



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Product Lifecycle Management (PLM) Portal Access Management Training Session

25 May 2023, 11:00 – 12:30 Central European Time (CET)
Webinar: WebEx





1

Welcome / Introduction

11:00 – 11:10

Kristiina Puusaari

eAF Product Owner, EMA

2

Access Management Pre-requisites

11:10 – 11:15

João Costa

Customer Portfolio Lead, EMA

3

Roles Overview

11:15 – 11:25

João Costa

Customer Portfolio Lead, EMA

4

Real-case Examples of granting access to the PLM Portal – eAF

11:25 – 11:35

João Costa

Customer Portfolio Lead, EMA

5

Access Management Demonstration

11:35 – 11:55

João Costa

Customer Portfolio Lead, EMA

6

Q&A session

11:55 – 12:25

Moderator:

Caterina Scarpatti

eAF & PMS Change Management Team

7

Closing

12:25 – 12:30

Kristiina Puusaari, *eAF Product Owner, EMA*

João Costa, *Customer Portfolio Lead, 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

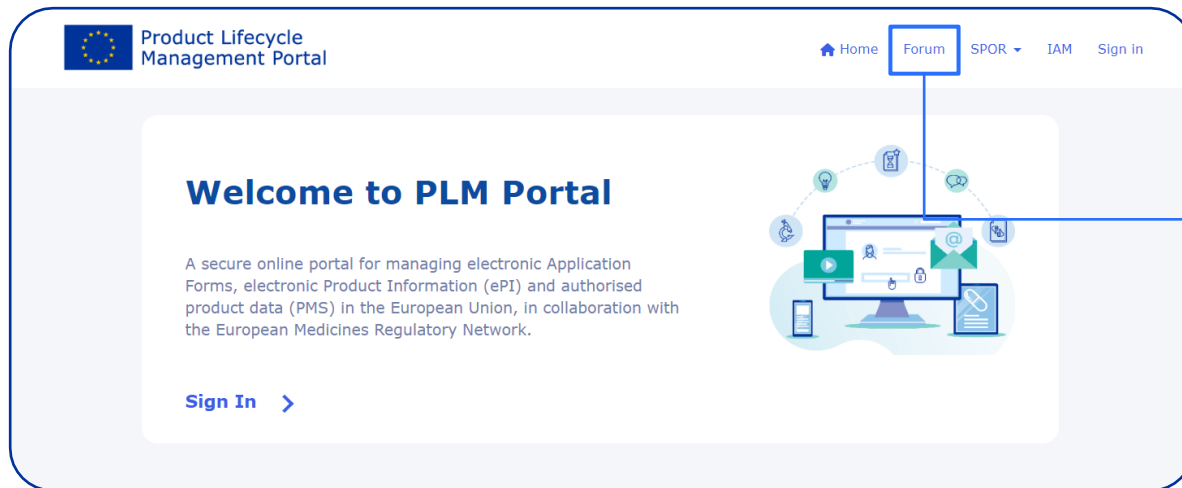


3. Questions will be shown on the screen and managed live in the Q&A session



Introduction

Kristiina Puusaari, *eAF Product Owner, EMA*



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](#)



Access Management pre-requisites

João Costa, *Customer Portfolio Lead, EMA*

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

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



**Guide to
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 \(OMS\)](#)



Roles Overview

João Costa, *Customer Portfolio Lead, EMA*

EMA	Administrators	Applicants
 EMA User Admin	 IRIS eAF Industry User Admin  External Organisation Administrator <i>(optional)</i>	 (UAT_) eAF Applicant Contributor  (UAT_) eAF Applicant Manager  (UAT_) eAF Applicant Coordinator - Be added as co-author - Edit applications - Select classifications - Privileges of <i>eAF Applicant Contributor</i> - Select products of my organisation - Create, finalise and delete my applications - Add co-authors - Privileges of <i>eAF Applicant Manager</i> - 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 of an Organisation, including CCI and product data from SPOR PMS
 - Adding an Applicant Coordinator shares all products and all applications of an Organisation, including CCI and product data from SPOR PMS

	Industry Users		NCA Users
<i>Role name:</i> <i>Grant:</i>	<i>IRIS / eAF Industry Admin</i>	<i>External Organisation Administrator (optional)</i>	<i>IRIS / eAF Competent Authority Admin</i>
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 ▪ eAF Applicant Coordinator	✓ The following role/s ▪ IRIS / eAF Industry Admin ▪ IRIS / eAF Competent Authority Admin	✓ The following role/s: ▪ eAF Competent Authority User

Applicant-related User Roles and Grants

	Industry Users			NCA Users
<i>Role name:</i> <i>Grant:</i>	eAF Applicant Contributor	eAF Applicant Manager	eAF Applicant Coordinator	eAF Competent Authority User
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	✗	✗	✗	✗



Real-case examples of granting access to the PLM Portal – eAF

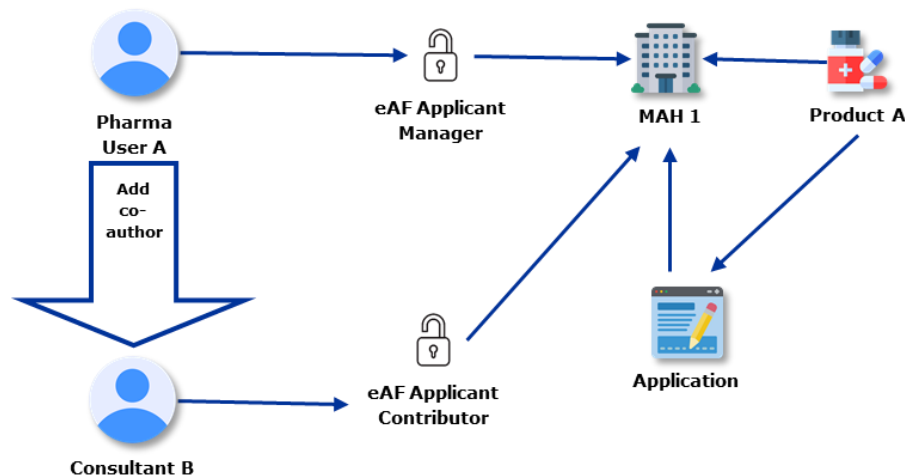
João Costa, *Customer Portfolio Lead, EMA*

Co-authoring with associated users

Scenario:

- **User A** works for **MAH 1**
- **User B** works for a consultancy who should **not** see all **MAH 1** products
- **User A** has the **eAF Applicant Manager** role for **MAH 1**
- **User A** creates an **eAF** for **product A**
- **User A** shares the created **eAF** with **User B** by adding **User B** as co-author
- **User B** requests the **eAF Applicant Contributor** role for **MAH 1**

Applicable to: Consultancy without access to products



- **User B** gets access to the **eAF** created by **User A** and, subsequently, to **product A** (as soon as **User B** has the **eAF Applicant Contributor** role authorised for **MAH 1**)

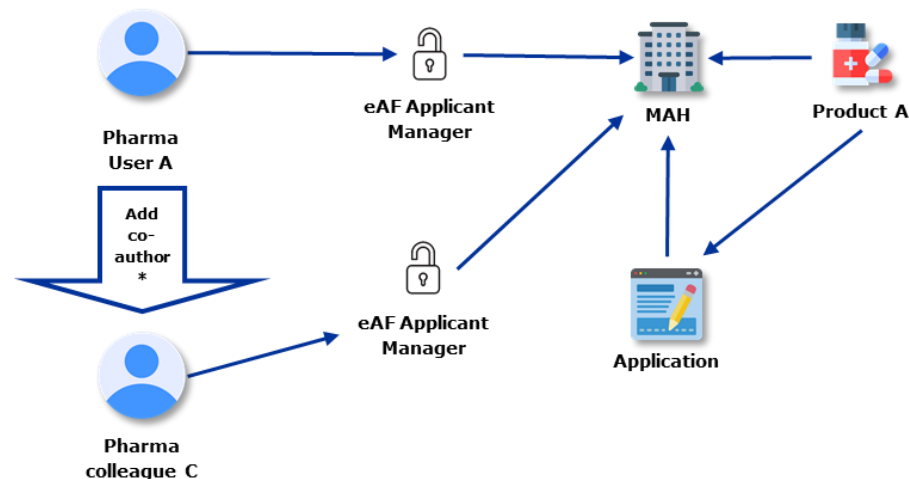


Co-authoring with associated users

Scenario:

- Both **Users A** and **C** work for the same **MAH**
- Both **Users A** and **C** have the **eAF Applicant Manager** role for the same **MAH**
- User A** creates an **eAF**
- User A** shares the created **eAF** with **User C** by adding **User C** as co-author

Applicable to: Colleagues within my organisation;
Consultancy who is allowed to see my products



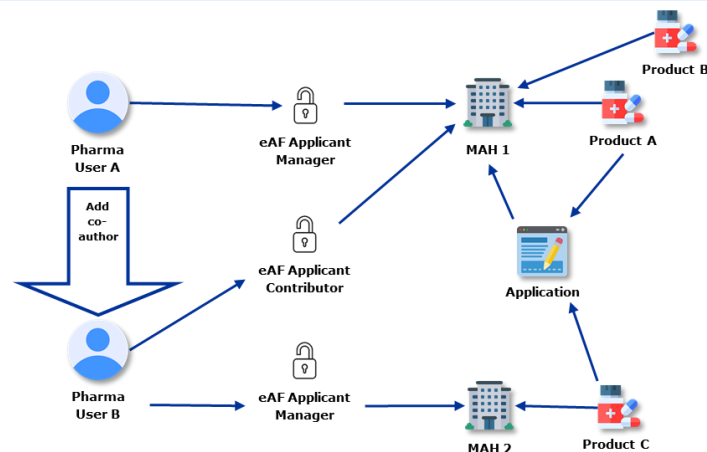
- User C** has the same rights as **User A** and can perform the same operations within the created **eAF** as **User A**

Worksharing

Applicable to: Worksharing with other companies

Scenario:

- **User A** works for **MAH 1**
- **User B** works for **MAH 2**
- **User A** has the **eAF Applicant Manager** role for **MAH 1**
- **User B** has the **eAF Applicant Manager** role for **MAH 2**
- **User A** creates an **eAF** for **Product A**
- **User A** shares the created **eAF** with **User B** by adding **User B** as co-author (from a different organisation)
- **User B** requests the **eAF Applicant Contributor** role for **MAH 1**



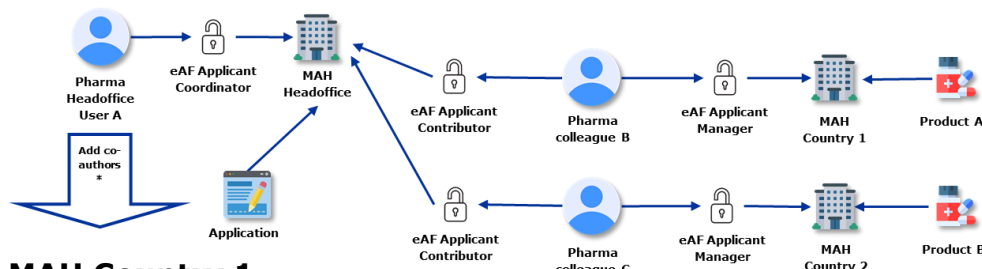
- **User B** gets access to the **eAF** created by **User A** and, subsequently, to **product A** (as soon as **User B** has the **eAF Applicant Contributor** role authorised for **MAH 1**)
- **User B** can add **product C** (because **User B** is **manager** for **MAH 2**)
- **User B** cannot finalise the **eAF** because **User B** is a **contributor** for **MAH 1** (where the application sits); **User A** can finalise the **eAF**
- **User A** can see commercially confidential information about **product C** in the FHIR XML export
- **User B** cannot see/add **product B** because **User B** is only a **contributor** for **MAH 1**

Head office of a multinational company submits

Scenario:

- **User A** works for **MAH Head office**
 - **User B** works for **MAH Country 1**
 - **User C** works for **MAH Country 2**
 - **User A** has the **eAF Applicant Coordinator** role for **MAH Head office**
 - **User B** has the **eAF Applicant Manager** role for **MAH Country 1**
 - **User C** has the **eAF Applicant Manager** role for **MAH Country 2**
 - **User A** creates an **eAF**
 - **User A** shares the created **eAF** with **User B** and **User C** by adding **User B** and **User C** as co-authors (from different organisations)
 - **User B** requests the **eAF Applicant Contributor** role for **MAH Head office**
 - **User C** requests the **eAF Applicant Contributor** role for **MAH Head office**
- User B and User C** get access to the **eAF** created by **User A** (as soon as **User B** and **User C** have the **eAF Applicant Contributor** role authorised for **MAH Head office**)
- **User B** and **User C** add their **products (A and B, respectively)**
 - **User A** finalises and adds the application to the dossier

Applicable to: Head office setting up applications
Each member adds their details



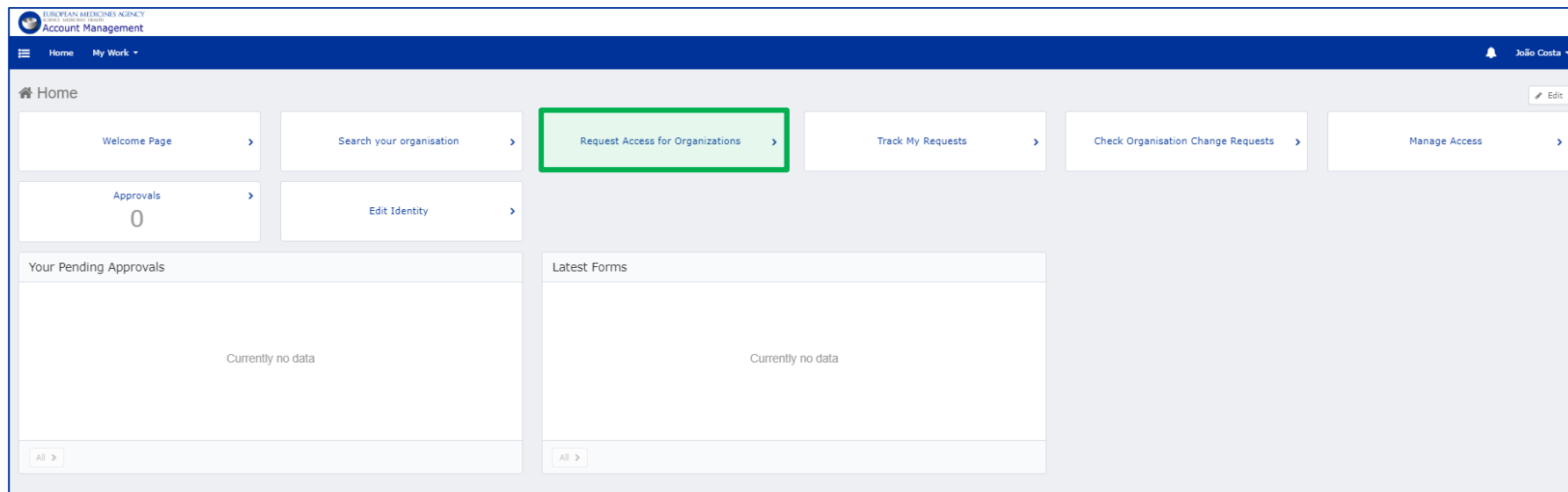


Access Management Demonstration

João Costa, *Customer Portfolio Lead, EMA*

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



1



Pick an account

 surname_n@id.ema.europa.eu

 Use another account

2



surname_n@id.ema.europa.eu

Enter 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 XXXXXXXX34

 Call +XX XXXXXXXX34

[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



Q&A session

Moderator: Caterina Scarpatti, *eAF & PMS Change Management Team*



Closing

Kristiina Puusaari, *eAF Product Owner, EMA*

João Costa, *Customer Portfolio Lead, EMA*



Have your EMA account created/active



Request the role(s) you need



Have your role(s) approved



Test your permissions

-
- Check the [PLM Portal – Guide to registration](#)
 - Click on , available on the right-hand side of the PLM Portal, to **engage with the PLM Chatbot**
 - Use the [PLM Portal Forum](#) to ask each other questions, provide suggestions, and discuss best practices
 - Get **technical support** by using directly the [PLM Portal-eAF section of the EMA Service Desk portal](#).



Further information

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

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Telephone +31 (0)88 781 6000

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