EMA
EUROPEAN MEDICINES AGENCY

Training session on Human variations web-based electronic Application Form (eAF) for non-CAPs

Product Lifecycle Management Portal

10 September 2025

Agenda

1. **Welcome & Introduction**
   10:00 – 10:05
   Kristiina Puusaari
   eAF Product Owner

2. **Training on non-CAPs in web-based eAF**
   10:05 – 10:55
   Kristiina Puusaari
   eAF Product Owner

3. **Q&A**
   10:55 – 11:25
   Francesco Stella
   eAF Change Management Team

4. **Closing**
   11:25 – 11:30
   Kristiina Puusaari
   eAF Product Owner

Housekeeping

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

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**. Please find the link on the event web page

Send your questions via Slido

Join at
slido.com
#EAF1009

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

Poll – Preferred Deep-Dive Demo Sections

What section would you like to **deep-dive** into during today's webinar?

Please connect to Slido using the QR code below or by typing the code #EAF1009 into www.slido.com and provide your answer to the Poll.

Note: We will explore all the listed sections, but would like to provide you the opportunity to choose which section you would like to explore in more details

Aim of this Webinar

- **Introduction to PLM Portal the web-based Human variations eAF**
- **Variation eAF implementation key points**
- **Recent achievements**
- **Known issues**
- **Navigate through the web-based eAF**
- **Next steps**
- **Annexes**

For Questions: www.slido.com code: #EAF1009

Introduction to PLM portal web-based Human variations eAF

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

eAF key changes from pdf eAF to web eAF

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Current **PDF** forms use **outdated technology** and take long time to open	A modern **web-based input** form for applicants with a familiar, human readable pdf output and a **new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

WHAT DOES NOT CHANGE

The **PDF *output* format**

The process to submit the **variation applications** (eCTD package)

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

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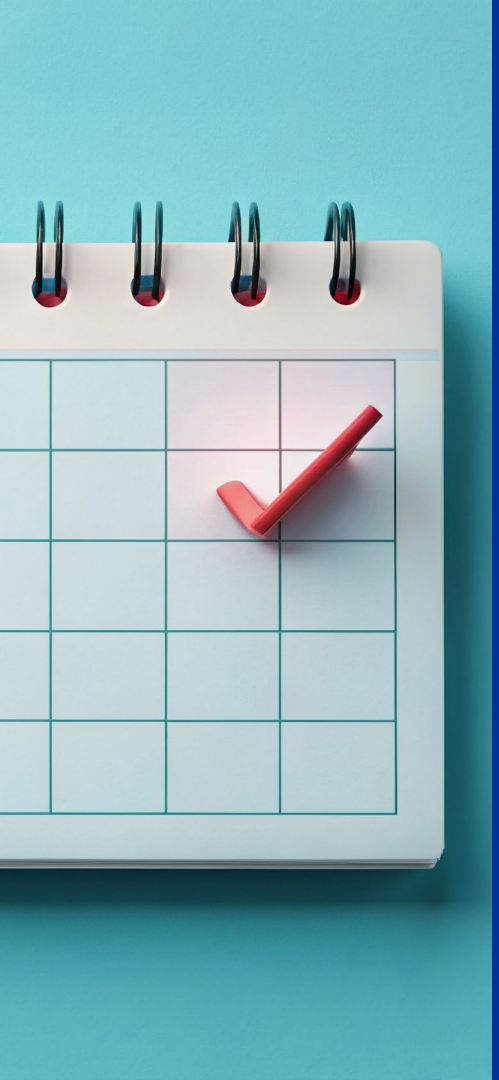


Variation eAF implementation key points

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

Human variations eAF – Key steps and milestones

2022 – 2024

Nov 2022	Go-live of Human variations eAF supporting CAPs only
May 2024	Strongly recommended use of Human variations eAF for CAPs following PMS CAPs release

2025

Q1	Q2	Q3	Q4
Go-live of optional use of Human variations eAF supporting non-CAPs	Recommended use of Human variations eAF for non-CAPs		Strongly recommended use of Human variations eAF for non-CAPs, where applicable* 29th September 2025

Incremental release of the new UX design

eAF FHIR 2.2.5 (25 September 2025)

Incremental release of new features, including maintenance and optimisation updates and performance improvements

Exploring structured changes in eAF

2026 and beyond (TBC)

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 the Human variations web-form only

TBC

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

TBC: To be confirmed, more precise information will be communicated in due time
Note: CAPs and NAPs data in PMS are 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

Dev activities for Human variations eAF

* on the condition that no major issues are identified

EMA

Recent achievements

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

eAF – Human Variations electronic Application Form

Achieved Objectives 25Q3
Enable use of two parallel PLM Portal eAF UI/FHIR/PDF versions so applicants can submit variations under both guidelines and meet legal requirements
Link to an existing OMS entity in IRIS, letting users retrieve the latest organisations in the present/proposed section
Add remaining UX/UI features to the present/proposed section to improve usability, make form creation easier, and support future structured changes
Add remaining UX/UI features to product selection so the eAF can better handle large applications

Human variations eAF – **Strongly Recommended** use for all Variations

- The PLM Portal web-based variation form will be **in Strongly Recommended use for all non-CAP variations** from Wednesday 29 September 2025.

- Issues, concerns, bugs should be reported via the **EMA ServiceNow tool** – please pay attention to the correct category.

Note: ***Strongly Recommended Use*** *=The web-based eAF should be used in most cases. The interactive PDF should only be used if specific constraints prevent the use of the web-based eAF (e.g., technical issues or missing features).*

Human variations eAF - statistics

3960 non-CAP applications
created in the PLM Portal since February 2025

3185 Centralised Procedure application forms received by EMA
since the go-live

Human variations eAF - Changes

Form Version Selection (new variation classification)

Product Selection (further improvements coming by the end of Q3 25)

Present and Proposed

- **Selection of Organisation directly from OMS**
- **Easier view of present and proposed sections**
- **Enhanced Editing**
- **ATC Code**
- **Custom Ordering (now available only in UI, will be in the PDF after FHIR deployment)**

Known issues

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

Consult the previous training explanation at the following link
https://www.youtube.com/watch?v=gKqFsID9TvI&t=26m43s

Known Issues and Bugs

List of **known issues and bugs** is **continuously reviewed** and fixes are planned for each sprint.

Reminder

Please review the eAF **Release Notes** and **Navigation Guide** if you have issues. If you experience a known issue please consider if you need to raise a service desk ticket and carefully select the correct category in ServiceNow

PMS and IRIS dataverse dependencies – corrupted products and organisational data issues

1. Corrupted Products (*affecting CAPS and non-CAPs)*

A small number of corrupted products are still visible in the eAF causing errors when selected, and while a list of these products is unavailable, the PMS team is working on a fix and users should raise a service desk ticket if affected.

2. Duplicate Products (*affecting CAPS and non-CAPs)*

Some packaged medicinal products appear under two different medicinal products due to data errors from xEVMPD/PMS, causing eAF errors that block progress, users should report the issue via a service desk ticket. In most of these cases you may be asked to use the interactive PDF version instead.

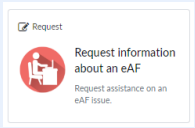
3. Missing Products (*affecting only non-CAPs)*

Approximately 19,000 non-CAP medicinal products (mainly with combined dose forms) are missing from PMS due to data errors, making them unavailable in the PLM Portal eAF. In most of these cases you may be asked to use the interactive PDF version instead.

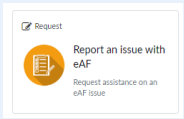
4. Organisational data issues (*affecting CAPS and non-CAPs)*

A known issue in the intermediate dataverse layer from where the Organisation data is fetched to the eAF is continuing to impact number of products/users/applications. A platform level review is ongoing to ensure that the issue can be solved without negatively affecting various different systems that feed from this data

How can EMA be notified of eAF technical issues?



Ask a Question in EMA Service Desk



Report an Incident in EMA Service Desk

For issues related to organisational data from OMS, report an incident in EMA Service Desk

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

Consolidated NEW technical issues/new feature requests/questions on web-based eAF 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

For Questions: www.slido.com code: #EAF1009

Navigate through the web-based eAF

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

Live Training/Demonstration

Join at
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#EAF1009

Q&A

Next Steps

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

eAF Q3 events

Training session on Human variations web-based electronic Application Form (eAF) for non-CAPs 01 July 2025 (Link to the Event Page)

Q&A clinic on web-based electronic Application Form (eAF) functionalities

08 July 2025 (Link to the Event Page)

eAF Training on web-based electronic application form functionalities for CAPs

15 September 2025 (Link to the Event Page)

Quarterly System Demo – Q3 2025

17 September 2025 (Link to the Event Page)

Q&A Clinic on web-based electronic application form functionalities

30 September 2025 (Link to the Event Page)

Q&A Clinic on web-based electronic application form functionalities

09 October 2025 (Link to the Event Page)

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Thank you

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Useful materials and guidance for PLM portal eAF

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

Overview of guidance documents

eAF Product User Interface guides:

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

SPOR Guide:

- On-boarding of users to SPOR data services

How to stay informed on eAF Work

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

Training and Q&A sessions:
Keep track of the upcoming and past eAF webinars through the EMA website event page

Announced via EMA's Website Events Pages - with registration

eAF Release notes, guidance documents, videos

- Check available documents and updates

Check regularly

Quarterly System Demos

- See the latest developments
- Give your feedback on features and priorities
- **Next system demo:** 17 September 2025

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

For Questions: www.slido.com code: #EAF270225

Process to request access to PLM portal eAF

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

eAF User Registration Process – Roles overview

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

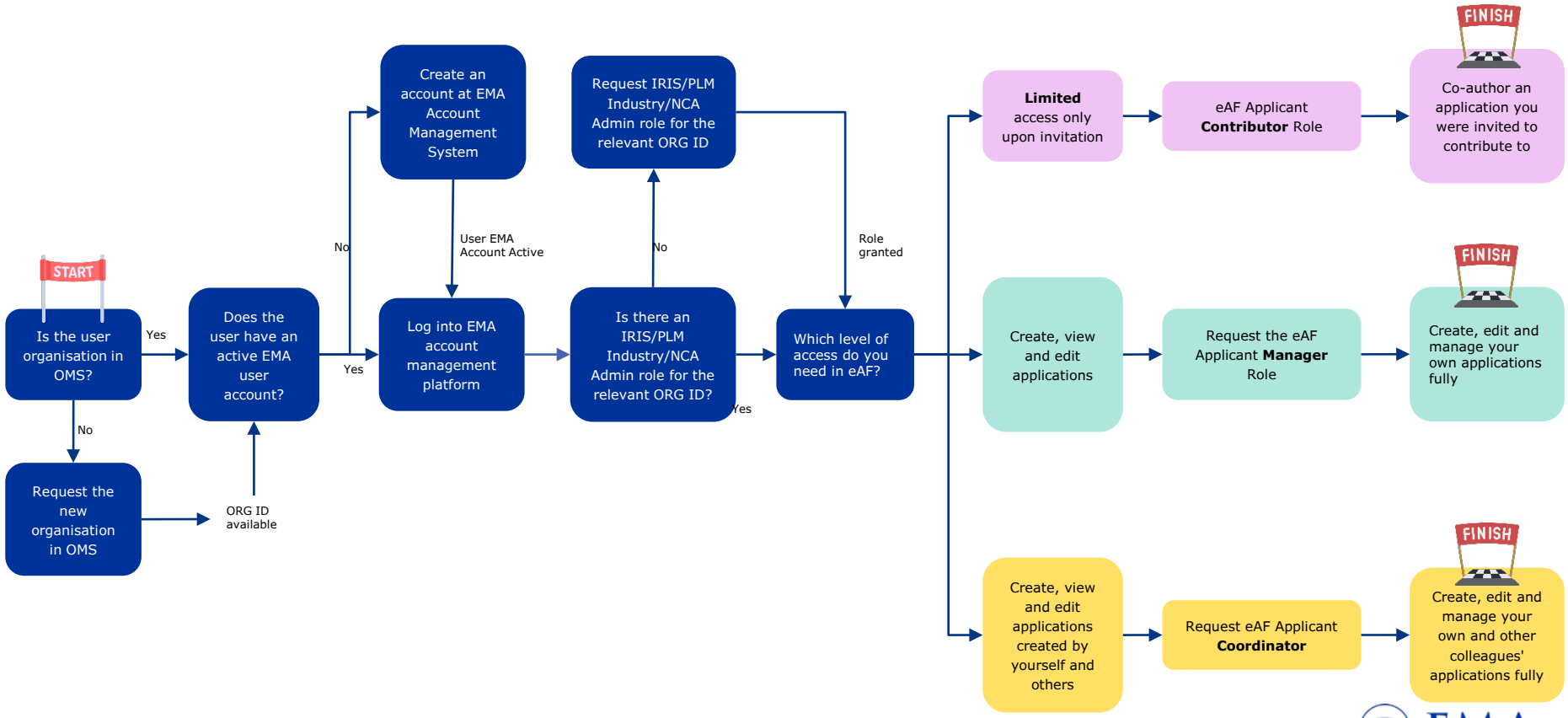
User	Role names	eAF Access Level
Industry user(s)	eAF Applicant Contributor	View, limited edit
	eAF Applicant Manager	View, edit, export
	eAF Applicant Coordinator	View all, edit all, export all

Regulator roles

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

For Questions: www.slido.com code: #EAF270225

eAF User Registration Process



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