EMA
EUROPEAN MEDICINES AGENCY

eAF - Training on Web-based Application Form Functionalities for non-CAPs Variations

11 February 2025

Agenda

1	**Welcome & Introduction** *10:30 – 10:35*	**Kristiina Puusaari** *eAF Product Owner*
2	**Training on non-CAPs in web-based eAF** *10:35 – 11:55*	**Kristiina Puusaari** *eAF Product Owner*
3	**Q&A** *11:55 – 12:25*	**Francesco Stella** *eAF Change Management Team*
4	**Closing** *12:25 – 12:30*	**Kristiina Puusaari** *eAF Product Owner*

Aim of this Webinar

- **Introduction to the web-based eAF to MAHs**
- **Variation eAF implementation key points**
- **Key actions for MAHs**
- **Process to request access to PLM Portal eAF**
- **Known issues**
- **Navigate through the web-based eAF**
- **Next steps**

Introduction to PLM Portal web-based variation eAF

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

eAF Key Changes

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Current **PDF** forms use **outdated technology** and take long time to open	A modern **web-based input** form for applicants with a familiar, human readable pdf output and a **new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

The process to submit the **variation applications**

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

Variation eAF implementation key points

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

eAF updated implementation key points

Background – 2024 work

What we did:

- Released updated CAPs and non-CAPs in eAF
- Strongly recommended the use of web eAF for CAPs
- **Performance Improvements**
- **Updated product search**
- **Improved Present and Proposed section**
- **General improvements and fixes**

What we found:

- Data issues in PMS in CAPs and non-CAPs
- OMS changes not reflected in PLM Portal*
- Bugs in functionalities relating to non-CAPs in eAF
- Need for further performance improvements

2025 Plan

Q1 2025:

- Start of **optional** use for **non-CAP** (MRP/DCP/NP) **procedures**. Continue strongly recommended use for CAP procedures.
- Further improvements to the Present and Proposed section
- Further performance improvements
- Updated Proof of Payment and finalization section
- Launch Integrity stamp feature

Q2 - Q4 2025:

- Further data fixes (delivered by the PMS team)
- Incremental release of fixes
- Further user interface (UX redesign) and performance improvements implementation
- Collecting and prioritizing enhancements as requested by users following the start of production use for non-CAP functionalities
- Technical exploration on the initial structured changes implementation

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

*OMS changes are not reflected in the PLM Portal due to existing architecture of intermediate systems requiring further technical changes

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Key actions for MAHs

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

Summary of actions & tips for users

To do

1. **Request a role** in IAM for your organization – please do not request double roles!
2. **Log in to the PLM portal eAF** and create an application form
3. **Follow** the established process for submission of eAFs

Important

1. Read the eAF **User Guide for Navigation** and **release notes**
2. **Familiarise** yourselves with the system
3. Check the **list of known issues** and subsequently collect any issues/problems in the PLM Portal eAF
4. Provide **consolidated feedback** to EMA via email to plm.valuestream@ema.europa.eu
5. **Refrain** from raising **service desk tickets** on **change requests** to allow the team to concentrate on supporting production applications

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

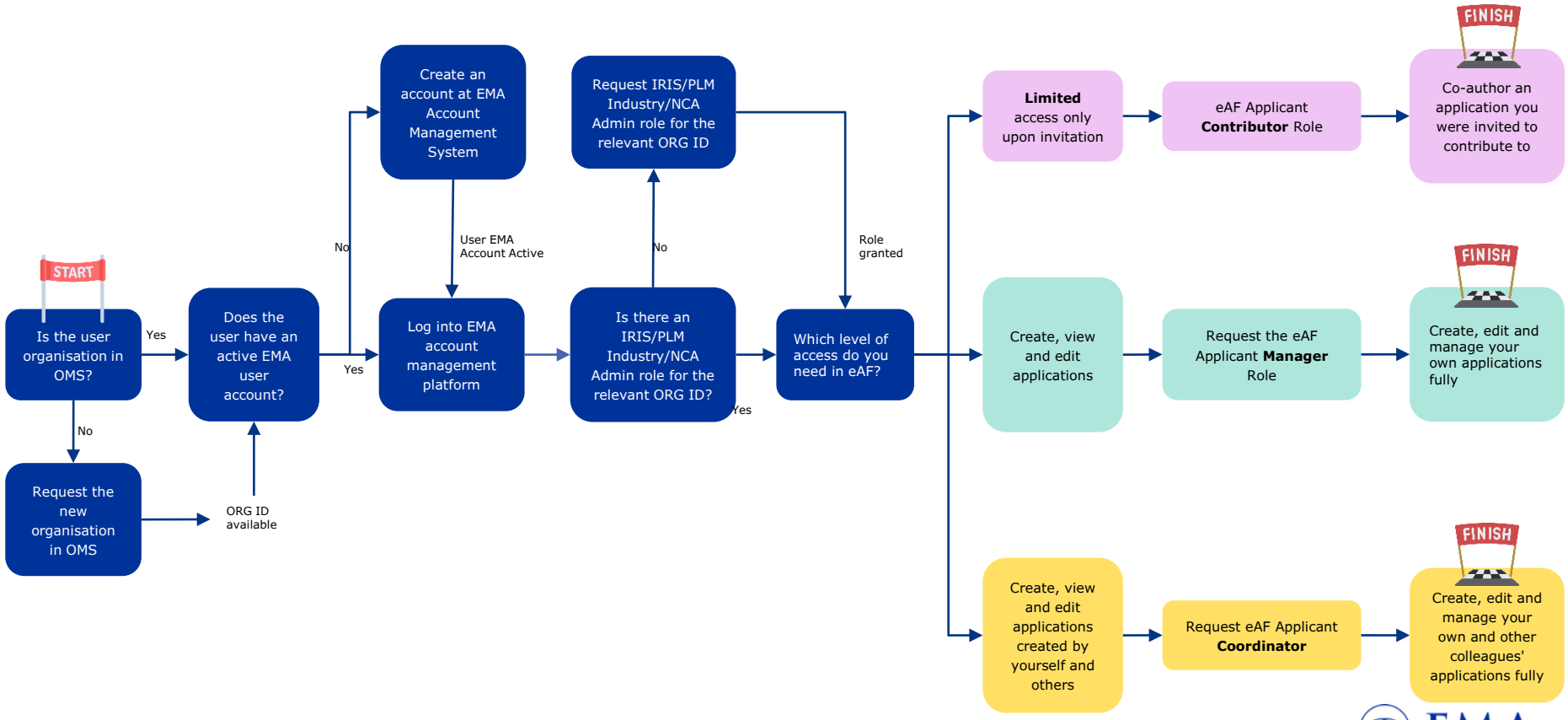
Industry roles

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

eAF User Registration Process



Known issues

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

Known Issues

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

- 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

Currently Known Issues (1/6)

Proof of Payment section – not working for variations containing multiple NAPs (from different MS). Also Proof of Payment section does not currently work as designed if there is a mix of NAPs and CAPs in the form

We are currently working to address issues in the Proof of Payment section related to mixed NP variations and mixed CAP/NP variations as quickly as possible. For the time being, please, do not report the issue and simply use the interactive pdf eAF form until the issue has been fixed. It is anticipated that the fix will become available before end of Q1 2025.

Currently Known Issues (2/6)

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 ???? ? ??????????? ?? ??????????? ???????

Currently Known Issues (3/6)

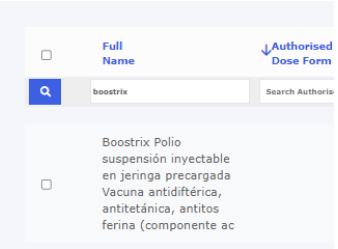
For multilingual countries, just one name in one language is shown in the main page of the eAF (the same name will be in the exported pdf)

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



Errors in saving products

In certain scenarios there may be issues in saving products in the form, this can be due to the users 'roles' in the form or a bug related to a business rules in the form – we are investigating this!

Currently Known Issues (4/6)

Present and Proposed section: ATC code update/changes are not displayed properly in the pdf export

The web-based form can be used for variations on the ATC code, however, it is recommended that the free text fields in present and proposed section are used instead of the ATC code function to avoid issues in the pdf export

Medical Devices section is not currently working in the web-based form

For variations where the section 4d for Medical Devices needs to be filled in, please use the interactive pdf eAF

Present and Proposed section: EMA procedure number selection in the 'Other applications' field

The selection for other EMA procedure numbers does not work, to provide procedure number please use the add procedure number field instead

Currently Known Issues (5/6)

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

Orphan medicinal products/paediatrics

For variations where the sections 4a and 4b need to be filled in for Orphan medicinal products and/or paediatrics, please use the interactive pdf eAF if the correct options and selections are not available

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.

Currently Known limitations (6/6)

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.

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

Navigate through the web-based eAF

Kristiina Puusaari

European Medicines Agency - eAF Product Owner

Live Demonstration

See recording on event web-page

Next Steps

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Upcoming events

eAF training on web-based application form functionalities for CAPs and non-CAPs variations - 27 February 2025 (10:30 – 12:30 CET) – Event web-page

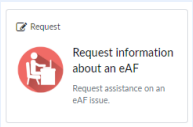
Q&A Clinic #1 on web-based application form functionalities for CAPs and non-CAPs variations – 06 March 2025 (11:00 – 11:30 CET) – Event web-page

Q&A Clinic #2 on web-based application form functionalities for CAPs and non-CAPs variations - 13 March 2025 (11:30 – 12:00 CET) – Event web-page

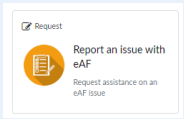
Public system demo - 26 March 2025

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

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

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:
- Training on CAPs and Non-CAPs (27 Feb 2025)
- Q&A Clinic (06 Mar 2025)
- Q&A Clinic (13 Mar 2025)

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:** 26 March 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: #EAFNONCAPS