improved data quality less likely to have issues with PMS migration and data being used by eAF
5. Review of DMP information in XEVMPD	To address and improve data quality of development medicinal products before they are heavily used in CTIS	**From Q1 2024 -** EMA to start a review of development terms and: • identify replacement proposed/standard terms • identify sponsors to be contacted	*Impact:* • Standard/proposed term EV Codes to be referenced in DMPs instead • Sponsors/EMA to update DMP information – ***no timeline defined yet, further details in 2024*** *Benefit:* Improved data quality of DMPs

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	WHY	HOW & WHEN	IMPACT on users:
6. Review of AMPs as part of pre-advice note checks	To assess AMPs that are subjects to PhV fee for MAHs with outstanding PhV fee debts	**From Q1 2024 -** EMA to verify the marketing authorisation status of AMPs with NCA's information	*Impact:* none *Benefit:* To prevent billing to be generated for products where the marketing authorisation is no longer valid
7. MRPs/DCPs under the national phase to be submitted as pending products - new MA value available in XEVMPD	To support successful eAF implementation	**From Q1 2024 -** New MA status value ***'Valid – pending national phase'*** will be made available in XEVMPD with guidance in Chapter 3.II on how/when to use it	*Impact:* Additional records to be submitted to XEVMPD *Benefit:* To allow the transition period for the mandatory use of the web-based eAF by including products pending authorisation under the national phases

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8. MFA deployment in XCOMP

WHY

To increase security of the EudraVigilance system and protection of the data held within XCOMP

HOW & WHEN

From Q1 2024 - Multifactor Authentication (MFA) to be deployed in XCOMP

IMPACT on users:

Impact:

- **All XCOMP users** to check that their MFA credentials are set-up with the EMA
- **XEVMPD and EV training participants** to request access to XCOMP via the EMA Account management portal **following their registration for the training course** with DIA or EMA

Benefit: increased security of EV system

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Key Takeaways and Conclusions

For Questions: www.slido.com code: #3713705

Conclusions

- This presentation explained what are the **submission requirements** for marketing authorisation holders and **how authorised medicinal product data is currently managed in the XEVMPD**
- Sponsors were reminded of their **submission requirements** and an overview of **how development medicinal product data should be submitted in the XEVMPD** was provided
- The **relationship between XEVMPD, PMS and eAF** was clarified
- Information on **statistics and planned improvements** for 2023 was shared

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Quiz Time

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Any questions on the webinar?

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SPOR week webinars

SPOR week is a **full week of webinars** during which 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 and XEVMPD Data Governance	17 April 2023	10:00-12:00 CET
Service Desk for SPOR and XEVMPD	17 April 2023	14:00-16:00 CET
Referentials Management Service (RMS)	18 April 2023	10:00-12:00 CET
Organisation Management Service (OMS)	18 April 2023	14:00-16:00 CET
Substance Management Service (SMS)	19 April 2023	10:00-12:00 CET
Product Management Service (XEVMPD)	19 April 2023	14:00-16:00 CET
Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API	20 April 2023	10:00-12:00 CET
EMA Account Management	20 April 2023	14:00-16:00 CET

For Questions: www.slido.com code: #3713705

Further information

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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

Glossary (2/4)

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

Glossary (4/4)

EUROPEAN MEDICINES AGENCY

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