Human Variations eAF (DADI) training session

8 November 2022, 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 **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.*

Join at
slido.com
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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

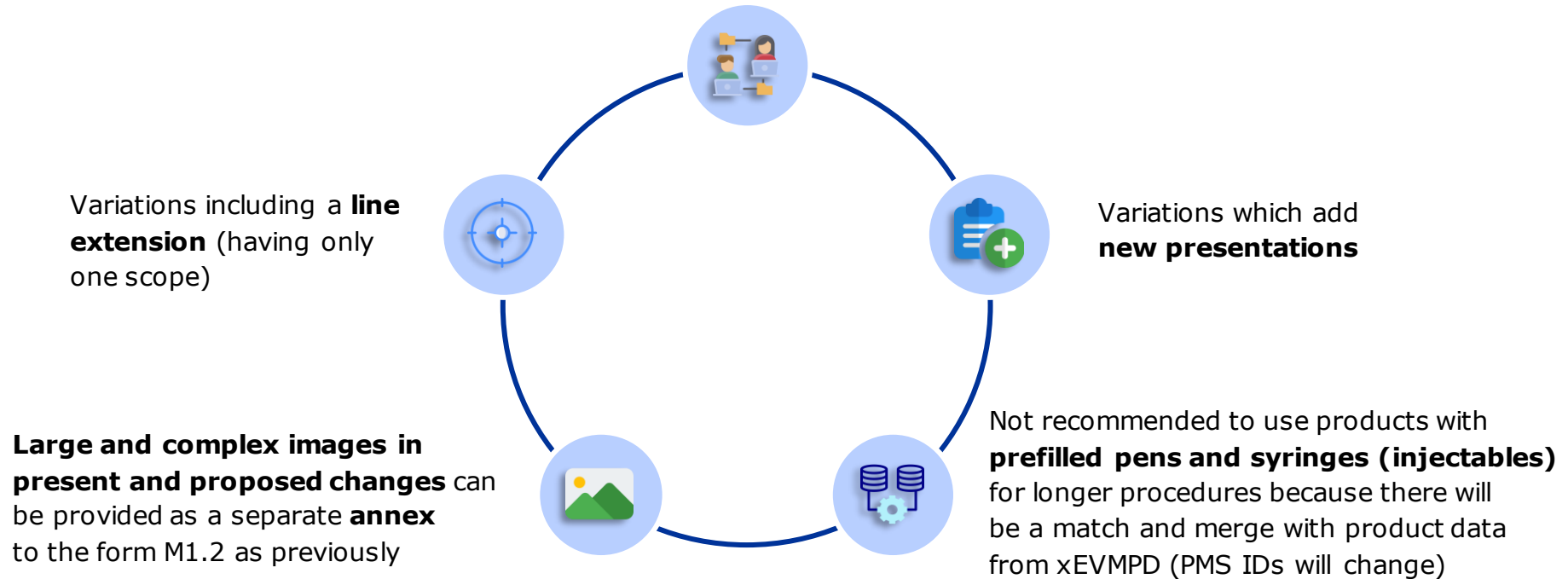- PLM Portal Registration Guide
- PLM Portal Navigation Guide

Scenarios for which the eAF can be used

Kristiina Puusaari, *eAF Product Owner, EMA*

CAP and NAP **work sharing**

Variations including a **line extension** (having only one scope)

Variations which add **new presentations**

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)

Release Notes and change control process

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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: 1.0.0.0

Version Goal: Go-Live PLM Portal

Date: 04/11/2022

Environment: production

Version content (testable functionalities/use cases)

Version content

Functionality/use case	Component	Short description
Implementation of the Product Lifecycle Management Portal	PLM Portal	This implementation is the first version of the portal
Implementation of the web based human variation application form	Human Variations eAF Version 1.0.0	This implementation is the first version of the web-based form for human variations based on the NTA APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, September 2021
Implementation of the human readable pdf export	PDF Version 2.0.0	This implementation is the first version of the pdf rendition export
Implementation of the FHIR xml	FHIR XML 1.0.0	This implementation is the first version of the FHIR xml export

Known Issues

ID	Component	Short description
Known limitation	PLM Portal	Copy application feature not available yet
Known limitation	Human Variations eAF	Cannot select 'includes line extension' when single scope added
Known limitation	Human Variations eAF	It is not possible to change the 'Friendly name'
Known limitation	Human Variations eAF	Form cannot be used for variations that add new presentation
Known limitation	Human	Delay in display of packaged medicinal products in product selection.

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Access management & data visibility by role

Joao Costa, Platform Manager, EMA

Roles Overview

EMA	Administrators	Applicants	
		(UAT_) eAF Applicant Contributor	• Be added as co-author • Edit applications • Select classifications
EMA User Admin	**IRIS eAF Industry User Admin**	**(UAT_) eAF Applicant Manager**	• Privileges of *eAF Applicant Contributor* • Select products of my organisation • Create, finalise and delete my applications • Add co-authors
	External Organisation Administrator *(optional)*	**(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						Regulators (NCA)
	Applicants			Administrators			Applicants
	eAF Applicant Contributor	eAF Applicant Manager	eAF Applicant Coordinator	*IRIS eAF Industry Admin	*External Organisation Administrator (optional)	*IRIS eAF Competent Authority Admin	eAF Competent Authority User
Create application	✖	✔	✔	✖	✖	✖	✔
Edit application	✔	✔	✔	✖	✖	✖	✔
Add co-author/s	✖	✔	✔	✖	✖	✖	✔
Be added as co-author	✔	✔	✔	✖	✖	✖	✖
Select products	✖	✔ of that organisation	✔ of that organisation	✖	✖	✖	✔ of that country
Select classification	✔	✔	✔	✖	✖	✖	✔
Finalise application	✖	✔	✔	✖	✖	✖	✔
Delete application	✖	✔	✔	✖	✖	✖	✔
Manage all applications	✖	✖	✔ of that organisation	✖	✖	✖	✔ of that country
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	✖

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
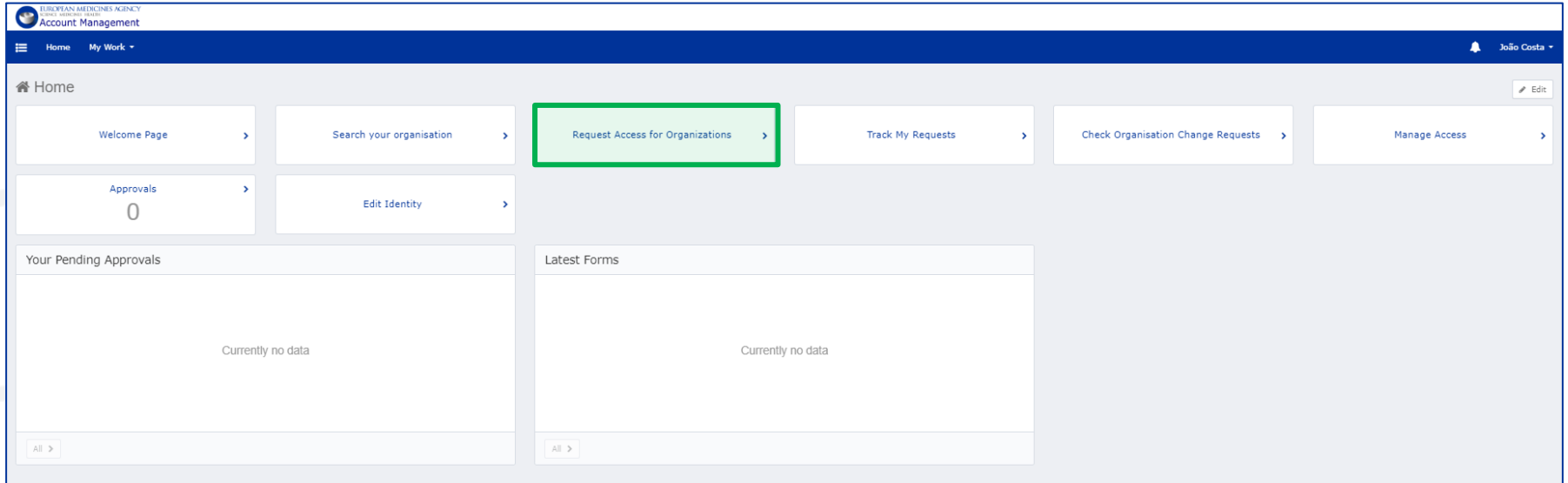
User Guide for Registration

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"
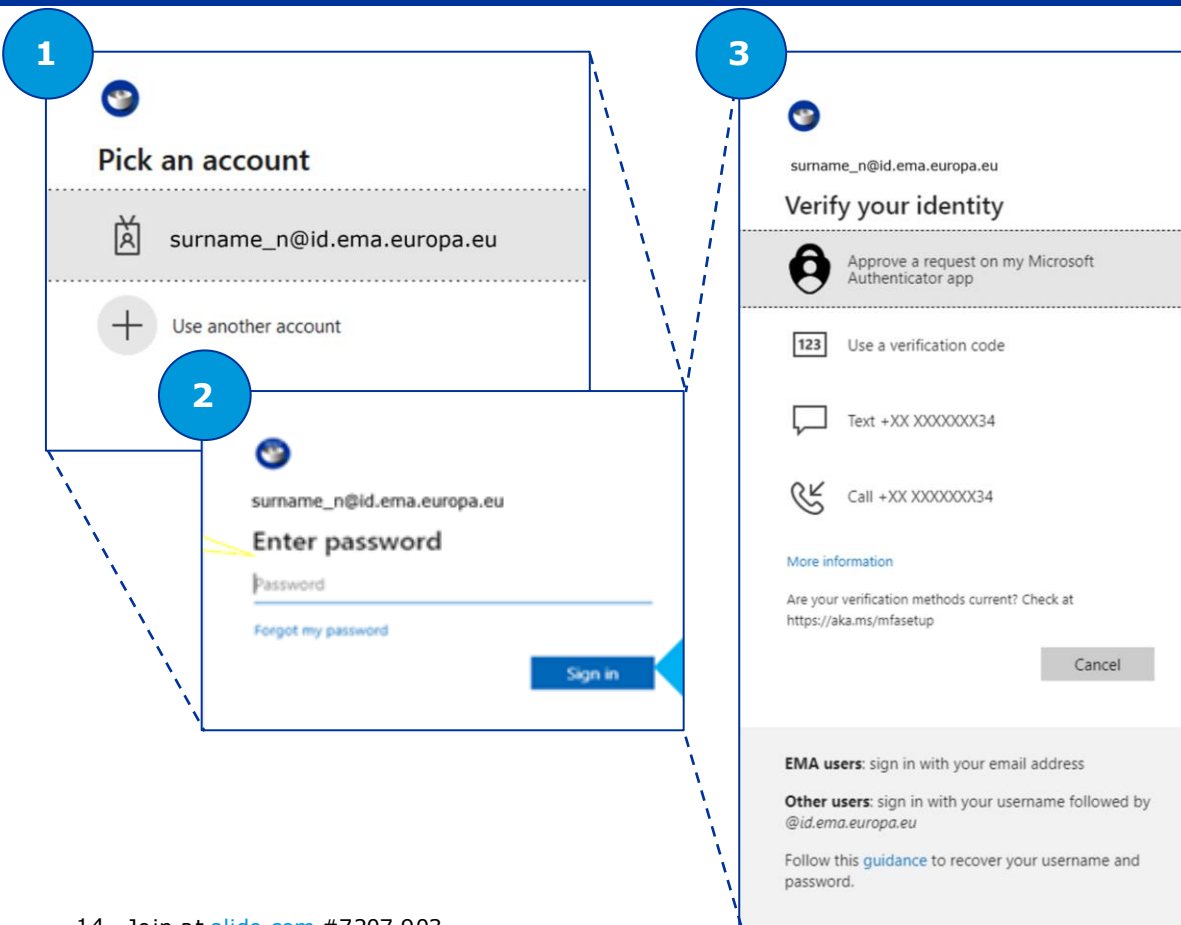- FAQs

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

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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

123 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*

Closing

Kristiina Puusaari, *eAF Product Owner, EMA*

Further information

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

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