Welcome and housekeeping notes

*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: #2552894

Welcome and housekeeping notes

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1

Join via **QR code** or **slido.com**

2

Send or upvote the questions you want to hear answered

3

Questions will be shown on the screen and **managed live in the Q&A session**

4

Questions not addressed during this session may be addressed in **subsequent webinars** and/or in **FAQ** document in SPOR Portal

1 For Questions: www.slido.com code: #2552894

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Product Management Service (XEVMPD)

19 April 2023

SPOR Week – 17-20 April 2023

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

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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**

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Agenda

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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 Data Quality (DQ) Management**
7. **XEVMPD statistics**
8. **XEVMPD Documentation & help**
9. **XEVMPD and its relationship with PMS and eAF**
10. **XEVMPD recent & planned activities**
11. **Key Takeaways and Conclusions**
12. **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

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

- Product data is **submitted and maintained** in the Article 57 database/ XEVMPD by **MAHs and sponsors**.
- AMP data is validated by the EMA to ensure **standardisation**
- **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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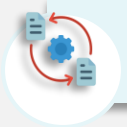
Pre-submission requirements

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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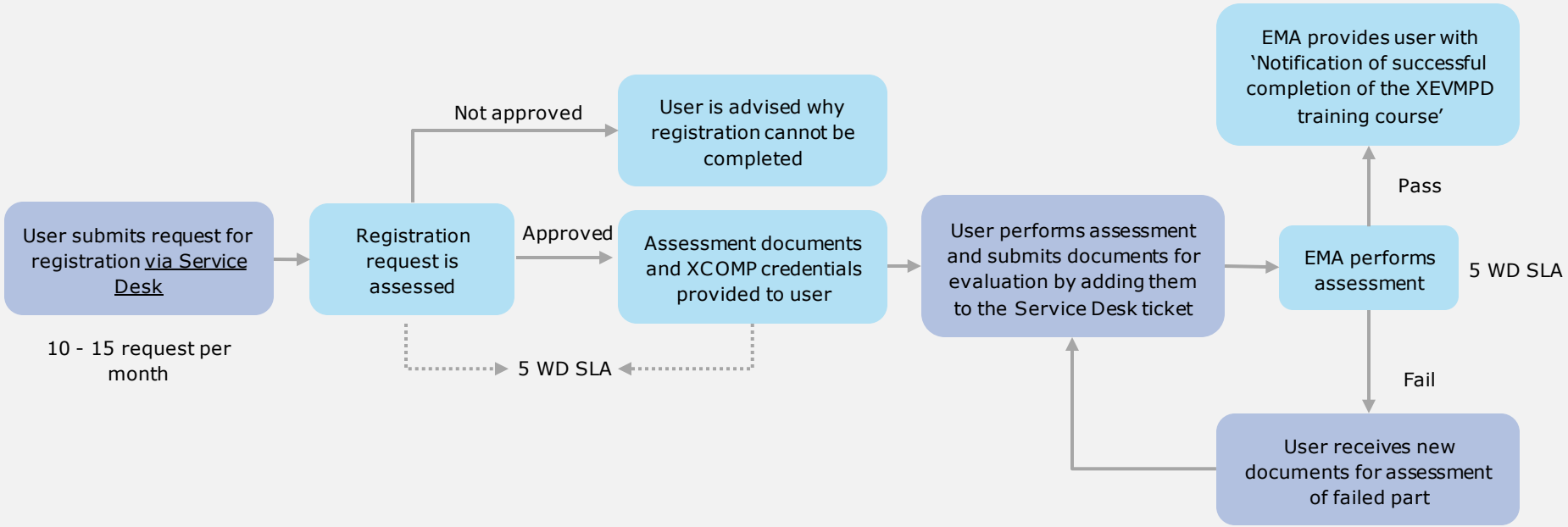
XEVMPD e-learning training process



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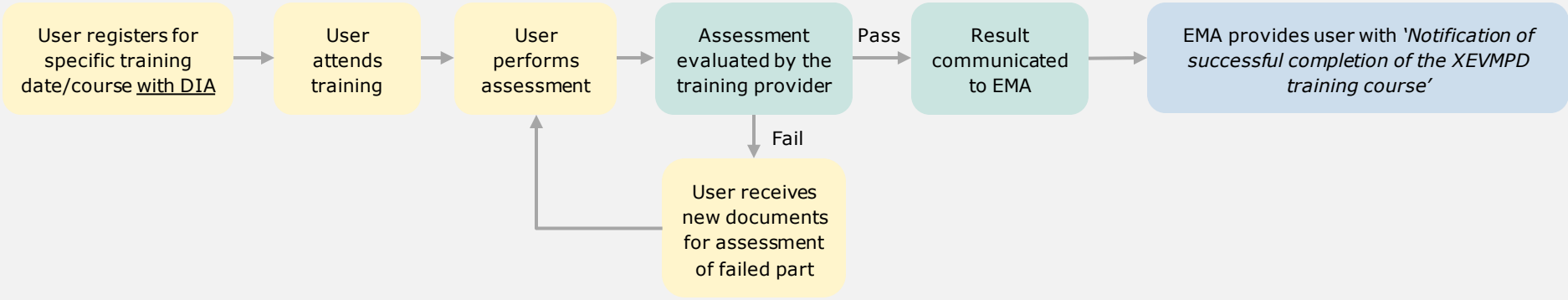
XEVMPD face-to-face training process



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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
- 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

XEVMPD Process

Presented by Marcos Fernandez Gomez

XEVMPD Data management processes

EMA Data Steward

Bussiness lead/ Product Owner

SPOR User

AMP/DMP submission

Data Stewardship

Data services
- Proactive data curation (e.g. AMP validation)
- Data cleansing and corrections, FUPs with users

Data publication
Monthly publication of AMP data to share PhV contact details

Customer Service

Request Information

Request Services

Report technical issues

Data Quality Management

Quality Control
Sampling & checking of performed activities

Data profiling
Monitoring & investigation across entire data

Quality Assurance
Root causes & process improvements

Service Management

Service Coordination
With Data governance & IT delivery

Performance management
- Invoicing
- KPI reporting
- Customer satisfaction

Data management processes are defined, operational and are monitored/reported on

Details for each SPOR domain elaborated in individual webinars this week.

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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

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

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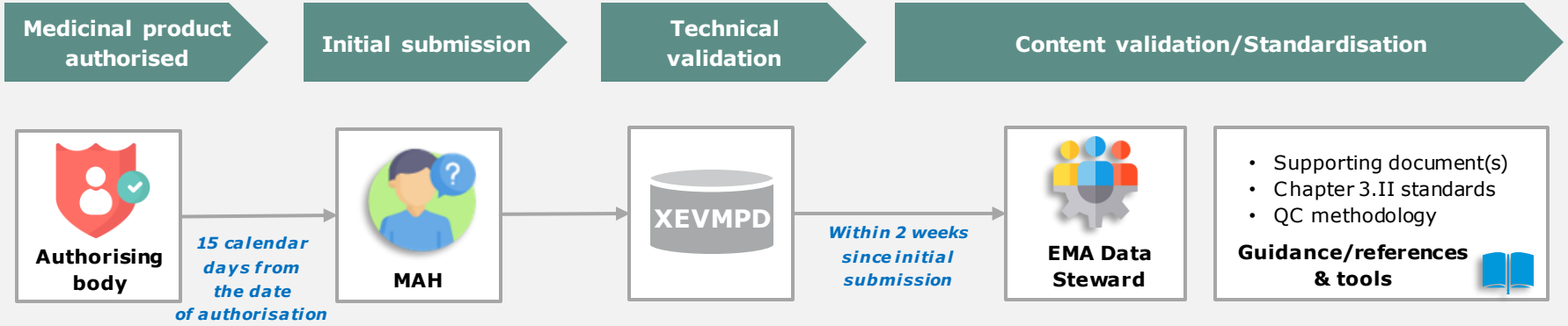

Submit AMP data in XEVMPD:

- **Insert AMP information**, including MAH/PSMFL/QPPV information
- 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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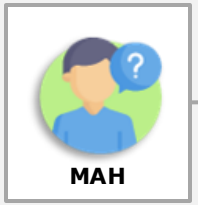
Content validation outcome - AMP validated/flagged for FUP

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, raise 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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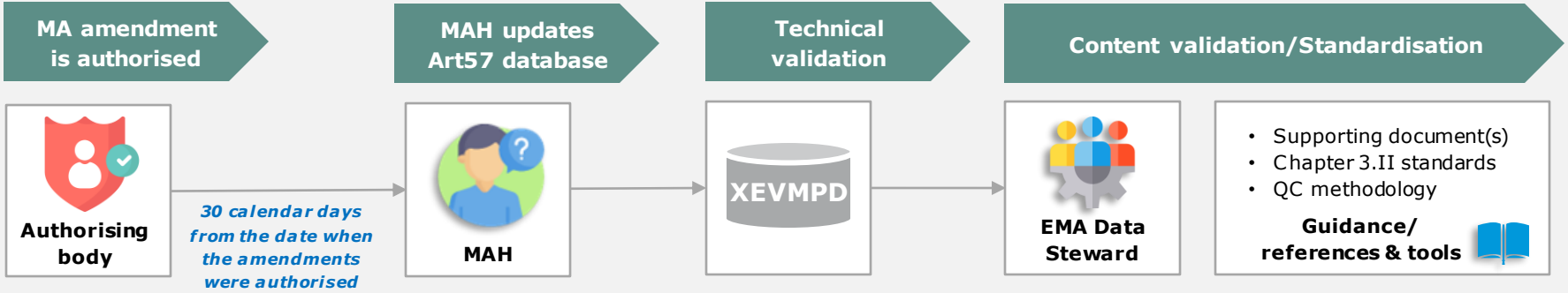
AMP: Amendments following regulatory procedure process



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

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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*

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Data Publication

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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

For Questions: www.slido.com code: #2552894

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')

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

- CTA to be submitted in the European Union Drug Regulating Authorities Clinical Trials (EudraCT) database
- From 31 January 2022 clinical trials can be registered via the Clinical Trials Information System (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

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

Request rejected

Reasons for rejection explained to requestor

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

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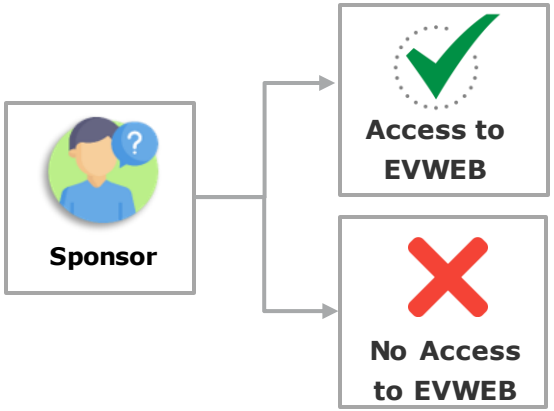
EU product number = Product EV Code (a code assigned to a specific product record in the XEVMPD)

- **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

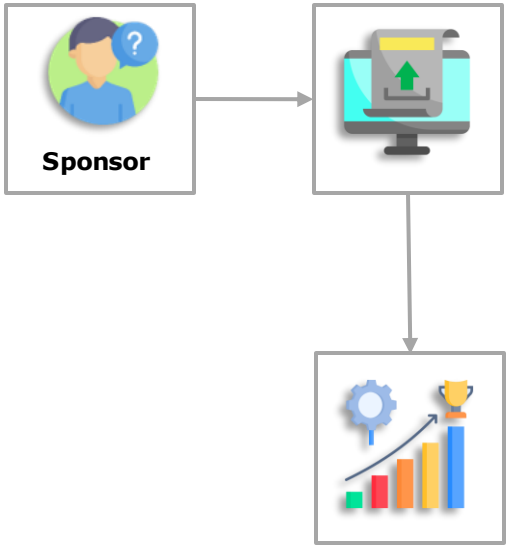
Submit a new EMA Service Desk request for XEVMPD/Art.57 Services*

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

 For Questions: www.slido.com code: #2552894

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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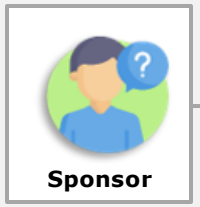
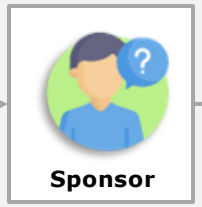
Initial submission → **Technical validation** → **Outcome**



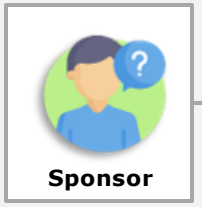


Insert successful

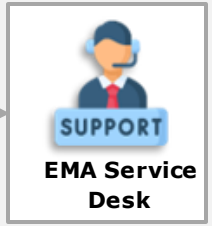
EV Code is assigned
DMP entry is **flagged as 'Valid' in XEVMPD**

DMP EV code is retrievable in CTIS the following day

Insert unsuccessful



Questions & support



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: #2552894

Points to consider for submissions (1/3)

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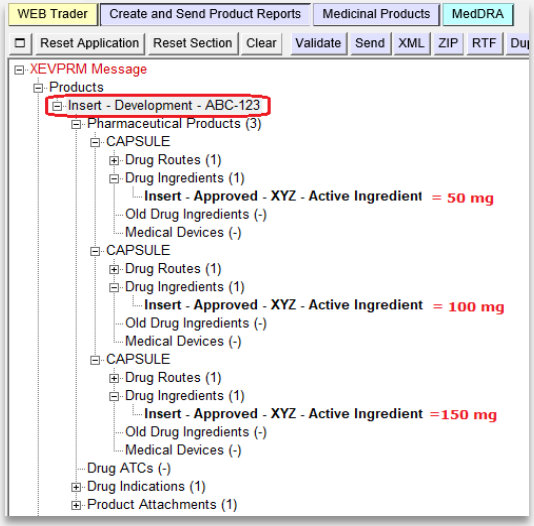
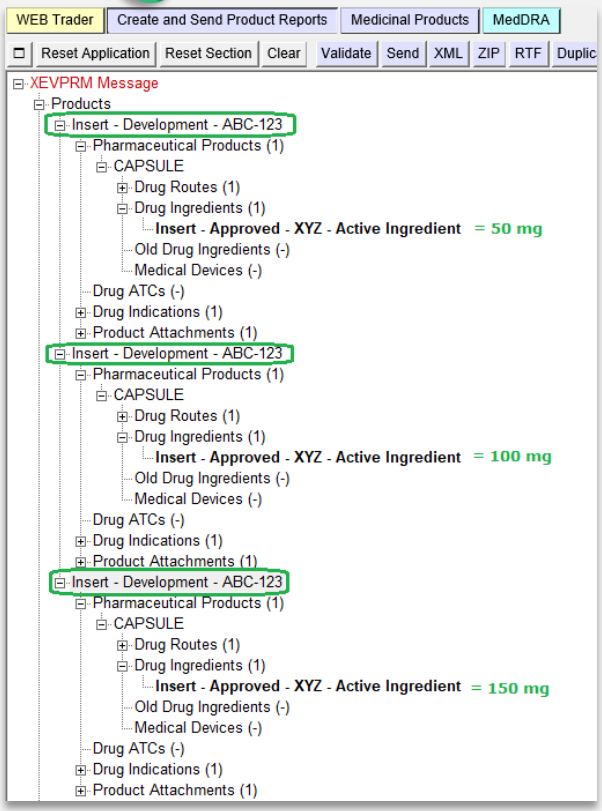
An **active substance** is studied in a clinical trial in the **same pharmaceutical dose form** with **different strengths** → **separate development medicinal products** must be submitted to the XEVMPD for each pharmaceutical product

An EV Code will be assigned to each development medicinal product.

Incorrectly entered



Correctly entered



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Points to consider for submissions (2/3)

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Same medicinal product studied by different sponsors

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

- 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 by the owner organisation

Points to consider for submissions (3/3)

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*

For Questions: www.slido.com code: #2552894

XEVMPD Data Quality Management

Presented by Marcos Fernandez Gomez

XEVMPD Data Quality Management at a glance

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Data services
Identified defects/errors are corrected in in XEVMPD

Proactive

Reactive

Quality Assurance
- Root causes are analysed and where possible preventive actions are identified/ implemented
- Process improvements

Activity Monitoring

Data mgmt Task

Quality Control
- Product validation Tasks are routinely sampled (~20%) and inspected to detect errors
- Sampled tasks are re-inspected by EMA to calibrate QC results

Data Monitoring & Follow-up communication

Data E.g.
QPPV
PSMFL
SmPc

Data Profiling
- Profiles are built to identify data not meeting the DQ rules
- Notifications are sent to MAHs if QPPV or MFL codes are wrong or missing or if SmPC is missing

DQ Defects
- Defects/errors are classified into **Major/Medium/Minor**

Issues
- Issues reported to Service Desk on DQ of Orgs/Locs

SUPPORT

Customer Services

Data Quality is ACCEPTABLE if:

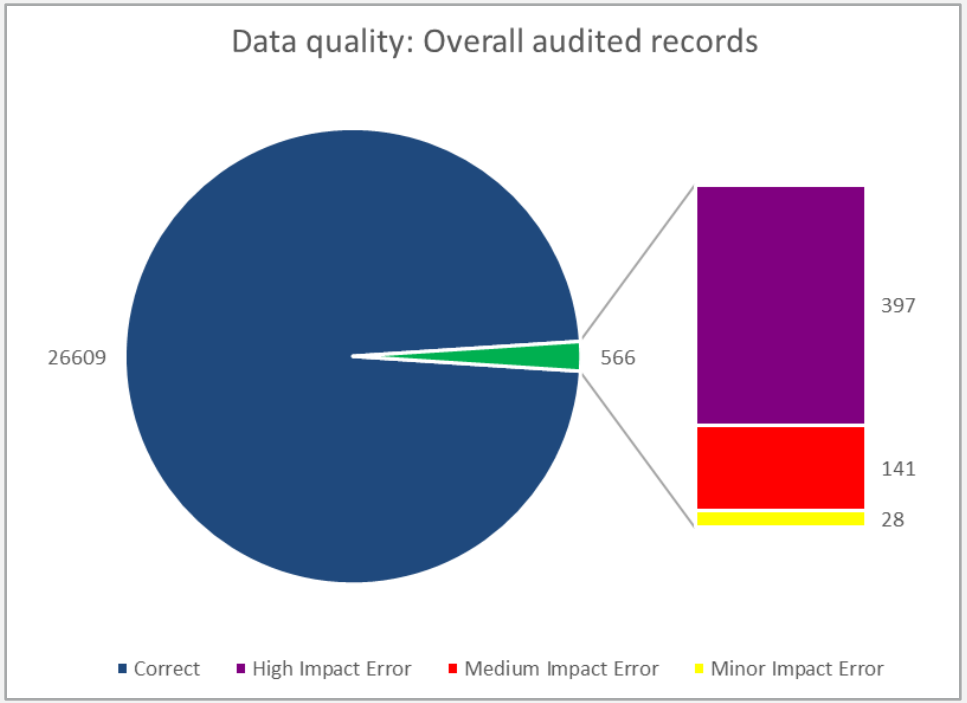
<0.001% major errors (Auth details, name, Farm dose form, ...)

<0.005% medium errors (MedDRA, ATC codes)

<0.01% minor errors (package)

For Questions: www.slido.com code: #5882317

Error Type	Error category	Justification
Major	Legal basis	Major impact on internal processes (PV fees, ICSRs, etc.)
	Organisation details	
	Authorisation country, status, number	
	Name and name parts	
	Pharmaceutical dose form	
Medium	Authorisation procedure	Lower impact on internal processes
	MedDRA codes	
	Potential MAH duplicate identified	
	ATC Codes	
Minor	PV email and phone	Minor or no impact on processes
	MFL details	
	Package description	



- **Number of products audited in 2022:** 27.175
- **Number of products without errors:**
- 26.609 **(97,9%)**
- **Number of products with any type of error:** 566 **(2%)**

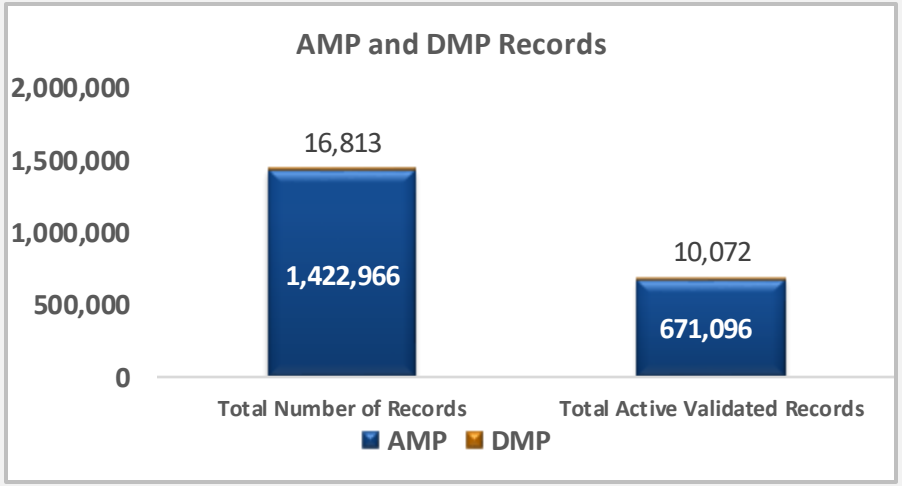
- **Number of high impact errors:** 397
- **Number of medium impact errors:** 141
- **Number of low impact errors:** 28

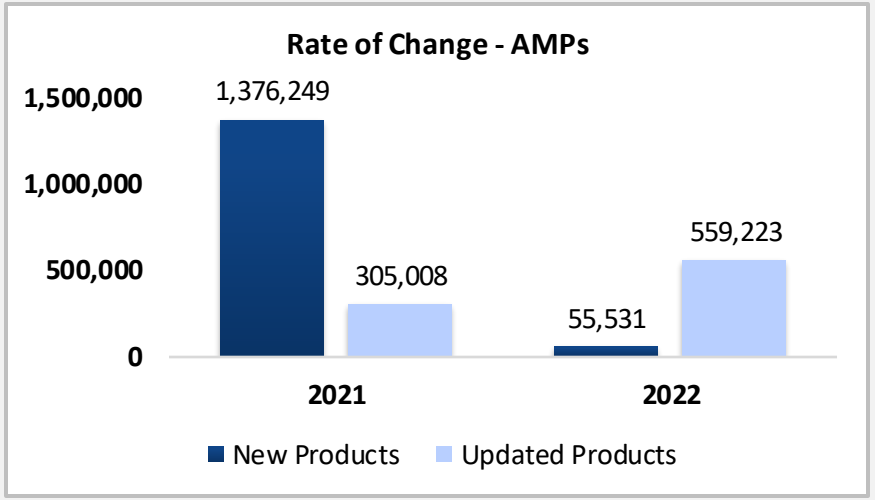
 For Questions: www.slido.com code: #2552894

XEVMPD Statistics

Presented by Marcos Fernandez Gomez

XEVMPD in numbers



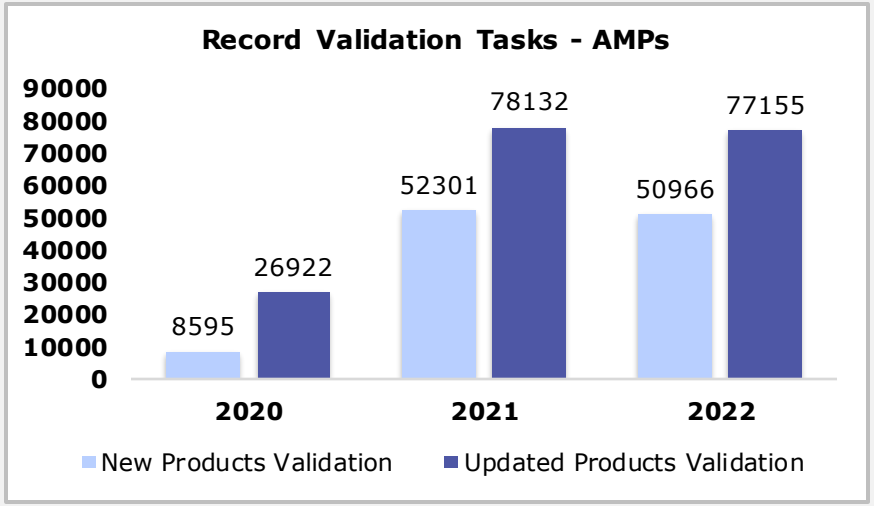


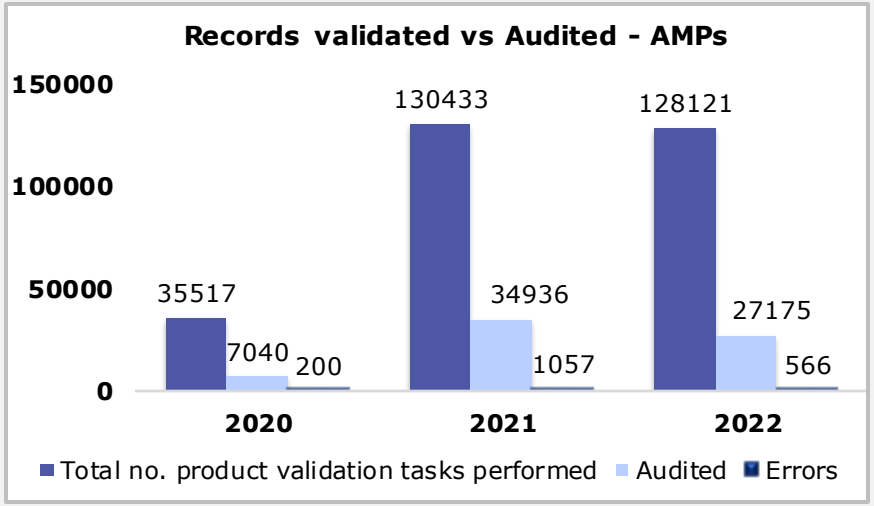
- **Total Nr of Records:** Total number of products (AMPs, DMPs; including nullified and invalidated)
- **Total Active Validated Records:** Total number of products (AMPs, DMPs; excluding nullified and invalidated; including validated only)

- 2021 was the first year to start counting this KPI
- XEVMPD receives **10 times** more updates than new records

For Questions: www.slido.com code: #2552894

Product Validation





- **New Records Validated:** All new EEA AMPs are validated.
- **Total Active Validated Records:** more than 20% of updates are validated at the end of the year. Prioritisation is based on available capacity.

- Product validations are audited to guarantee high quality on validations.
- A total of 27.175 records were audited in 2022
- Only **2% of records had any error in the validation**
- (1% on indications, 1% paediatric use, Renewal Date and Excipient name, 1% others)

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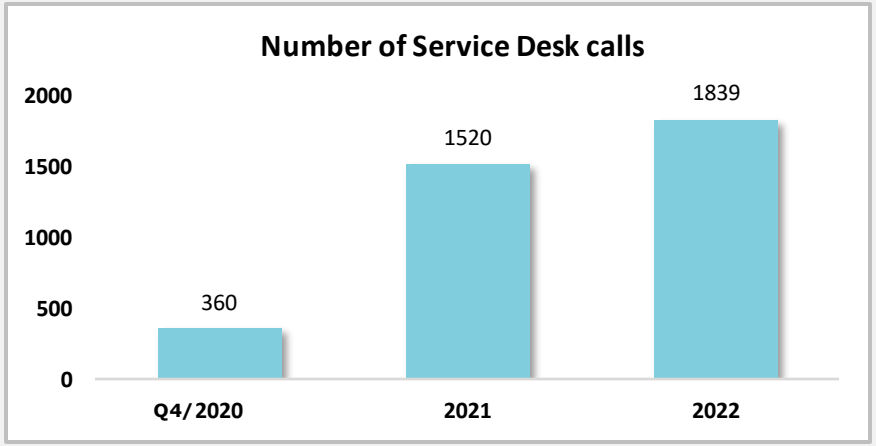
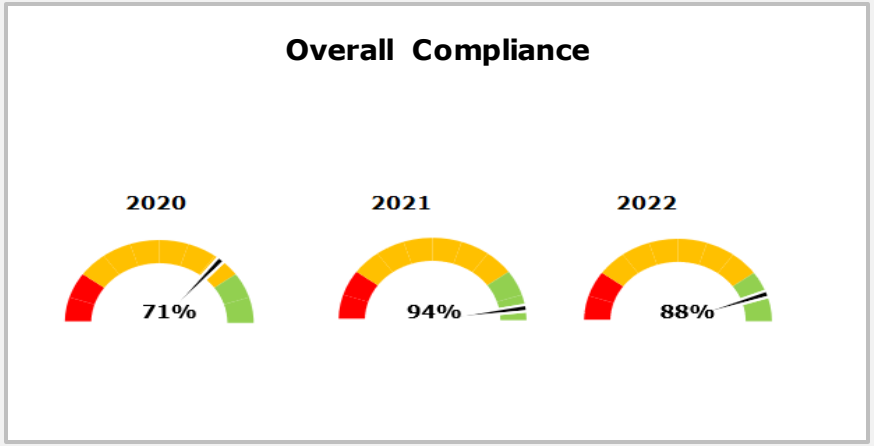
Note: KPIs started end of 2020

XEVMPD Statistics – Service Desk

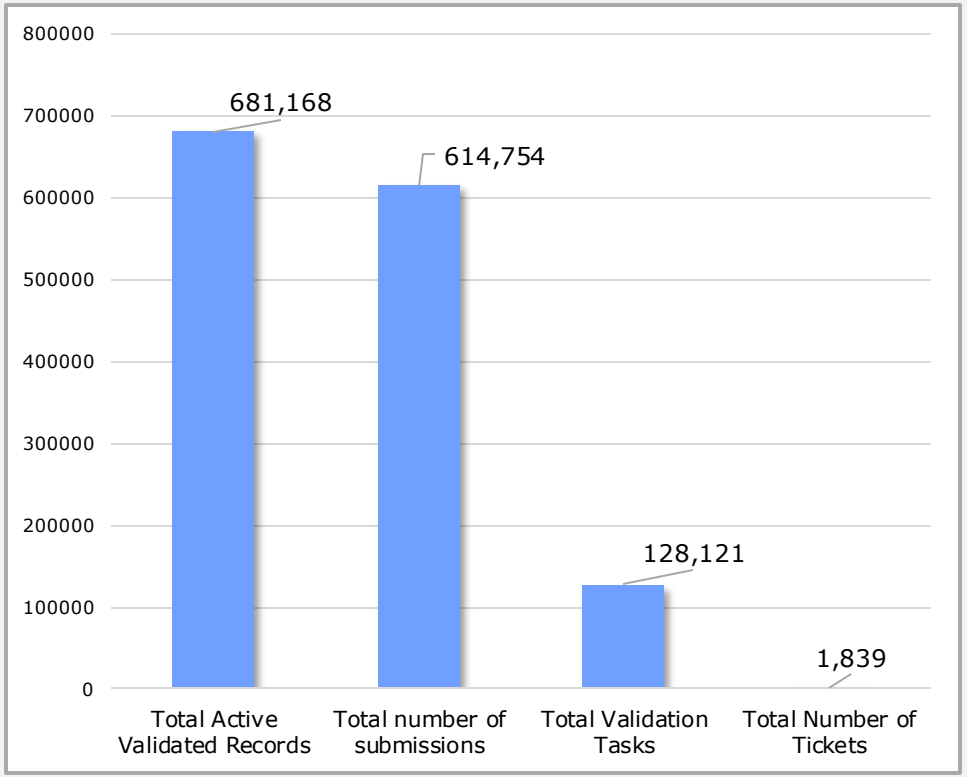




- Number of tickets is increasing every year as more processes are handled through Service Desk
- In 2022, e-learning started to be managed through Service Desk

- Overall compliance is linked to SLAs met for every ticket type.
- Incidents related to e-learning (mostly IT related) were not addressed into the SLAs
- SLA overall compliance is within the target score

Overview of XEVMPD Statistics - 2022



- Number of records and submissions increased every year
- Main activity: validation of records submitted to XEVMPD (new or updated records)
- Service Desk tickets has increased over the years, it represents requests for training/questions/etc and represents less than 5% of all processing

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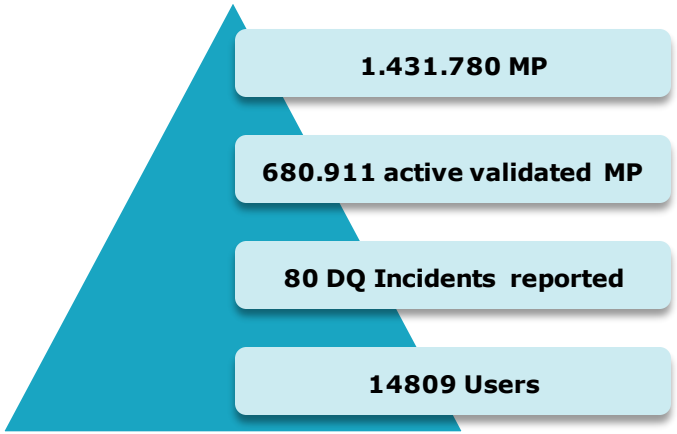
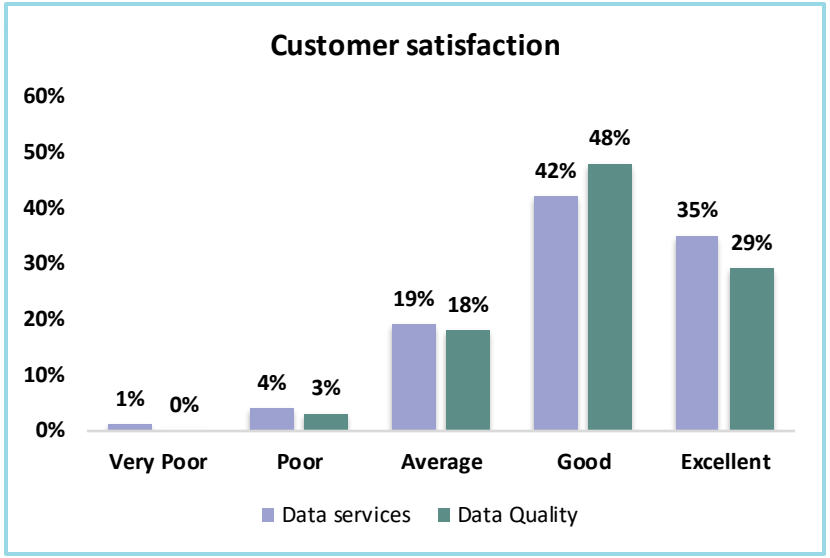
Customer Satisfaction

User Perspective

Customer Satisfaction Survey



- **Low level** of DQ incidents in Art 57 in 2022:
- **Only 1%** of users report DQ Incidents (80 DQ incidents/14809 users)



Data services: *change requests, customer service, documentation*

Data Services and **Data Quality** in XEVMPD were positively rated overall by users with over **77%** as "Good" or "Excellent"

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Documentation overview & help

Presented by Veronika Baker

XEVMPD documentation & help (I)

EUROPEAN MEDICINES AGENCY

EMA corporate website

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

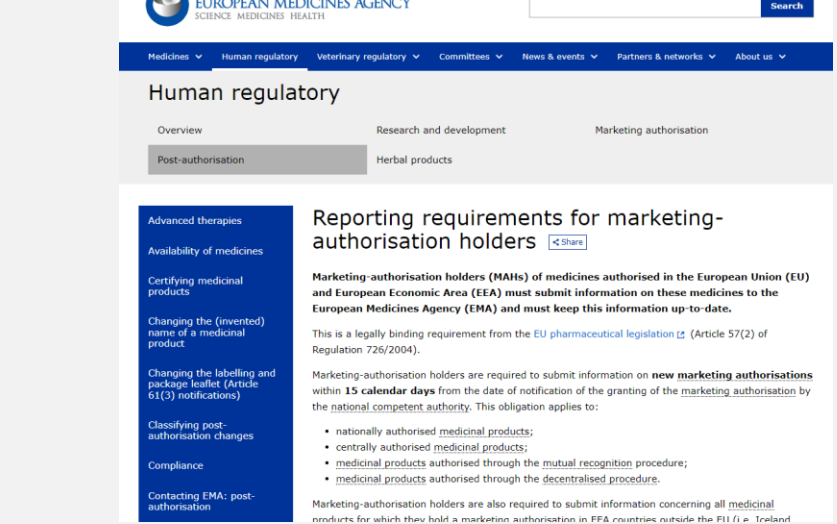
- To request information, support with XEVMPD data management, report technical issues
- Managed through the ServiceNow Portal

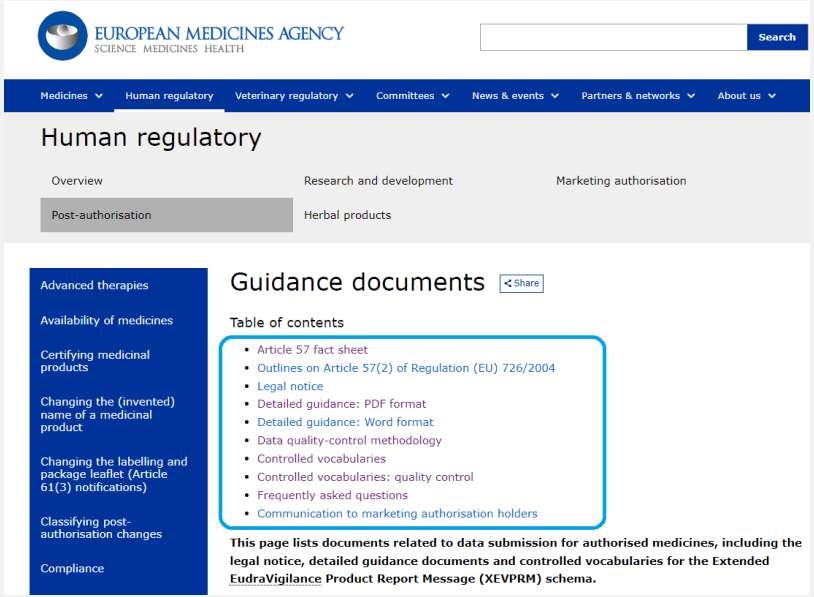
For Questions: www.slido.com code: #2552894

EMA corporate website

What:

- Background information for **marketing authorisation holders**
- Documents related to data submission for **authorised medicines**





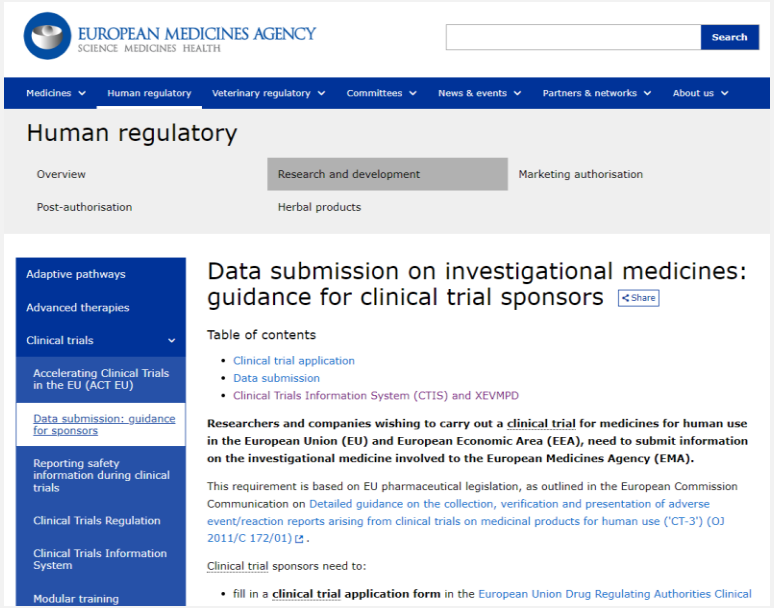
XEVMPD documentation & help (III)

EUROPEAN MEDICINES AGENCY

EMA corporate website

What:

- Background information for **sponsors of clinical trials**
- Documents related to data submission of **investigational medicines**



For more information and guidance:

Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD) (PDF/1.01 MB)

First published: 20/10/2021
Last updated: 04/01/2022
EMA/186412/2021

Electronic submission of investigational medicinal product (IMP) data to the Extended EudraVigilance medicinal product dictionary (XEVMPD) - Frequently asked questions and answers (FAQs) (PDF/473.83 KB)

First published: 20/10/2021
EMA/157035/2021

 For Questions: www.slido.com code: #2552894

XEVMPD documentation & help (IV)

EUROPEAN MEDICINES AGENCY

EMA corporate website

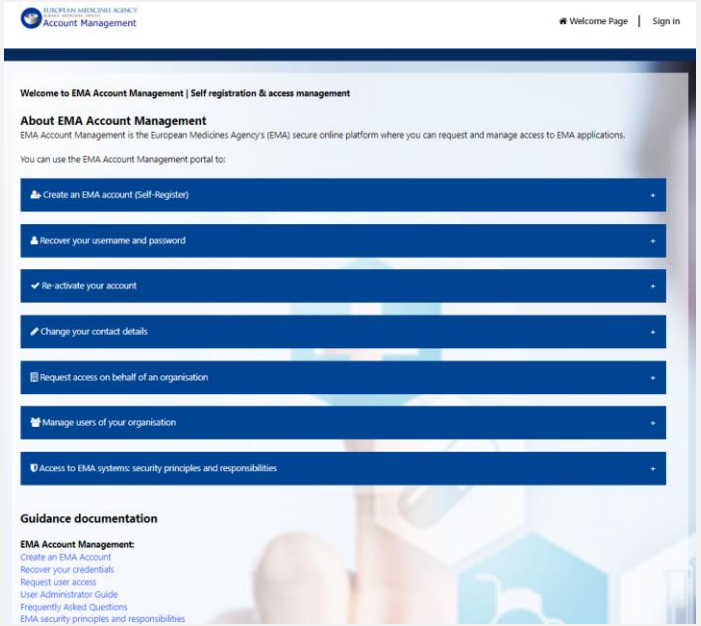
What:

- Information on how to register for product reporting
  - EMA EudraVigilance Registration Manual provides detailed instructions

EMA Account Management portal

What:

- General guidance on how to register users and use IAM tool



For Questions: www.slido.com code: #2552894

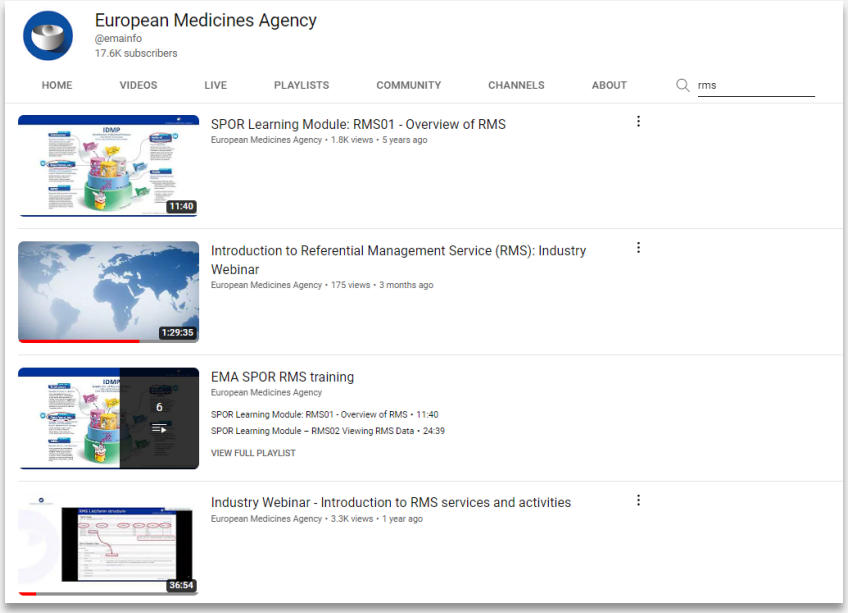
XEVMPD documentation & help (V)

EUROPEAN MEDICINES AGENCY

EMA YouTube Channel

What:

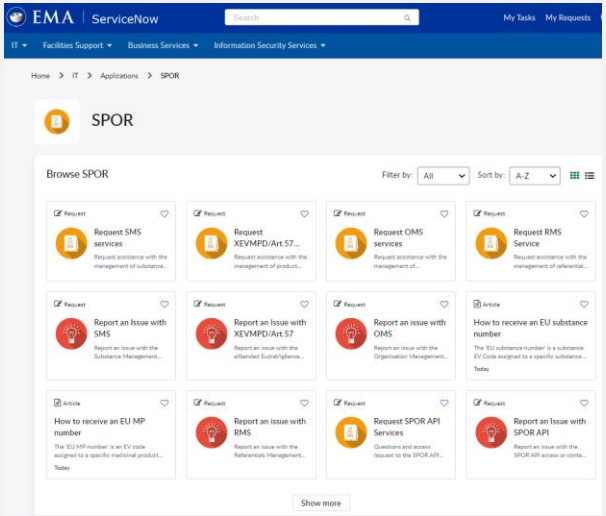
- Videos of webinars
  - Related PPTs can be found in SPOR portal



ServiceNow - SPOR Dashboard

What:

- To request XEVMPD related information
- To request support with management of XEVMPD data and/or to register for XEVMPD e-learning training knowledge evaluation
- To report a technical issue with the XEVMPD

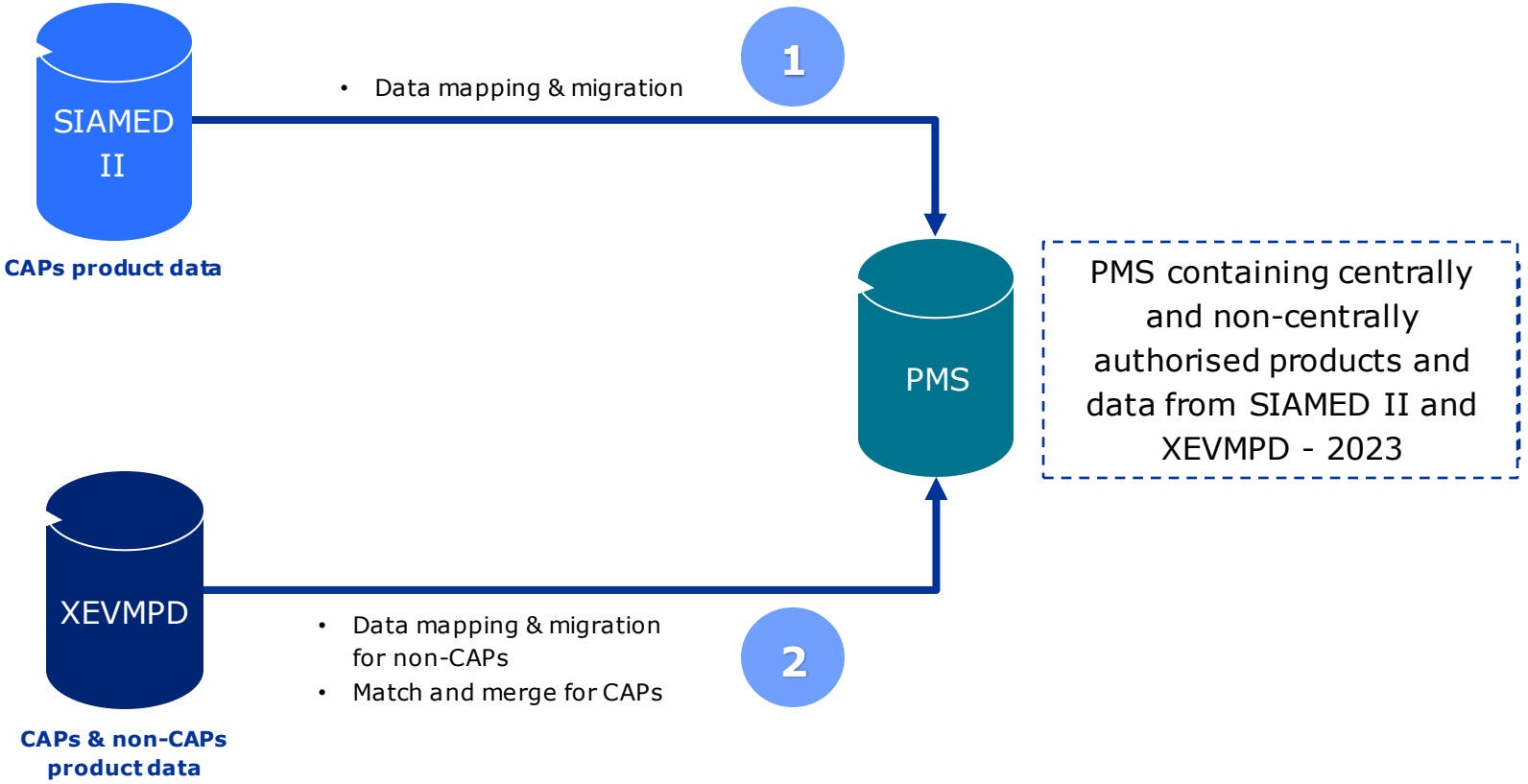


For Questions: www.slido.com code: #2552894

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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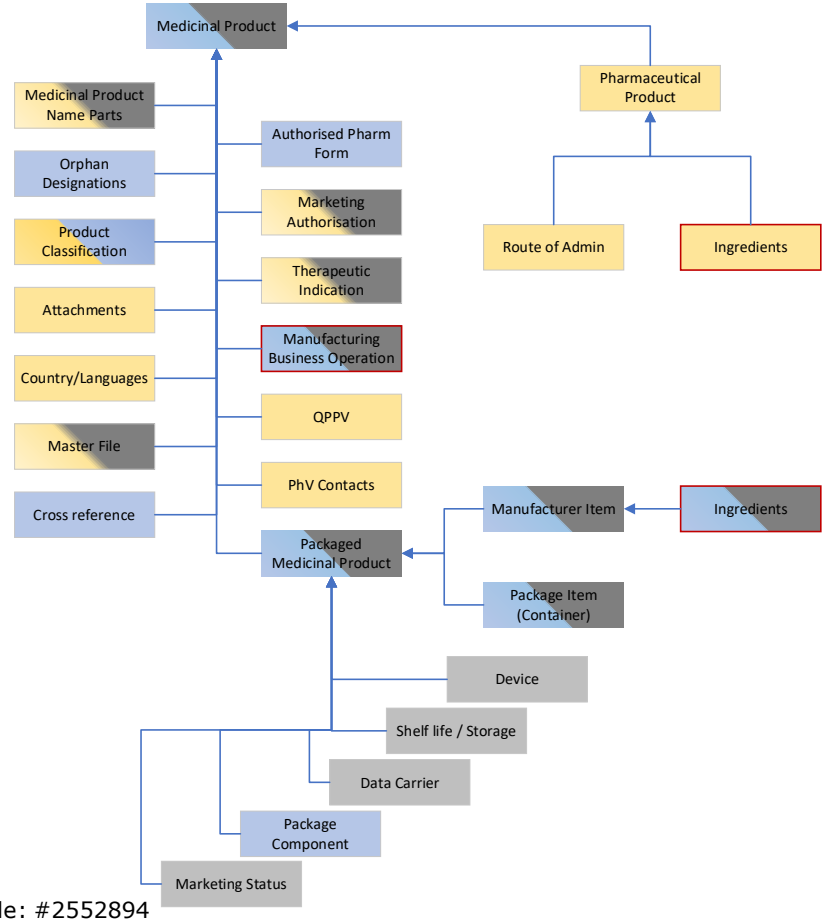
XEVMPD data used in PMS

EUROPEAN MEDICINES AGENCY

From end of Q2 2023



Legend:

- Fields coming from Art. 57
- Fields coming from SIAMED
- Fields without migrated info
- Fields coming from Art. 57 but missing data
- Fields coming from SIAMED but missing data
- Fields to be checked with highest priority

For Questions: www.slido.com code: #2552894

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 LI 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

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

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Examples

EUROPEAN MEDICINES AGENCY

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

For Questions: www.slido.com code: #2552894

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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EUROPEAN MEDICINES AGENCY

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).

 For Questions: www.slido.com code: #2552894

XEVMPD - PMS - eAF: FAQs

EUROPEAN MEDICINES AGENCY

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 during 2023.

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 Q3 2023.
- In the meantime, please use the PDF eAF for these products and do not submit them to XEVMPD until further notice

For Questions: www.slido.com code: #2552894

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 – Q3 2023

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 submission with direct submissions to PMS for CAPS and NAPS

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XEVMPD recent & planned activities

Presented by Veronika Baker

XEVMPD recent changes

EUROPEAN MEDICINES AGENCY

Multi-factor authentication (MFA) deployed in XEVMPD production *on 28 March 2023*

XCOMP to follow, *date TBC*

Second (optional) language code field available in EVWEB *from April 2023* to allow to reference 2 language codes **in attachments** with content in two languages

Access to EV/XEVMPD to be reviewed and confirmed by QPPV/RP (or trusted deputy) in EMA Account Management portal **every 6 months** *from Q3/2023*

Chrome update (version 113) scheduled for *26 April 2023* **affecting IE Tab extension**

- **No impact for users who deployed IE Tab from the Chrome Web Store** (EMA recommended solution)
  - the IE Tab listing in the Chrome Web Store has already been updated with a workaround solution
  - the update will be automatic
- **Impact on users who deployed IE Tab with an offline or custom deployment package**; these users should **update the IE tab extension** to at least version 16.3.28.1 to avoid a breaking change that will be coming. Contact the EMA Service Desk for assistance.

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Planned XEVMPD activities

EUROPEAN MEDICINES AGENCY

	Q1 2023	Q2 2023	Q3 2023	Q4 2023
Deliver efficient and effective regulatory data services	**XEVMPD – Customer Services**			
	Objections to AMP validation changes to be raised via Request XEVMPD/Article 57 services in EMA Service Desk (from May)			
	Knowledge base articles to be created in EMA Service Desk			
	XEVMPD - Data Management (Data services)			
	Process change: CV lists (referential terms/MAH organisations/substances) to be extracted from SPOR Portal			
	Increased new product validation (1/week -> 2/week)			
	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 MAH data cleansing exercise in XEVMPD			
			4 Remap of development substances in DMPs	
Improve customer satisfaction and success	**XEVMPD – Documentation**			
	Chapter 3.II update & publication			
	Review & condense of XEVMPD docs & Review & update of information on XEVMPD related webpages			
	XEVMPD – Awareness & visibility			
		SPOR week	SPOR webinars	SPOR Customer Satisfaction survey
Modernise Data & Information Management	Information Management Modernisation initiatives			
	Prioritised Epics (eAF, IRIS, ePI, shortages and other)			

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XEVMPD Data Management (Data services)

EUROPEAN MEDICINES AGENCY

WHY

HOW & WHEN

IMPACT on users:

MAH organisation details submission according to OMS rules/standards

To support successful PMS implementation and OMS synchronisation

- MAHs to insert MAH details in the XEVMPD as they were submitted to OMS
  - (i.e.; MAH info is provided in accordance with the rules/ standards for the organisation name and address specified by OMS);
  - **LOC ID** to be referenced in the 'Comment ' field (0.18) of the MAH organisation entity in XEVMPD

--> *Q2/2023*

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.

1

Submission of proposed terms

To support successful PMS & eAF implementation

- Proposed terms from the relevant XEVMPD lists are requested/created in RMS and will then be created in XEVMPD by RMS team

  --> *Planned start Q2/2023*
- Creation of proposed terms in XEVMPD to be blocked

  --> *date TBC*

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.

2

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XEVMPD Data Quality (I)

EUROPEAN MEDICINES AGENCY

MAH organisation data cleansing exercise

WHY

To improve the MAH organisation list in the XEVMPD and support successful PMS implementation and OMS synchronisation

HOW & WHEN

- **EMA to nullify** MAH organisations flagged as obsolete by MAHs (around 60)
- **EMA to review** country code fields of an MAH entity **and correct**, if required *(e.g.; an MAH entity referencing 'London' and country 'Northern Ireland')*
- **MAH to review** information in the 'Comment' field (O.18) **and remove** information that should not be there (e.g.: *"change of name and address…", "company renamed….", "change of company name but same legal entity…", "company name changed…."* etc.)

-> by end of Q2/2023

IMPACT on users:

Impact: Update of MAH data in the XEVMPD

Benefit: Improved data quality

For Questions: www.slido.com code: #2552894

XEVMPD Data Quality (II)

EUROPEAN MEDICINES AGENCY

Re-map of development substances in DMPs to approved substances

WHY

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

HOW & WHEN

- **EMA to request** supporting documentation from sponsors
  -> *From Q2/2023*
- **Sponsors to provide** supporting docs by specified date **or update** DMPs to reference the replacement approved substance
- EMA to perform re-liking of development substances to approved substances in DMPs
  -> *From Q3/ 2023*
- **EMA to perform** development substance nullifications
  -> *from Q4/2023*

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

Benefit: Improved data quality

For Questions: www.slido.com code: #2552894

Key Takeaways and Conclusions

For Questions: www.slido.com code: #2552894

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

For Questions: www.slido.com code: #2552894

Any questions on the webinar?

 For Questions: www.slido.com code: #2552894

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: #2552894

Further information

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

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