EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eAF – Human Variation electronic Application Form (eAF) Training Session and Q&A Clinic for Industry stakeholders

08 November 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 – 10:35

Kristiina Puusaari
eAF Product Owner

3 **Q&A**
10:35 – 10:55

Moderator:
Isabella Pedon
eAF Change Management Team

4 **Closing**
10:55 – 11:00

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 on the event web page.

Send your questions via Slido

Join at
slido.com
#EAFTRNQA

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

- **Variation eAF timelines**
- **Key actions to MAHs**
- **Known issues**
- **Next steps**
- **Q&A**

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Variation eAF timelines

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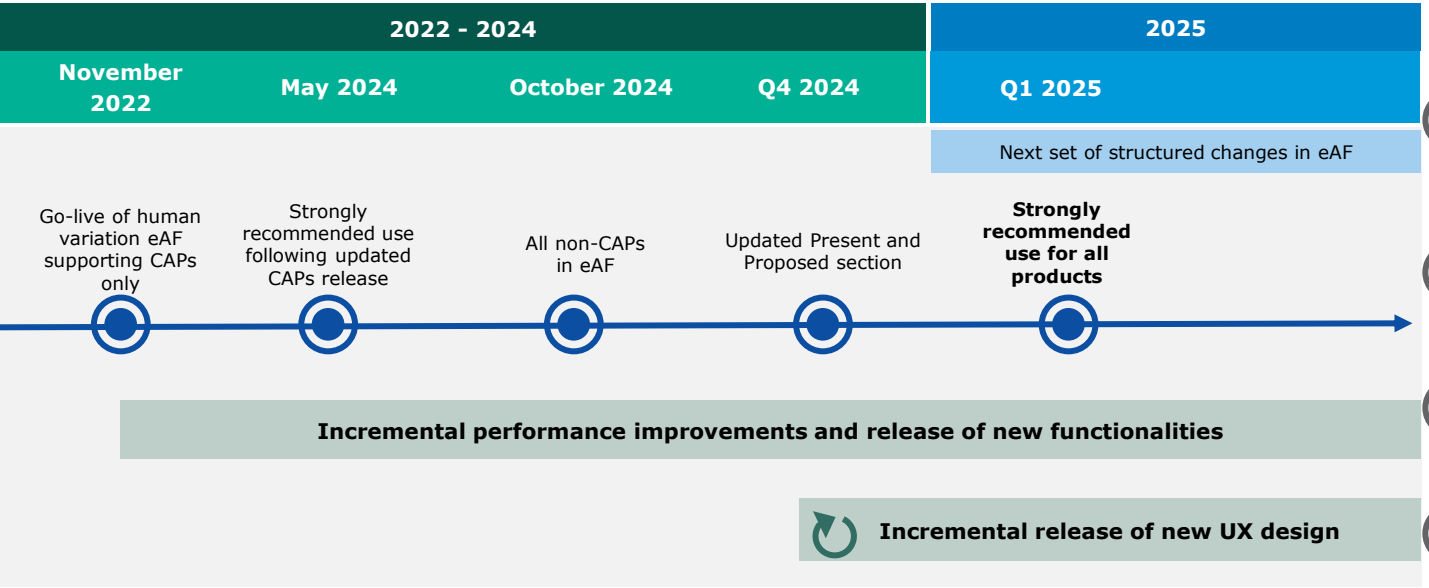
Human Variations electronic Application Form (eAF) – Key steps and milestones (October 2024)

OUTDATED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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Most important known issues

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Currently known issues (1/4)

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 (2/4)

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 filter was implemented in the **eAF** in the planned release of 28th October. Number of 'nullified' products are still present in the system due to that data being still available in the IRIS dataverse from where the products are coming.

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

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Currently known issues (3/4)

Some medicinal products have duplicate data

These **products can be seen in the variation eAF** as active, valid products and are available for selection, however, there are data errors behind the 'scenes' that will only surface when trying to export the pdf. The multiplication of e.g. ingredients or other product data will cause an error in the form preventing export/finalisation.

We are currently reviewing the best way to correct these issues and one solution maybe removing all ingredients from all products for a short time. This should not prevent the use of the form and will actually enable exports again for affected products.

You can still use the forms for CAPs to submit in production, even though the 'active substance field' maybe empty – the application will not be rejected by the EMA. We will launch more communication on the next steps asap once the final agreement on the next steps is reached.

You can check the product in the PUI to see if product has multiple ingredients

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Currently known issues (4/4)

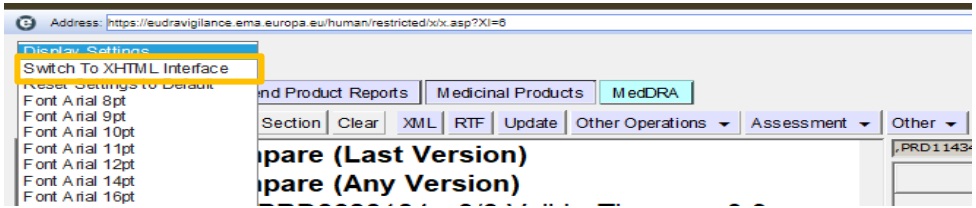
Cyrillic characters showing '?' in the full presentation name

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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Next steps

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Upcoming changes and bug fixes

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Coming in Q4 2024

- Updated application list – coming on Monday 11th November 2024
- Data fixes (e.g. nullified product/duplicate removal)
- Application contact person section – multiselect for member states (non-CAPs)
- More user-friendly Present and Proposed section
- More performance improvements
- 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 variations - 14 November 2024 (10:00 – 10:30 CET)

Public system demo: 12 December 2024

Upcoming training sessions and information webinars (Q1 2025)

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

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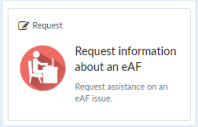
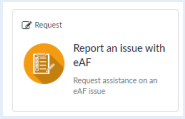
Which ServiceNow ticket type to select?

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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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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