EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eAF – Training session on non-CAPs in web-based eAF

17 October 2024

Agenda

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1 **Welcome & Introduction**
10:00 – 10:05

Kristiina Puusaari
eAF Product Owner

2 **Training on non-CAPs in web-based eAF**
10:05 – 11:10

Kristiina Puusaari
eAF Product Owner

3 **Q&A**
11:10 – 11:25

Moderator:
Isabella Pedon
eAF Change Management Team

4 **Closing**
11:25 – 11:30

Kristiina Puusaari
eAF Product Owner

Housekeeping

To ask questions, you can use **Slido**.

We might not be able to respond to all questions, but we will collect them in a document and try to reply in a timely manner.

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

We will **record** the session and make it available on EMA YouTube Channel and on the event web page.

A **live broadcast is also available now**. Please find the link on the event web page

Send your questions via Slido

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Join at

slido.com

#TRNNONCAPS

1. Join via the QR code or link

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

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Aim of this Webinar

- An introduction to the web-based eAF to MAHs
- Variation eAF timelines
- Key actions to MAHs
- Process to request access to eAF
- Known issues
- Navigate through the web-based eAF
- Next steps

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Introduction to PLM Portal web-based variation eAF

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eAF Key Changes – why are we doing this?

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FROM	TO
Current PDF forms use outdated technology and take long time to open	A modern web-based input form for applicants with a familiar, human readable pdf output and a new machine-readable xml for digital processing (FHIR data exchange)
Limited use of structured data	ISO IDMP/FHIR compliant structured data can be (re)used to populate web forms. They also guarantee two-way exchange of data between application web forms and PMS
Manual, labor intensive procedure management	Enable streamlined and simplified processes, with automated data imports and lean process and technology (i.e. IRIS) to facilitate procedure handling by regulators

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What web-based eAF will and will not change

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eAF will change:

PDF-format electronic application forms to web forms for:

- Variations
- Initial marketing authorisations
- Renewals (human only)

Human and **veterinary** forms

Centrally authorised product (CAPS) and **Nationally authorised product (non-CAPS including MRP/DCP/NP)** applications

eAF will NOT change:

The **current PDF *output* format**

The process to apply for or submit the **Marketing authorisation/ variation/renewal applications**

The content of the **application form in the submission package**

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Variation eAF timelines

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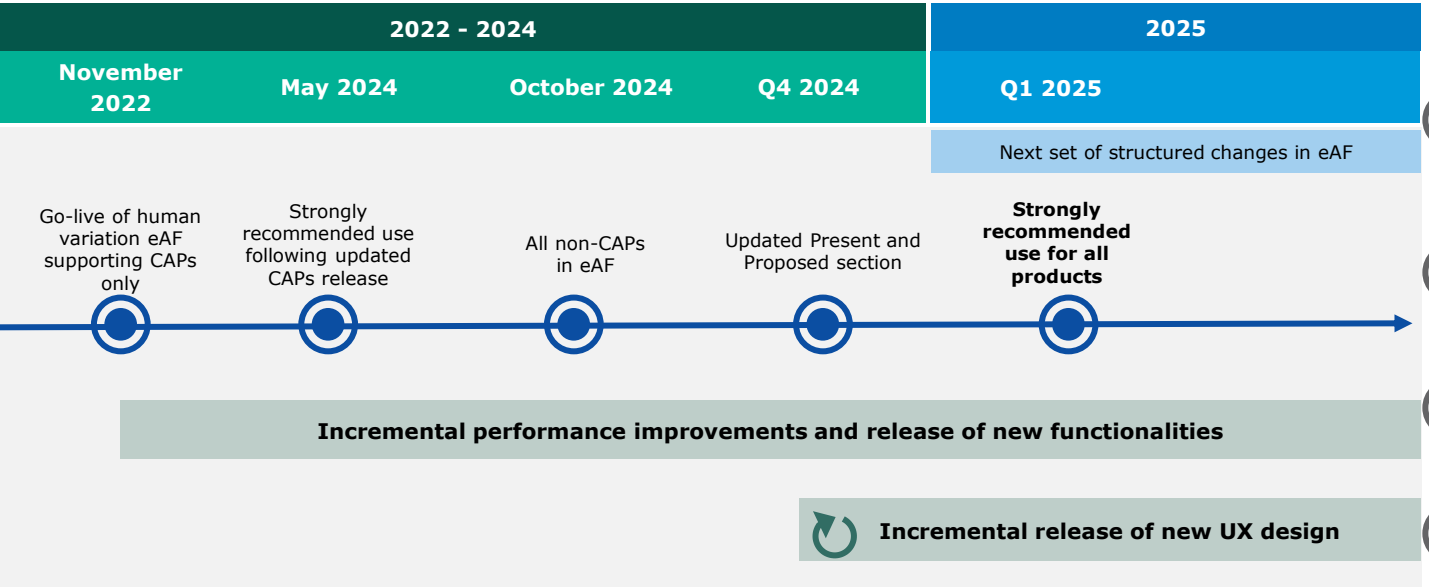
Human Variations electronic Application Form (eAF) – Key steps and milestones (October 2024)

OUTDATED



2025 & beyond	
UAT minus 2 months	UAT* announcement (*"Transition ready" form available)*
2 months after UAT	Confirmation of transition period start date
2 months after confirmation	Start of transition period
6 months after transition start	Use of variations web-form only

2026 & beyond	
Analysis & development of web forms	Marketing Authorisation Applications, Veterinary variations, Renewals

**2nd external UAT to confirm functionalities required for mandatory use

Note: CAPs and NAPs data in PMS is sourced from EMA's internal database and XEVMPD

Acronyms

CAPs: Centrally Authorised Products

NAPs: Nationally Authorised Products

XEVMPD: eXtended EudraVigilance Medicinal Product Dictionary

Legend

Key Milestone

Key Milestone

Dev activities for Human variations eAF

Recurring activity

Timeframes

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eAF updated implementation timeline | Key points

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Background – Q2 and Q3 2024 work

What we did:

- Released updated CAPs in eAF*
- Strongly recommended the use of web eAF for CAPs
- Add Package feature
- **Released Performance Improvements**
- **Updated product search**

What we found:

- Data issues in PMS in CAPs and non-CAPs
- OMS issues affecting the PLM Portal, IRIS and UPD users
- Bugs in functionalities relating to non-CAPs in eAF
- Need for further performance improvements

Q4 2024 - H2 2025 Plan

Q4 2024:

- All non-CAPs in eAF. Recommended use for EMA led mixed CAP/non-CAP WS procedures
- Improved Present and Proposed section
- Further performance improvements

Q1 2025:

- **Recommended** use **for non-CAP procedures**
- Enhancements to non-CAP functionalities as requested by users
- Start development of the next set of structured changes (e.g. packages, manufacturers)

Q2 to Q4 2025:

- Further development and release of structured changes
- Incremental release of other features and fixes

Acronyms

API: Application Programming Interface
CAPs: Centrally Authorised Products
Non-CAPs: All nationally Authorised Products (incl. MRP/DCP/NP)
PMS: Product Management Service
PLM: Product Lifecycle Management
UI: User Interface

*including split & match-merge processes. The "Match-merge" process serves to include data from XEVMPD to products already released in PLM Portal. The "split" process serves to make released products ISO-IDMP compliant. Both processes are explained in detail in EU IG Chapter 7

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Key actions to MAHs

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Summary of actions & tips for users to review products in eAF

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To do

1. **Request a role** in IAM for your organisation
2. **Log in to the PLM portal eAF** and create an eAF to view products available to you
3. **Verify** that data submitted to XEVMPD is **correctly displayed in eAF**

Important

1. Read the eAF **User Guide for Navigation**
2. **Familiarise** yourselves with the system by **filling in eAFs** - ideally in parallel to your pdf eAFs
3. Compare if there are any issues/problems in the PLM Portal eAF preventing the use of the form
4. Provide **consolidated feedback** to EMA via email to plm.valuestream@ema.europa.eu
5. **Refrain** from raising **service desk tickets** on **non-CAP issues/change requests** to allow us concentrate on supporting ongoing production applications

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Process to request access to PLM Portal eAF

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eAF User Registration Process – Roles overview

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eAF User roles

Admin roles

User	Admin role names
Industry user(s)	IRIS/PLM Industry Admin
NCA user(s)	IRIS/PLM NCA Admin
EMA user(s)	IRIS/PLM EMA Admin

Industry roles

User	Role names	eAF Access Level
Industry user(s)	eAF Applicant Contributor	View, limited edit
	eAF Applicant Manager	View, edit, export
	eAF Applicant Coordinator	View all, edit all, export

Regulator roles

User	Role names	eAF Access Level
NCA user(s)	eAF Competent Authority User	View, edit, export

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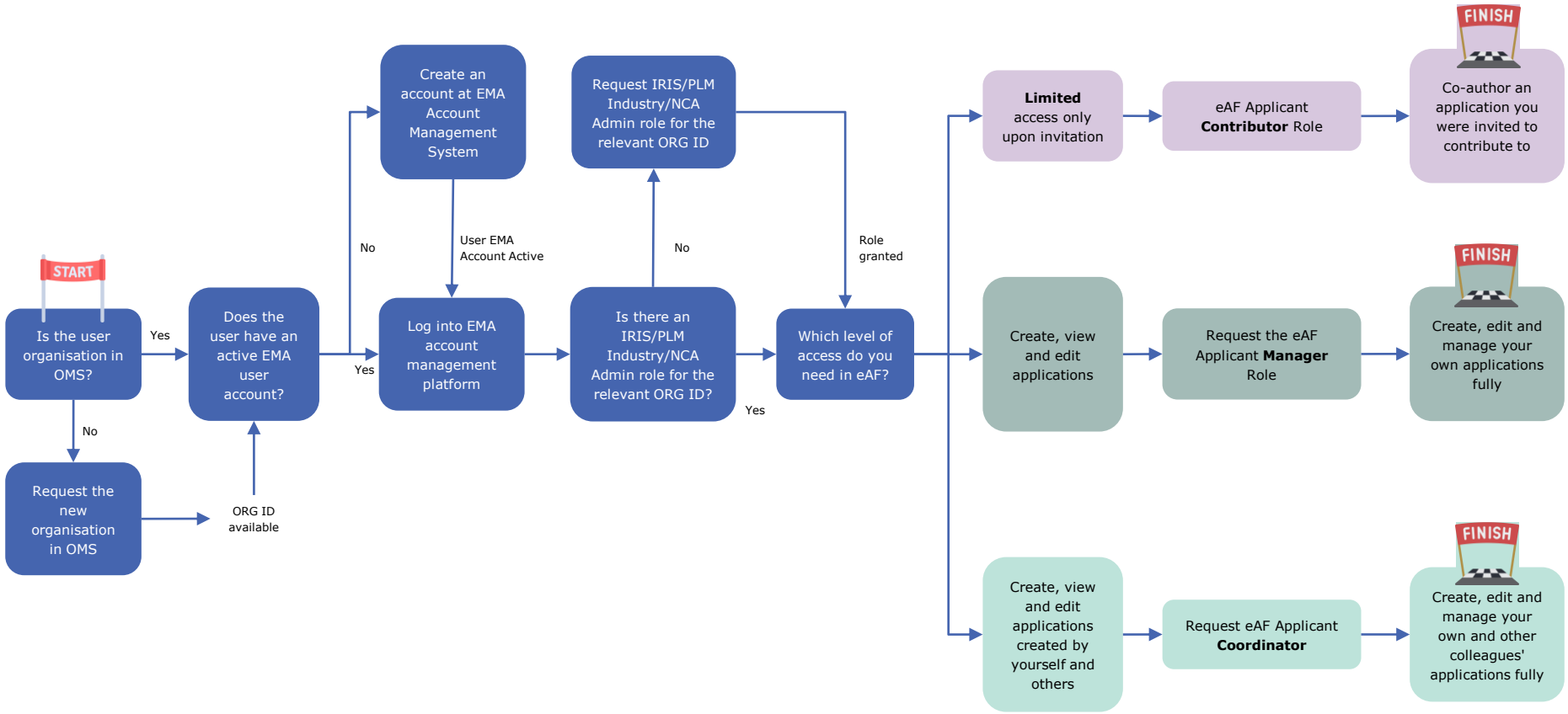
eAF User Registration Process



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Known issues

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Known issues

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Some technical issues and PMS data issues were identified in the eAF - majority of these are already prioritised and/or planned to be fixed

Please **do not open a ticket** in Service Desk if **you identify any known issues** when filling in the eAF/reviewing the products/product data → stakeholders will be notified as we solve the issues.

List of currently known issues available in next slides

Note: Only **some products** are affected by data issues.

Note: Only **some procedure types/functionalities** are affected by technical issues/limitations

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Currently known issues (1/7)

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Some medicinal products are nullified in PMS

These **nullified products can be seen in the variation eAF** as active, valid products and therefore might be duplicates of other products. Selecting these products may and in most cases especially for CAPs will cause an error in the form.

Nullified products will be **removed from the eAF** in the planned release of 28th October.

You can check the XML export or the PMS API and look for the status:

```
<status>
    <coding>
        <extension url="http://ema.europa.eu/fhir/extension/termVersion">
            <valueInteger value="3" />
        </extension>
        <system value="http://spor.ema.europa.eu/v1/lists/200000005003" />
        <code value="200000005007" />
    </coding>
</status>
```

Nullified

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Currently known issues (2/7)

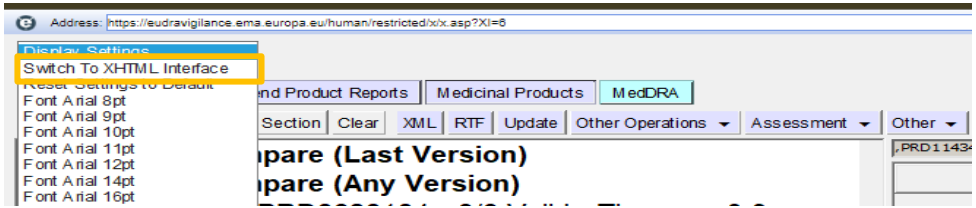
Cyrillic characters showing '?' in the full presentation name

This is not an issue but a reflection of what we have in XEVMPD.

Please, remember that messages with special characters must be sent from XHTML view to avoid adding question marks characters instead of Greek or Cyrillic characters.

If the database field already contains question marks then a new product version must be sent (using XHTML view) to amend the missing Greek or Cyrillic characters.

	↓ PMS ID	Full Name
☐	700000124933	????????? ?????????? 150 mg ?????? ???????
☐	700000118667	????????? ????? 100 mg ????????? ????????
☐	700000113781	???????? 100 mg/g ???
☐	700000111370	???????????????? ??????? 500 mg ???? ? ??????????? ?? ?????????? ???????



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Currently known issues (3/7)

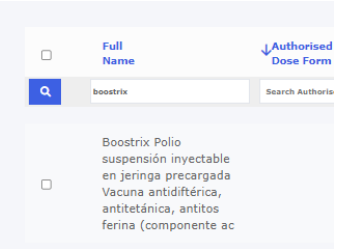
For multilingual countries, just one name in one language is shown in the main page of the eAF (the same name will be in the exported pdf)

All names are displayed when opening the product in PUI, in **eAF** only **one name** in **one language is visible and searchable** i.e. you will not find the product if searching using the product name as search attribute in another language

Full product name will be truncated if it's too long

The truncated name is displayed in the portal and in the pdf

MA Number(s) [8]	Full name [21]	MA Holder name	Member state	Pharmaceutical Form [22]
PA 1077/101/001	IPV-Boostrix suspension for injection in pre-filled syringe Diphtheria, tetanus, pertussis (acell	Glaxosmithkline (Ireland) Limited	Ireland	Suspension for injection in pre-filled syringe



Duplicate medicinal products available for selection

Synchronisation routine errors are occasionally creating duplicate products which can cause an error in the form

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Currently known issues (4/7)

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Product selection filtering

- is not working as expected, especially when searching using authorised dose form as search attribute
- Fixes are under development – expected fix in the planned release of 28th October

Issues with the level of detail in the pdf export for non-CAP products authorised on 'medicinal product level'

- for products which have been authorised in member states that have the authorisation on the 'medicinal product level' both, the medicinal product and packaged medicinal product are displayed in the pdf export.
- This issue is **not** affecting products for which the authorisation is on the packaged medicinal level i.e. each package has its own unique MA number

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Currently known issues (5/7)

Products Authorised through MRP/DCP procedures are not visible in the pdf export unless the MRP variation number has been linked to those products

- The portal UI doesn't not indicate that this is a mandatory field for MRP/DCP. The products are visible in the portal, however, they are not displayed in the pdf export

Concurrent users

- there is currently a limitation in the system where 2 or more users **can** work at the same time in the same application form, however, the **changes cannot be saved at the same time** and this could lead into data loss by one of the concurrent users. It is strongly recommended to organise a workflow internally to avoid any data loss.

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Currently known issues (6/7)

Error message in Type(s) of Change(s) – scope selection: known issue where selection of all conditions and documentations

- Intermitted issue: selection of all conditions and documentations using the high level tickbox will result an error message saying all conditions and documentations should be selected or note should be provided.

Incorrect calculation of number of selected scopes (classification categories) displayed on the summary page

- Intermitted issue: calculation is incorrect on the portal summary page, however, the correct number selected scopes is displayed in the pdf export.

Contact Person section

- For non-CAP variations that have the **same contact person** in **multiple member states**, it is not possible to multiselect the MS. The details and organisation selection needs to be repeated.
- Fix expected to be deployed on 28th October 2024

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Currently known issues (7/7)

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Medical Device section – various issues

- e.g. EU Authorised Representative option missing

Proof of Payment section

- For non-CAP variations, it is **not possible to indicate details for pre-payments**
- Multiselection of member states for same payment details not possible
- Fix and updated rules (New Fee Regulation) expected by late Q4 2024

Conditions and documentations are presented in different order from the variation classification guideline

- Technical limitation

Annexed documents and Declarations in Finalisation section are displayed in random order

- Technical limitation

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Navigate through the web-based eAF

Product UI Demo

Live Demonstration

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Next steps

Upcoming changes and bug fixes

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Coming in Q4 2024

- Data fixes (e.g. nullified product/duplicate removal)
- More user-friendly Present and Proposed section
- More performance improvements
- Application contact person section – multiselect for member states (non-CAPs)
- Proof of Payment: various changes due to New Fee Regulation and non-CAPs)
- Updates as per the variation regulation (mainly non-CAPs; e.g. super-grouping, WS etc)

Q1 2025 and beyond

- Further data fixes (PMS/IRIS)
- eAF integrity stamp
- Alternative organisation names
- Explore structured changes (e.g. packages, manufacturers, medical devices)
- Delete application
- Fixes related to access/address/OMS issues

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Upcoming events

- **Q&A Clinic on eAF for non-CAP variations - 25 October 2024** (10:00 – 10:30 CEST)
- **Webinar for NCAs on web-based eAF variation– 7 November 2024** (11:00 – 12:00 CET)
  NCA event - registration available soon on EU-NTC
- **Training and Q&A Clinic Human Variation eAF - 8 November 2024** (10:00 – 11:00 CET)
- **Q&A Clinic on eAF variations - 14 November 2024** (10:00 – 10:30 CET)
- **Public system demo:** 12 December 2024

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How can EMA be notified of eAF technical issues/questions?

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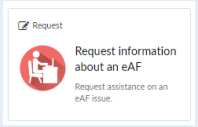
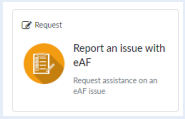
Which ServiceNow ticket type to select?

Ask a Question in EMA Service Desk



Ask a Question via email:
plm.valuestream@ema.europa.eu

Report an Incident in EMA Service Desk



Consolidated NEW technical issues/new feature requests/questions on the non-CAP functionalities via email:
plm.valuestream@ema.europa.eu

PMS data issue follow PMS guidance (either Service Desk or directly submitting corrections to xEVMPD

Note: Interactive pdf = the 'old' eAF from eSubmission website vs the PLM Portal web-based eAF

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Audience Q&A

ⓘ Start presenting to display the audience questions on this slide.

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Please fill in the survey

ⓘ Start presenting to display the poll results on this slide.

Overview of guidance documents

eAF Product User Interface guides:

- PLM Portal eAFGuide to Registration
- PLM Portal eAF Navigation Guide (eAF User Guide)
- PLM Portal eAF Release Notes

eAF FHIR XML:

- EU IG Chapter Introduction – EU Implementation guide
- EU IG Chapter 1 version 5 → registration requirements
- EU IG Chapter 5 version 2 → Data access to medicinal products for human use
- Annex A to EU IG Chapter 5

SPOR Guide:

- On-boarding of users to SPOR data services

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How to stay informed on eAF Work

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eAF News page

Check:
- News
- Events announcements
- Updates

Check regularly

PLM Newsletter

- See planned PMS engagement activities for upcoming quarter
- **Subscribe** here

Receive via email quarterly after subscription

eAF webinars

Latest training sessions:
- non-CAPs training (17 Oct 2024)
- Q&A sessions (Oct & Nov 2024)
- Trainings/webinars on updates (Nov/Dec 2024)

Announced via EMA's Website Events Pages - usually with registration

eAF Release notes, guidance documents, videos + PLM Portal Forum

- Check available documents and updates
- Ask questions (Forum)

Check regularly

Quarterly System Demos

- See the latest developments
- Give your feedback on features and priorities
- **Next system demo:** 12 Dec 2024

Announced via EMA's Website Events Pages - broadcast live

eSubmissions Web Page

Find:
- eSub home page
- PLM Portal eAF page
- Interactive pdf eAF page

Check for general info on eAFs

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