EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Human Variations eAF training session

02 February 2023, 10:00 – 11:30 Central European Time (CET)
Webinar: WebEx

Agenda

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

Kristiina Puusaari
eAF Product Owner, EMA

2   **Scenarios for which the eAF can be used**
10:05 – 10:10

Kristiina Puusaari
eAF Product Owner, EMA

3   **Access management & data visibility by role**
10:10 – 10:25

Joao Costa
Platform Manager, EMA

4   **Filling in and exporting the eAF**
10:25 – 11:10

Kristiina Puusaari, *eAF Product Owner, EMA*
Noel Diamant, *eAF Product Owner, UNICOM**

5   **Q&A session**
11:10 – 11:25

Moderator:
Cristina Pepato
eAF & PMS Change Manager

6   **Next Steps and Closing**
11:25 – 11:30
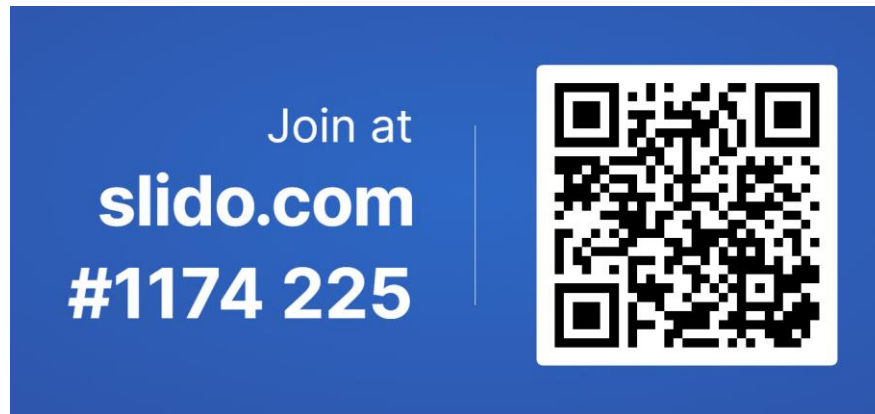
Kristiina Puusaari
eAF Product Owner, EMA

*Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel.***

*At certain points 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](#).*

1. Join via the QR code or link

2. Send or upvote the questions you want to hear answered

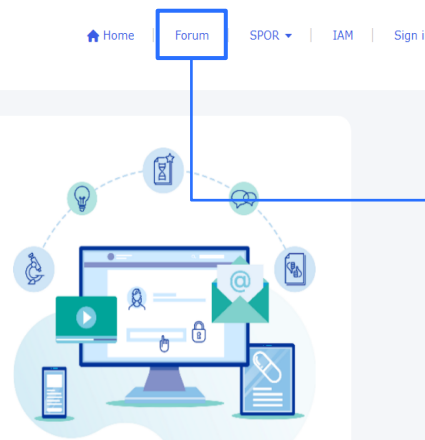**3. Questions will be shown on the screen and managed live in the Q&A session**

Introduction

Kristiina Puusaari, *eAF Product Owner, EMA*

Overview of PLM Portal and Forum

PLM Portal Homepage link:
https://plm-portal.ema.europa.eu/

PLM Portal Forum link:
https://plm-portal.ema.europa.eu/forums/

Available Training Videos

- How to monitor Application Forms Status on the PLM Portal (link)
- How to select the scope of the variation application on the PLM Portal (link)
- How to fill in the "Procedural Information" section of the eAF on the PLM Portal (link)
- How to fill in the "Additional Information" section of the eAF on the PLM Portal (link)
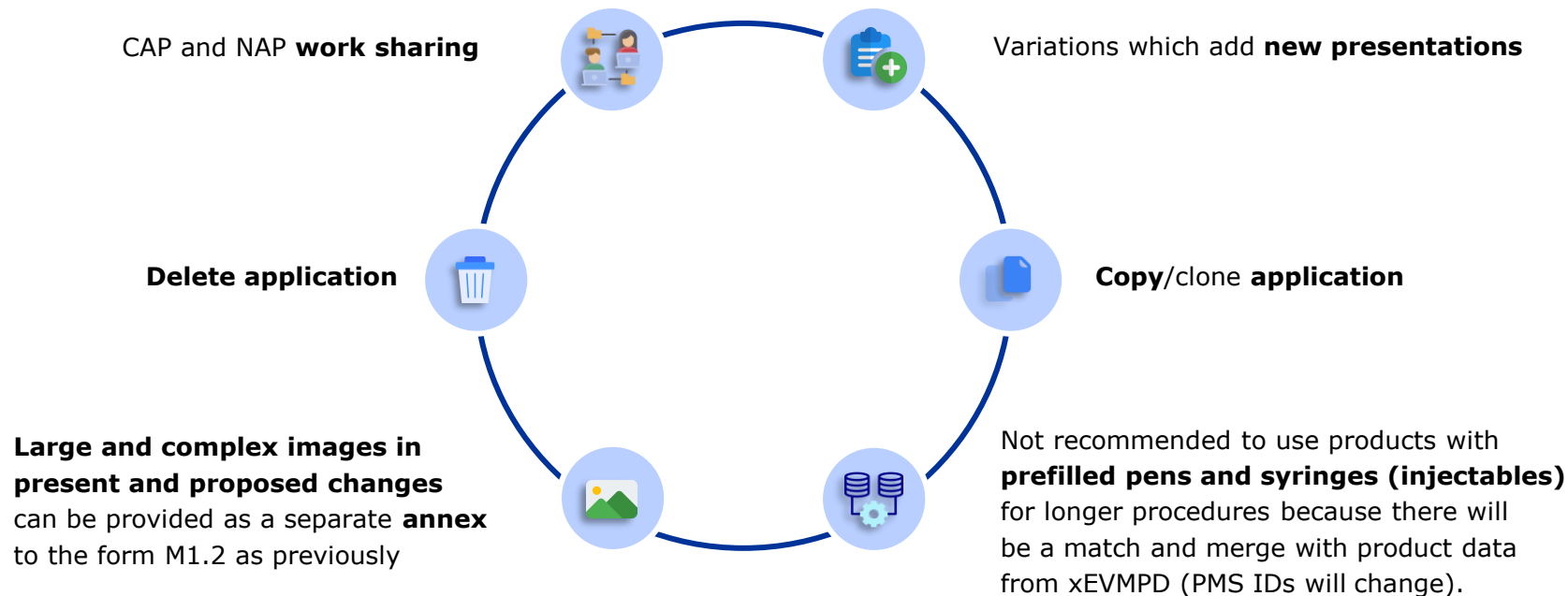- How to fill in the "Finalisation" section of the eAF on the PLM Portal (link)

User Guides

- PLM Portal Registration Guide
- PLM Portal Navigation Guide

Classified as public by the European Medicines Agency

Scenarios for which the eAF can be used

Kristiina Puusaari, *eAF Product Owner, EMA*

CAP and NAP **work sharing**

Variations which add **new presentations**

Delete application

Copy/clone **application**

Large and complex images in present and proposed changes can be provided as a separate **annex** to the form M1.2 as previously

Not recommended to use products with **prefilled pens and syringes (injectables)** for longer procedures because there will be a match and merge with product data from xEVMPD (PMS IDs will change).

WORK in PROGRESS

We are working on the list of limitations and solving them one by one, even if there are some more complex issues not depending on us (e.g. NAP Work Sharing).

About this Document

This document lists and briefly describes the new features and fixed issues included in each release of the PLM Portal.

The most recent release appears first.

The known issues are categorised per component or business process of the system so that users can easily identify which issues are relevant for them. The components currently used are:

Component	Short Description
PLM Portal	This component relates to the website, the UI (user interface),
Human Variations eAF	The business process where MAH's create and edit their variation eAF (electronic application form) on the PLM Portal.
PDF	The PDF that is available for download after the completion of an application
FHIR XML	The FHIR xml file attached to exported PDF

For additional information on the PLM portal see this:

- User guidance recording on the PLM Portal:
- User guidance documentation on the the PLM Portal:
- If you encounter any issue that is not addressed by the above, visit the EMA Service Desk portal: https://support.ema.europa.eu/esc
- For more general information, please visit: https://esubmission.ema.europa.eu/cessp/cessp.htm

Version: 1.0.1.4 (Release date 23/01/2023)

Version Goal: PLM Portal bug fix release

Date: 23/01/2022

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Short description
Implementation of the web based human variation application form	Human Variations eAF Version 1.0.1.4	This release note is for the BUGFIX version 1.0.1.4 release go-live 23/01/2023
Update of the human readable pdf export	PDF Version 2.0.2.2* *Please note that the newly introduced 4th number refers to technical changes in the pdfgen. These do not refer to change in the pdf output form used by business users.	This release note is for the BUGFIX version 2.0.2 release go-live 23/01/2023

Issues fixed in this version

ID	Description	Comments
24184 – web eAF	Add a link to the Guidance for applicants on precise scope	The Guidance for applicants for the preparation of the 'precise scope' section of the variation application form is now available via a link in the Precise Scope section (via 'info' button)
35219 – web eAF	Proposed Changes Section: Upload Image Error in Rich Text Box Field	It is now possible to include images in the Present and Proposed fields (the production issue has been fixed).
24565 – web eAF	Limit width of free text fields	The images are now displayed in more legible format in the present and proposed fields.
25713 – web eAF	Info text for commercially confidential data is incorrect	The information text explaining the details related to access management in relation to CCI have been clarified and corrected.

Known Issues

ID	Component	Short description
Known limitation	PLM Portal	Copy application feature not available yet
Known	Human	It is not possible to change the 'Friendly name'

Access management & data visibility by role

Joao Costa, *Platform Manager, EMA*

Roles Overview

EMA	Administrators	Applicants
EMA User Admin	**IRIS eAF Industry User Admin** **External Organisation Administrator** *(optional)*	**(UAT_) eAF Applicant Contributor** • Be added as co-author • Edit applications • Select classifications **(UAT_) eAF Applicant Manager** • Privileges of *eAF Applicant Contributor* • Select products of my organisation • Create, finalise and delete my applications • Add co-authors **(UAT_) eAF Applicant Coordinator** • Privileges of *eAF Applicant Manager* • Full access to all applications of my organisation
*Approve/Deny **Administrators** access requests*	*Approve/Deny **Applicants** access requests*	*Access to the **PLM Portal - eAF** Create / access / edit / manage electronic Application Forms*

DISCLAIMER: *When assigning the role, carefully consider the presence of **Commercially Confidential Information (CCI)***
- *Adding an Applicant Manager shares all products within an application including CCI and product data from SPOR PMS*
- *Adding an Applicant Coordinator shares all products within all applications of an Organisation including CCI and product data from SPOR PMS*

User Roles and Grants

Role name: / Grant:	Industry Users				NCA Users		
	eAF Applicant Contributor	eAF Applicant Manager	eAF Applicant Coordinator	IRIS eAF Industry Admin	External Organisation Administrator (optional)	eAF Competent Authority User	IRIS eAF Competent Authority Admin
Create application	✗	✓	✓	✗	✗	✓	✗
Edit application	✓	✓	✓	✗	✗	✓	✗
Add co-author/s	✗	✓	✓	✗	✗	✓	✗
Be added as co-author	✓	✓	✓	✗	✗	✗	✗
Select classification	✓	✓	✓	✗	✗	✓	✗
Select products	✗	✓ *	✓ *	✗	✗	✓ **	✗
Finalise application	✗	✓	✓	✗	✗	✓	✗
Delete application	✗	✓	✓	✗	✗	✓	✗
Manage all applications	✗	✗	✓ *	✗	✗	✓ **	✗
Approve / deny access roles requests	✗	✗	✗	✓ The following role/s: • eAF Applicant Contributor, • eAF Applicant Manager, or • eAF Applicant Coordinator	✓ The following role/s: IRIS eAF Industry Admin, IRIS eAF Competent Authority Admin	✗	✓ The following role/s: • eAF Competent Authority User

of that organization/company *
of that country **

Pre-requisites

To be an Applicant or an Administrator, you are required to have:

- an active **EMA user account** *(external e-mail address)*
- signed proof of authority *(only applicable to Administrators)*
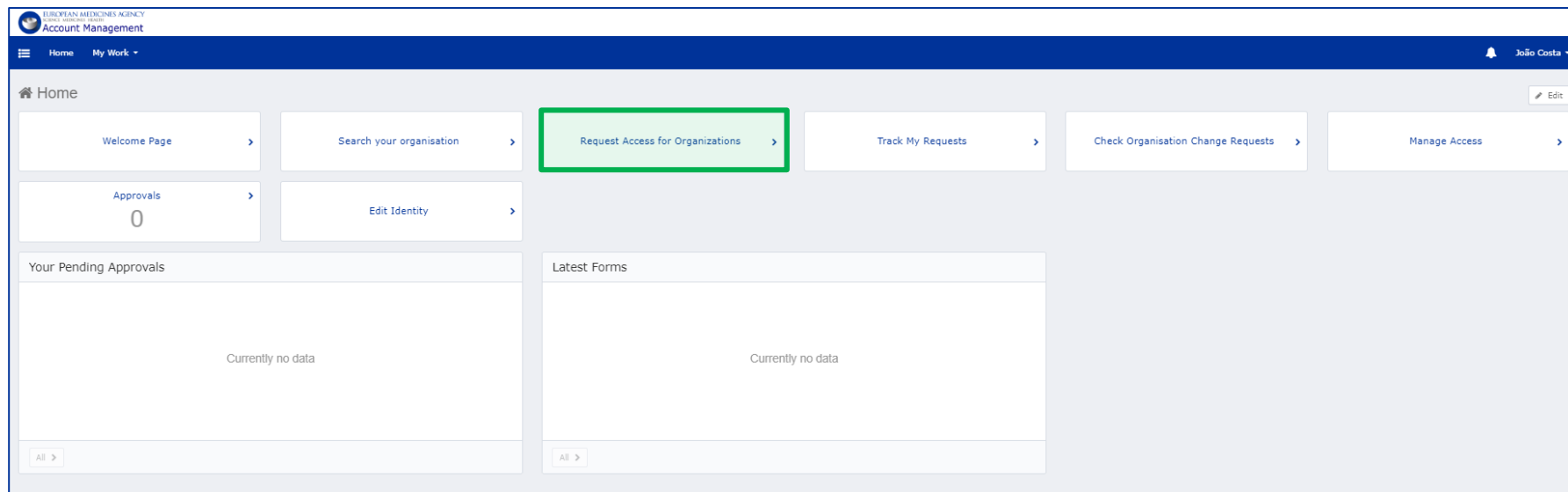- **role(s)** assigned to that account

User Guide for Registration

The **EMA Account Management** is the online platform where you can request and manage access to EMA applications. Refer to this platform to seek guidance on how to:

- Look up whether you already have an EMA account
- Re-activate your EMA account
- Recover your credentials
- Retrieve your username
- Reset your password
- Create an EMA account
- Request a user access role
- Manage users' access for your organisation as an "User Admin"
- FAQs

Note that the **organisation** on whose behalf you will be acting must be listed in the EMA's **Organisation Management Service (OMS)**

How to request user access role(s)

The **EMA Account Management** is the online platform where you can **request and manage access** to EMA applications

Signing into the PLM portal – eAF | Multifactor Authentication

1

Pick an account

surname_n@id.ema.europa.eu

Use another account

2

surname_n@id.ema.europa.eu

Enter password

Password

Forgot my password

Sign in

3

surname_n@id.ema.europa.eu

Verify your identity

Approve a request on my Microsoft Authenticator app

Use a verification code

Text +XX XXXXXXX34

Call +XX XXXXXXX34

More information

Are your verification methods current? Check at https://aka.ms/mfasetup

Cancel

EMA users: sign in with your email address

Other users: sign in with your username followed by @id.ema.europa.eu

Follow this guidance to recover your username and password.

- You must sign in with your username followed by @id.ema.europa.eu: *username*@id.ema.europa.eu

- The password is the same as in https://register.ema.europa.eu

- **Multifactor authentication (MFA)** is required:
  - > You can use the **Microsoft Authenticator app**, **SMS**, or **Call**
  - > Access **My Account** to manage your MFA methods

Filling in and exporting the eAF

Kristiina Puusaari, *eAF Product Owner, EMA*

Noel Diamant, *eAF Product Owner, UNICOM**

Q&A session

Moderator: Cristina Pepato, *eAF & PMS Change Manager*

Next Steps & Closing

Kristiina Puusaari, *eAF Product Owner, EMA*

System Demo - March 2023 (date will be announced soon)

eAF trainings in the next months

Q&A Clinics in the next months

Further information

http://esubmission.ema.europa.eu/cessp/cessp.htm

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