



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Human Variations eAF training session

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15 December 2022, 10:00 – 11:30 Central European Time (CET)  
Webinar: WebEx





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## Welcome / Introduction

10:00 – 10:05

**Kristiina Puusaari**

*eAF Product Owner, EMA*

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## Scenarios for which the eAF can be used

10:05 – 10:10

**Kristiina Puusaari**

*eAF Product Owner, EMA*

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## Access management & data visibility by role

10:10 – 10:25

**Joao Costa**

*Platform Manager, EMA*

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## Filling in and exporting the eAF

10:25 – 11:10

**Kristiina Puusaari**, *eAF Product Owner, EMA*

**Noel Diamant**, *eAF Product Owner, UNICOM\**

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## Q&A session

11:10 – 11:25

**Moderator:**

**Cristina Pepato**

*eAF & PMS Change Manager*

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## Next Steps and Closing

11:25 – 11:30

**Kristiina Puusaari**

*eAF Product Owner, EMA*



\*The UNICOM Innovation Action has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875299.

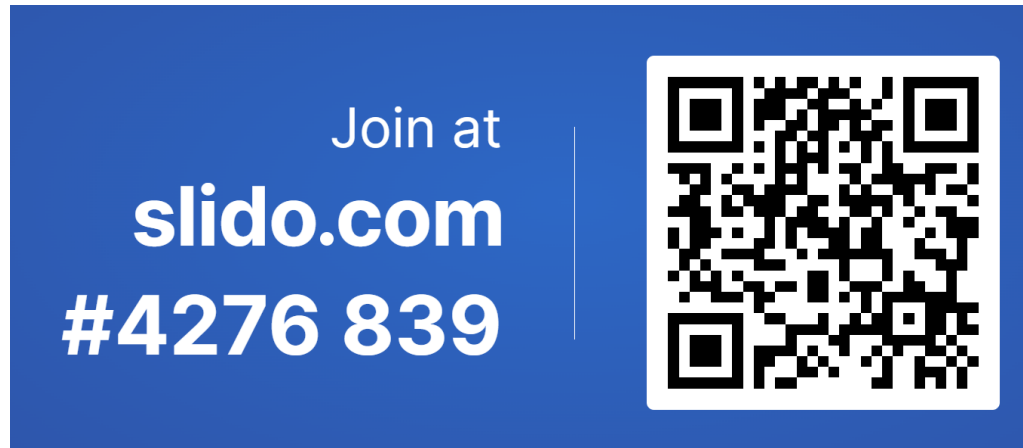


Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel**.



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

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Kristiina Puusaari, *eAF Product Owner, EMA*



## Product Lifecycle Management (PLM) Portal

Portal for applicants to fill in and generate electronic Application Forms for European Regulatory Procedures and to update Product Data

[Sign In](#) >



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

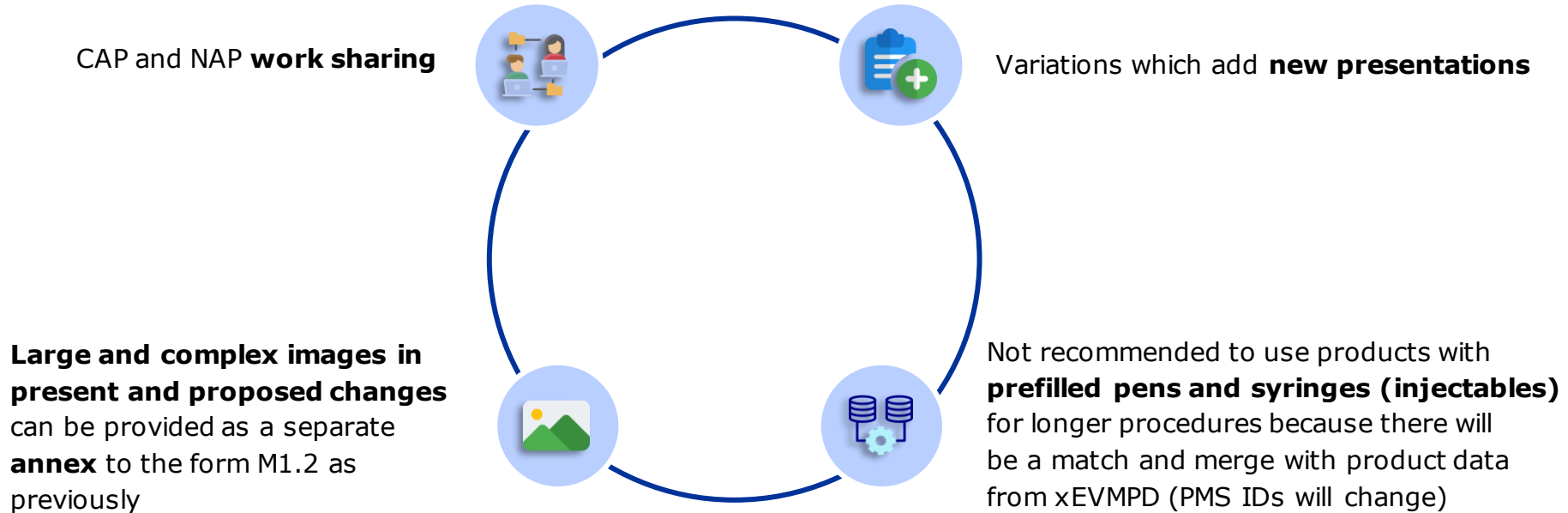
- PLM Portal [Registration Guide](#)
- PLM Portal [Navigation Guide](#)



# Scenarios for which the eAF can be used

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Kristiina Puusaari, *eAF Product Owner, EMA*



*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: 1.0.0.0

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.









# Access management & data visibility by role

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*Joao Costa, Platform Manager, EMA*



EMA	Administrators	Applicants	
 <p><b>EMA User Admin</b></p>	 <p><b>IRIS eAF Industry User Admin</b></p>  <p><b>External Organisation Administrator</b> <i>(optional)</i></p>	 <p><b>(UAT_) eAF Applicant Contributor</b></p>  <p><b>(UAT_) eAF Applicant Manager</b></p>  <p><b>(UAT_) eAF Applicant Coordinator</b></p>	<ul style="list-style-type: none"> <li>Be added as co-author</li> <li>Edit applications</li> <li>Select classifications</li> </ul> <ul style="list-style-type: none"> <li>Privileges of <i>eAF Applicant Contributor</i></li> </ul> <ul style="list-style-type: none"> <li>Select products of my organisation</li> <li>Create, finalise and delete my applications</li> <li>Add co-authors</li> </ul> <ul style="list-style-type: none"> <li>Privileges of <i>eAF Applicant Manager</i></li> </ul> <ul style="list-style-type: none"> <li>Full access to all applications of my organisation</li> </ul>
<p>Approve/Deny <b>Administrators</b> access requests</p>	<p>Approve/Deny <b>Applicants</b> access requests</p>	<p>Access to the <b>PLM Portal - eAF</b> Create / access / edit / manage electronic Application Forms</p>	






**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



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	✓ The following role/s: • IRIS eAF Competent Authority Admin • 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



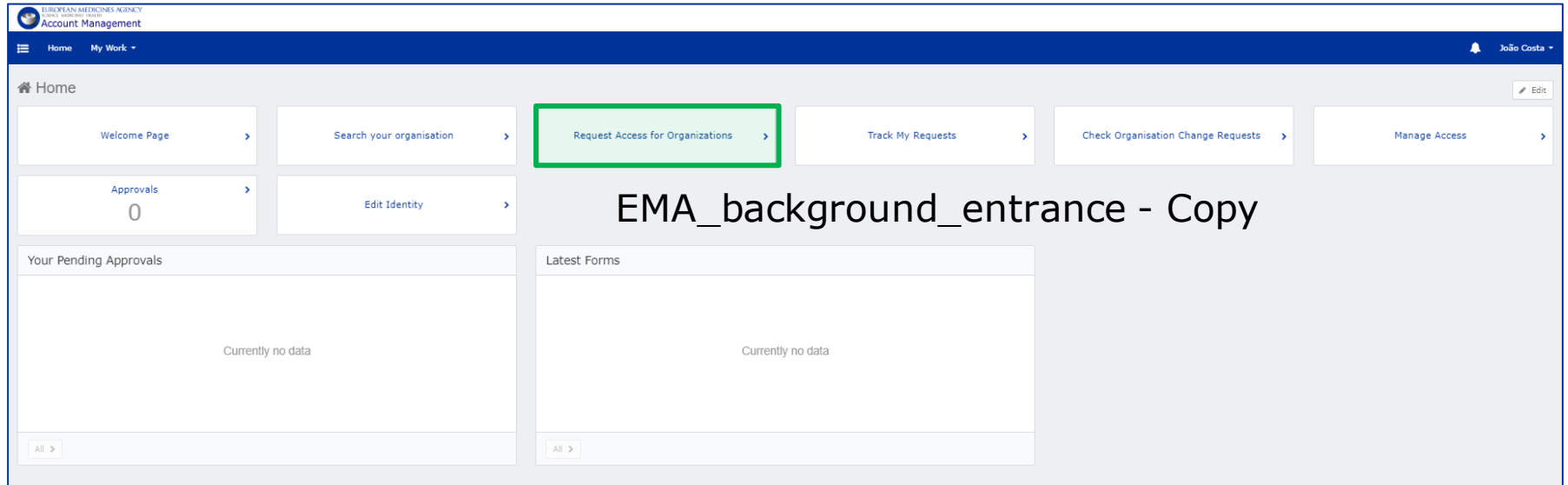
The **EMA Account Management** is the online platform where you can request and manage access to EMA applications. Refer to this platform to seek guidance on how to:

- [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





The screenshot displays the EMA Account Management interface. At the top, there is a navigation bar with 'Home' and 'My Work' options, and a user profile for 'João Costa'. Below the navigation bar, the main content area is titled 'Home' and contains several interactive cards: 'Welcome Page', 'Search your organisation', 'Request Access for Organizations' (highlighted with a green border), 'Track My Requests', 'Check Organisation Change Requests', and 'Manage Access'. There are also 'Approvals' and 'Edit Identity' cards. The 'Approvals' card shows a count of '0'. Below these cards, there are two sections: 'Your Pending Approvals' and 'Latest Forms', both of which currently display 'Currently no data'. An 'All >' button is visible at the bottom left of each of these sections.

EMA\_background\_entrance - Copy

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

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Kristiina Puusaari, *eAF Product Owner, EMA*

Noel Diamant, *eAF Product Owner, UNICOM\**



\*The UNICOM Innovation Action has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875299.





## Q&A session

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



## Next Steps & Closing

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Kristiina Puusaari, *eAF Product Owner, EMA*



● **Q&A Clinic** - 19 December 2022  
(14:30 – 15:00)

● **System Demo** - 21 December 2022  
(9:00 – 12:00)

● January Q&A Clinics (to be announced)



## Further information

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

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