



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## DADI eAF Training session

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26 July 2022, 11:00 – 12:30 Central European Time (CET)  
Webinar: WebEx





1

## Welcome / Introduction

11:00 – 11:05

**Cristina Pepato**

*DADI & PMS Change Manager*

**Kristiina Puusaari**

*DADI Product Owner, EMA*

2

## Impact for Applicants at go-live

11:05 – 11:15

**Kristiina Puusaari**

*DADI Product Owner, EMA*

3

## Access Management demonstration

11:15 – 11:35

**João Costa,**

*DADI Product Manager, EMA*

4

## Demonstration of the User Interface

11:35 – 11:55

**Kristiina Puusaari**

*DADI Product Owner, EMA*

5

## Q&A Session

11:55 – 12:25

**Moderator:**

**Cristina Pepato**

*DADI & PMS Change Manager*

6

## Closing

12:25 – 12:30

**Cristina Pepato**

*DADI & PMS Change Manager*



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



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



# Welcome

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Cristina Pepato, *DADI & PMS Change Manager*

Kristiina Puusaari, *DADI Product Owner, EMA*

## Context

- > The **Digital Application Dataset Integration (DADI) Network Project** will replace current interactive PDF format electronic application forms with **new web-based application forms** hosted on a **dedicated portal**
- > The new web-forms will facilitate compliance with **ISO Identification of Medicinal Products (IDMP)** standard for human medicinal products in accordance with Commission Implementing Regulation (EU) No 520/2012 (art. 25 and 26)
- > DADI will provide a human readable PDF output in line with the Notice to Applicants requirements
- > The PDF output will contain a machine-readable component with a larger dataset in a **FHIR** xml format, that facilitates exchange of the applications information across different systems



### DADI will change:



- > **PDF-format electronic application forms to web forms for:** Variations; Initial marketing authorisations; Renewals (human only); Forms for other procedures under consideration
- > **Human** and **veterinary** forms
- > **Centrally authorised product (CAPs)** applications at initial release of the form, and **Nationally authorised product (NAPs)** applications at second release.



### DADI will NOT change:

- > The **current PDF output format**
- > The process to apply for or submit **Variations** and **Marketing authorisation applications**
- > The content of the **application form in the submission package**



## October 2022 Go-live

- > **First release** of the web-based variation form for human medicinal products



### Scope

- > Limited to **Centrally Authorised Products (CAPs)** only
- > **Applications containing NAPs**, including National Procedures, Mutual Recognition Procedure and Decentralised Procedure **not yet supported**
- > **Available data for CAPs** coming from **EMA's internal database**



The scope change is due to the **complexity in synchronisation of the data between xEVMPD and PMS**



## March 2023 Release

- > **Second release** of the web-based variation form for human medicinal products



### Scope

- > Support **all** types of EU variations procedures (**both CAPs and NAPs**)
- > Includes **bug fixes**

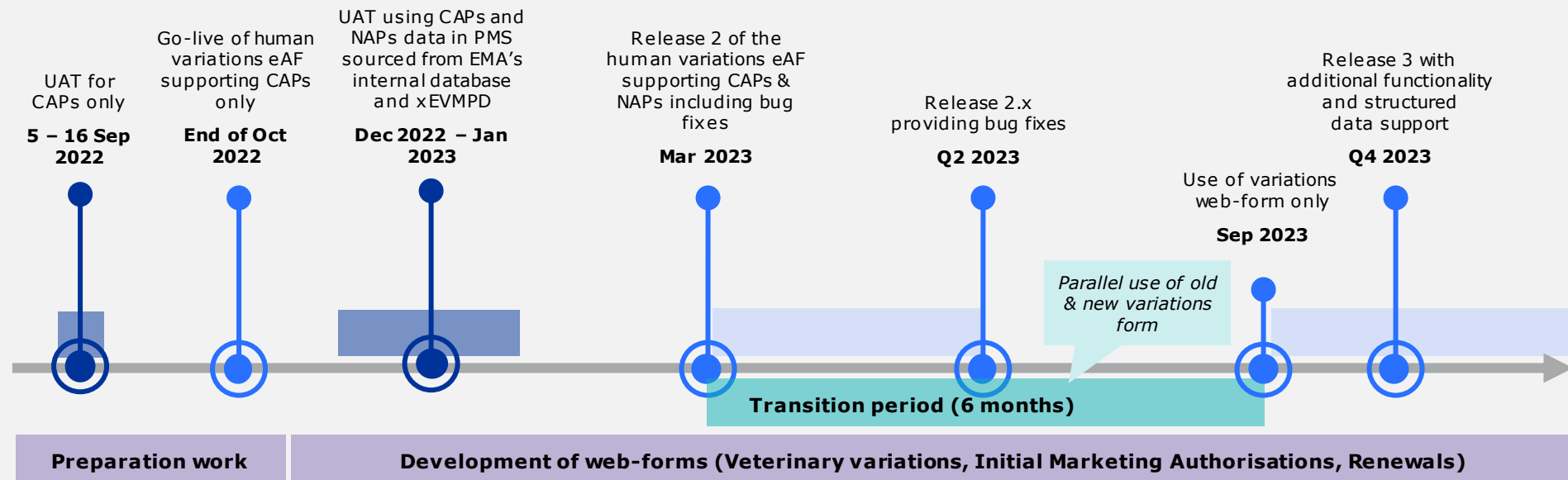


*Progressive release model following the EMA Agile development approach*

# Updated DADI Human Variation Form Timeline



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# Impacts for Applicants at Go-live

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Kristiina Puusaari, *DADI Product Owner, EMA*

## Applicants

## Consultancies



### Ways of working

- › Register to access application forms
- › Choose the level of access for users

- › Engage with MAH to ensure access is provided to necessary medicinal products



### Training

- › New web application functionalities

- › New web application functionalities



### Technology

- › Compliant web browsers & optional quality of life plugins
- › Manage webforms online instead of document management systems & email

- › Compliant web browsers & optional quality of life plugins
- › Manage webforms online instead of document management systems & email



### Data

- › Available data for CAPs coming from **EMA's internal database**
- › Users of an MAH may only select products of their organisation

- › Need to be associated to all MAHs in EMA IAM with an appropriate role to draft applications for them



### Procedural

- › Web-based forms to be used only for CAPs
- › CAPs and NAPs worksharing procedures should use PDF forms







- › Web-based forms to be used only for CAPs
- › CAPs and NAPs worksharing procedures should use PDF forms






# Access Management demonstration

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João Costa, *DADI Product Manager, EMA*

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

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

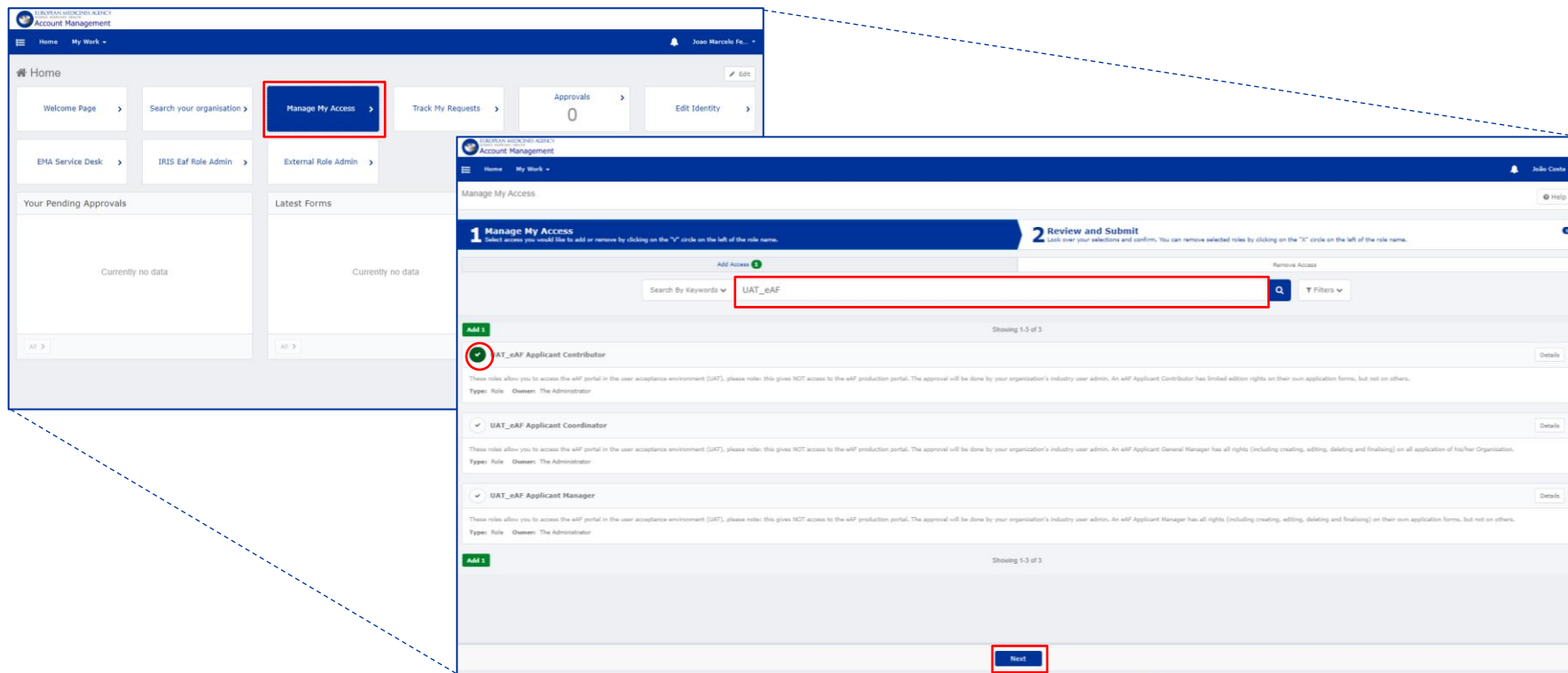
-  an active **EMA user account** (*external e-mail address*)
-  signed [proof of authority](#) (*only applicable to Administrators*)
-  **role(s)** assigned to that account

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)**

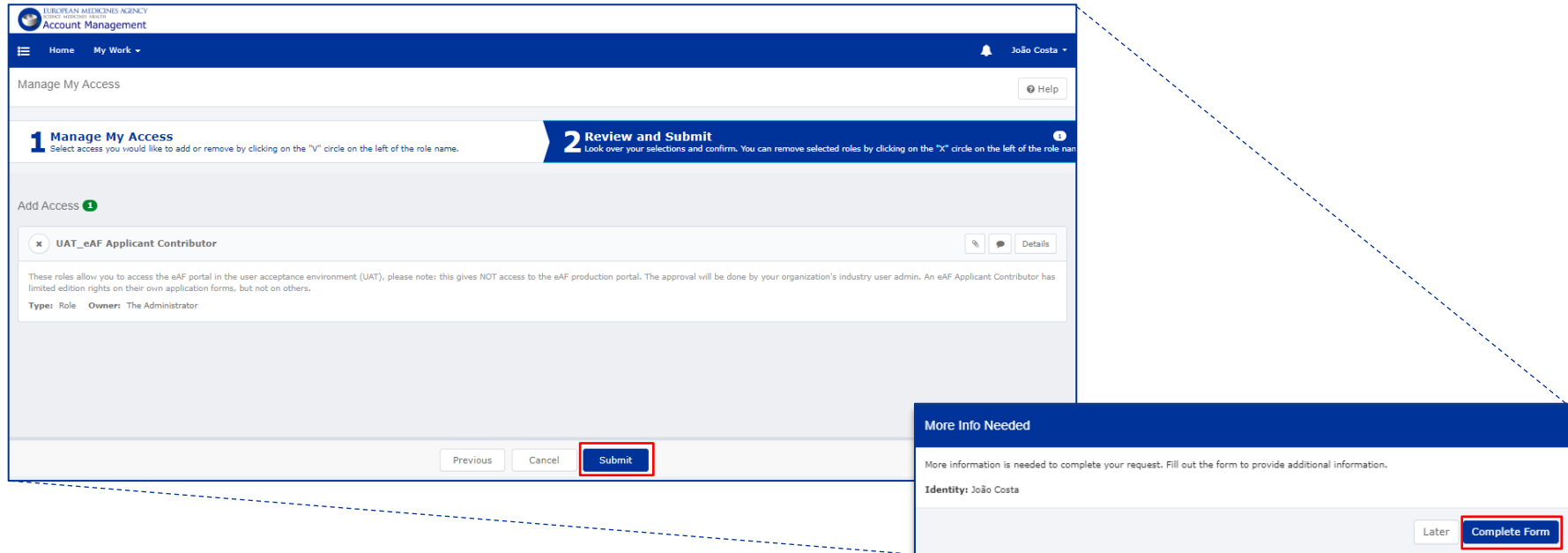
- [EMA Account Management](#) > Login > 'Manage My Access' > Search > Select role > 'Next'



The screenshot displays the EMA Account Management interface. The top navigation bar includes 'Home' and 'My Work'. The main content area is divided into two sections. The left section, titled 'Home', contains a 'Manage My Access' button highlighted with a red box. The right section, titled 'Manage My Access', shows a search bar with the text 'UAT\_eAF' entered, also highlighted with a red box. Below the search bar, a list of roles is displayed, including 'UAT\_eAF Applicant Contributor', 'UAT\_eAF Applicant Coordinator', and 'UAT\_eAF Applicant Manager'. The first role, 'UAT\_eAF Applicant Contributor', is selected, indicated by a green checkmark in a red circle. At the bottom right of the interface, a 'Next' button is highlighted with a red box.

# Requesting an access role

- 'Submit' > 'Complete Form'



EUROPEAN MEDICINES AGENCY  
Account Management

Home My Work

Manage My Access

1 Manage My Access  
Select access you would like to add or remove by clicking on the "v" circle on the left of the role name.

2 Review and Submit  
Look over your selections and confirm. You can remove selected roles by clicking on the "x" circle on the left of the role name.

Add Access

x UAT\_eAF Applicant Contributor

These roles allow you to access the eAF portal in the user acceptance environment (UAT), please note: this gives NOT access to the eAF production portal. The approval will be done by your organization's industry user admin. An eAF Applicant Contributor has limited edition rights on their own application forms, but not on others.

Type: Role Owner: The Administrator

Previous Cancel Submit

More Info Needed

More information is needed to complete your request. Fill out the form to provide additional information.

Identity: João Costa

Later Complete Form

- Search Organisation > Select your Organisation > 'Submit Request'

**How to**

If you need to search for an organisation, please see the instructions below. If you can not find organisation you can search in OMS and request the creation of a new organisation following this [guidance](#).

1. Search your Organisation
2. Select your Organisation \*
3. If your organisation is not shown, scroll down, you can load more results with the "Load more" button

Enter an organisation name or OMS ID to search for then select from the menu below.

ORG-10000 Example  
ORG-10000 Example  
ORG-10000 Example  
ORG-10000 Example

Load More

**Select your Organisation**

**Requested Roles**

IRIS EAF UAT Industry Contributor

**1. Search Organisation**

Enter an organisation name or OMS ID to narrow down the results. Select the correct organisation from the menu below by clicking on the drop-down arrow on the right.

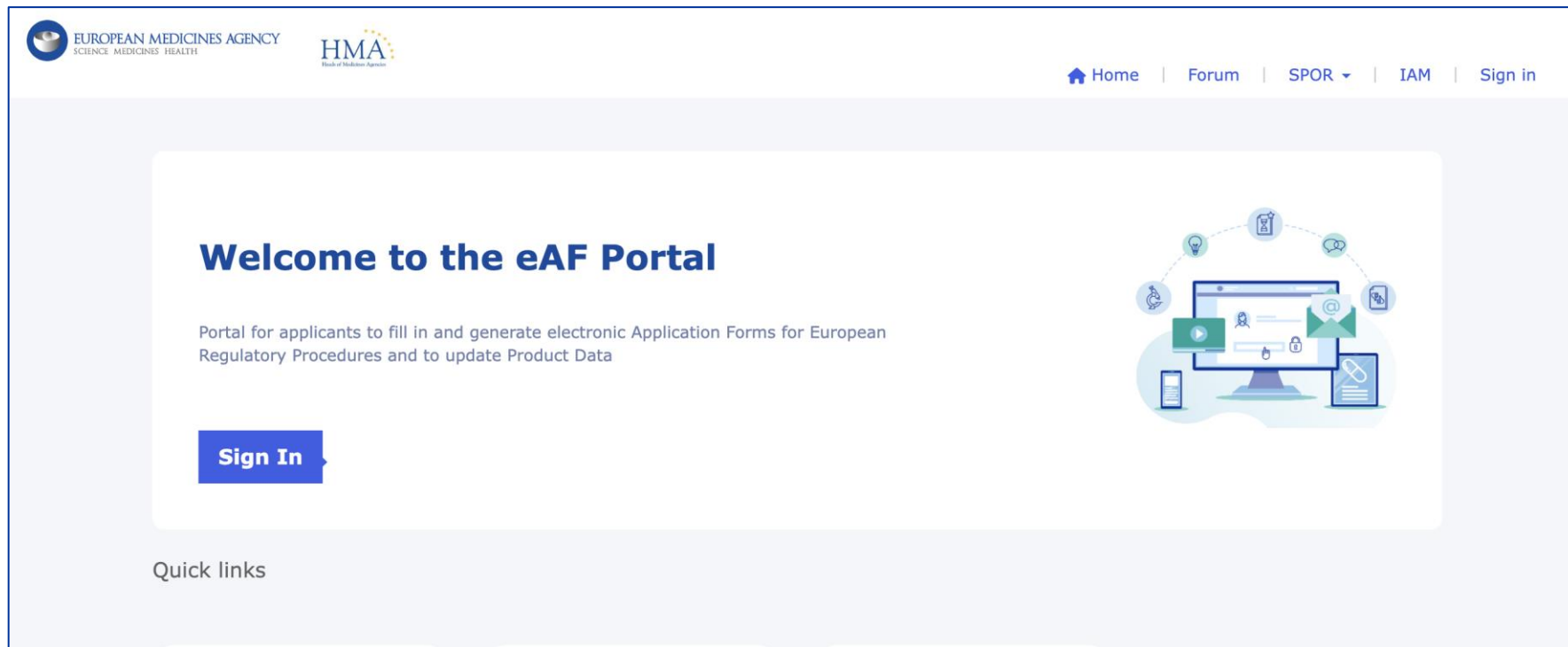
**2. Select your Organisation \***

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI. In case you cannot find your organisation in the list, please verify that it has been registered correctly with OMS <http://spor.ema.europa.eu/oms/w/>


Save for later Cancel Request Submit Request

*Upon approval, it may take up to 45 minutes to synch with and access the eAF Portal*

**UAT eAF portal:** <https://euema-prs-uat.powerappsportals.com/>



The screenshot shows the UAT eAF portal homepage. At the top left are the logos for the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA). The top right navigation bar includes links for Home, Forum, SPOR (with a dropdown arrow), IAM, and Sign in. The main content area features a large white box with the heading "Welcome to the eAF Portal" and a subheading: "Portal for applicants to fill in and generate electronic Application Forms for European Regulatory Procedures and to update Product Data". Below this is a prominent blue "Sign In" button. To the right of the text is a circular illustration containing icons for a lightbulb, a document, a speech bubble, a play button, a smartphone, a laptop, and a magnifying glass. At the bottom left of the main content area, the text "Quick links" is visible.



## Sign in

EMA: email, other users:

[Can't access your account?](#)

[Back](#) [Next](#)

**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.


Please note that:


- > You must sign in with your username followed by @id.ema.europa.eu:  
[username@id.ema.europa.eu](mailto:username@id.ema.europa.eu)
- > The password is the same as in <https://register.ema.europa.eu>
- > **Multifactor authentication** is required:
  - You can use the **Microsoft Authentication app** or **SMS**

# Signing in to the eAF portal



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**HMA**  
Health of Medicines Agency

[Home](#) | [Application Forms](#) ▾ | [Forum](#) | [SPOR](#) ▾ | [IAM](#) | [Arturo Test](#) ▾

Home > Application Forms

**Draft** | Deactivated | Completed | All






Create New Application Form

Column visibility

Refresh

Download

Application Form ID	Friendly Name	Application Form Type	Reference MAH	Modified By (Last User)	Modified On (Access Date)	Status	
VAR/22/77	IOANNIISST	Variation Form Human	UAT ORG (ORG-200036101)	Arturo Serna Leon	7/7/2022 1:51:09 AM	Draft	
VAR/22/58	Arturo test	Variation Form Human	UAT ORG (ORG-200036101)		6/22/2022 1:07:13 AM	Draft	
VAR/22/36	2022-06-14 test	Variation Form Human	UAT ORG (ORG-200036101)		6/22/2022 1:06:07 AM	Draft	

Showing 1 to 3 of 3 entries



# Demonstration of the User Interface

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Kristiina Puusaari, *DADI Product Owner, EMA*



## To note:

- > There are still some **bugs** present in the system and they may 'interfere' slightly with the demo
- > This is not the final version of the system that we will go-live with in October – the **development is still ongoing** and new features are being developed/tested, for example:
  - Devices
  - Improvements of Present and Proposed section

## UAT eAF portal: <https://euema-prs-uat.powerappsportals.com/>



[Home](#) | [Application Forms](#) | [Forum](#) | [SPOR](#) | [IAM](#) | [Kristiina Puusaari](#)

[Home](#) > [Application Forms](#) > [Draft Application Form](#)

1 Select Application Details

2 Add Co-Author

Application Form Type \*

Variation Form Human

Reference MAH ⓘ \*

European Medicines Agency

x

Q

Org ID

ORG-100013412

Address

Domenico Scarlattilaan 6  
Amsterdam 1083 HS  
Netherlands

Friendly Name \*

DADI eAF session 26th July 2022

LOC ID

LOC-100020264

Customer Account Number

—



Modified On

18/07/2022 12:38 AM

Create & Next

Cancel

# Demonstration of the User Interface



Home | Application Forms | Forum | SPOR | IAM | Kristiina Puusaari

## Product Selection

Variation From Human / Application for variation to a marketing authorization  
DAD1 eAF session 26th July 2022 / VAR/22/318 | Last Saved : 25/07/2022 16:31:57 PM

### Product Selection

Products concerned by this application

Column visibility | Show 10 rows | Refresh

Search | Add Product

Invented Name	Strength	Pharmaceutical Form	Active Substance	Authorisation Country	MAH	MA Number	MRP / CP Number	MRP Variation Number	Number of Available Packages	Number of Selected Packages	PHS ID	Add Product
No data available in table												

Showing 0 to 0 of 0 entries

Save | Validate | Cancel | Export

Type(s) of change(s)  
Pending

Procedural Information  
Pending

Proposed Changes  
Pending

Finalisation  
Pending

# Demonstration of the User Interface

Home > Application Forms > Product Selection > View/Select Product

Available Product(s)

Selected Product(s)

Column visibility

arixt

<input checked="" type="checkbox"/>	Name	PHS ID	MPID/ PCID	Active substance(s)	MA Number	MRP/DCP Number	Marketing Authorisation Holder	Authorisation Country	Authorisation Status
<input checked="" type="checkbox"/>	Arixtra 1.5 mg/0.3 ml - Solution for injection	600000000045	600000000045		EU/1/02/206	EMEA/H/C/000403	MYLAN IRE HEALTHCARE Limited	European Union	Valid
<input checked="" type="checkbox"/>	Arixtra 10 mg/0.8 ml - Solution for injection	600000000999	600000000999		EU/1/02/206	EMEA/H/C/000403	MYLAN IRE HEALTHCARE Limited	European Union	Valid
<input checked="" type="checkbox"/>	Arixtra 2.5 mg/0.5 ml - Solution for injection	600000000044	600000000044		EU/1/02/206	EMEA/H/C/000403	MYLAN IRE HEALTHCARE Limited	European Union	Valid
<input checked="" type="checkbox"/>	Arixtra 3 mg/0.4 ml - Solution for injection	600000001026	600000001026		EU/1/02/206	EMEA/H/C/000403	MYLAN IRE HEALTHCARE Limited	European Union	Valid
<input checked="" type="checkbox"/>	Arixtra 7.5 mg/0.6 ml - Solution for injection	600000000998	600000000998		EU/1/02/206	EMEA/H/C/000403	MYLAN IRE HEALTHCARE Limited	European Union	Valid

Review Selection

Cancel

Review Selection

Showing 1 to 5 of 5 entries (filtered from 3,222 total entries) 5 rows selected

# Demonstration of the User Interface



EUROPEAN MEDICINES AGENCY



[Home](#) | [Application Forms](#) | [Forum](#) | [SPOR](#) | [IAM](#) | [Kristina Puusaari](#)

## Product Selection

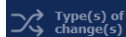
Variation From Human / Application for variation to a marketing authorization

OADT eAF session 26th July 2022 / VAR/22/318 Last Saved : 25/07/2022 21:01:11 PM



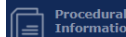
## Product Selection

Pending



## Type(s) of change(s)

Pending



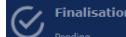
## Procedural Information

Pending



## Proposed Changes

Pending



## Finalisation

Pending

Products concerned by this application

[Column visibility](#) [Show 10 rows](#) [Refresh](#)

[Add Product](#)

	Invented Name	Strength	Pharmaceutical Form	Active Substance	Authorisation Country	MAH	MA Number	HRP / CP Number	PHS ID	MP ID	HRP Variation Number	Number of Selected Packages	Number of Available Packages
▼	Arixtra	2.5 mg/0.5 ml	Solution for injection		European Union	MYLAN IRE HEALTHCARE Limited	EU/1/02/206	EMEA/H/C/000403	6000000000044	6000000000044		0	7
▼	Arixtra	1.5 mg/0.3 ml	Solution for injection		European Union	MYLAN IRE HEALTHCARE Limited	EU/1/02/206	EMEA/H/C/000403	6000000000045	6000000000045		0	7
▼	Arixtra	7.5 mg/0.6 ml	Solution for injection		European Union	MYLAN IRE HEALTHCARE Limited	EU/1/02/206	EMEA/H/C/000403	6000000000098	6000000000098		0	7
▼	Arixtra	10 mg/0.8 ml	Solution for injection		European Union	MYLAN IRE HEALTHCARE Limited	EU/1/02/206	EMEA/H/C/000403	6000000000099	6000000000099		0	7
▼	Arixtra	5 mg/0.4 ml	Solution for injection		European Union	MYLAN IRE HEALTHCARE Limited	EU/1/02/206	EMEA/H/C/000403	6000000001026	6000000001026		0	7

Showing 1 to 5 of 5 entries

[Save](#) [Validate](#) [Cancel](#) [Export](#)

# Demonstration of the User Interface



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Home > Application Forms > Type(s) of Change(s) > Add Scope

Classification Level 1

Select Classification Level

Search

✓ Name ↑

- ☒ A. ADMINISTRATIVE CHANGES
- ☐ B. QUALITY CHANGES
- ☐ C. SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES
- ☐ D. PHF / VMP



## Type(s) of change(s)

Variation From Human / Application for variation to a marketing authorization

Demo grouping test / VAR/22/320 Last Saved : 25/07/2022 22:41:56 PM



## Product Selection

Completed



## Type(s) of change(s)

Completed



## Procedural Information

Completed



## Proposed

### Variations included for this application<sup>①</sup>

Refresh

Search

Add Scope

	Scope	Selected	Description	
▼	A.5.a The activities for which the manufacturer/importer is responsible include batch release	1	A.5.a - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible include batch release	⬇
▼	A.5.b The activities for which the manufacturer/importer is responsible do not include batch release	1	A.5.b - ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release	⬇

Showing 1 to 2 of 2 entries



Save



Validate



Cancel



Export





**Product Selection**  
Completed 

**Type(s) of change(s)**  
Completed 

**Procedural Information**  
Completed 

**Proposed Changes**  
Incomplete 

**Finalisation**  
Completed 

## Procedural Information

Domain

Human use

Type of Application

Grouped Regulatory Activity

Including a line extension

☐

Worksharing<sup>①</sup>

☐

IG / Supergrouping<sup>①</sup>

☐

Procedure Type<sup>①</sup>

Name ↑

Variation Type IB

Type of Authorisation

Name ↑

Centralised Procedure

Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)

☐ Name

☐ Indication

☐ Paediatric requirements

☐ Safety

☒ Quality

☐ Annual variation for human influenza vaccines

☐ Other


☐ Medical Devices

Variation Procedure Number

Procedure Number ↑

EMEA/H/C/004985/IB/12/G

Add





## Name and Address of MA Holder (Applicant) ⓘ

### Reference MAH ⓘ

European Medicines Agency

### Org ID

ORG-100013412

### Address

Domenico Scarlattilaan 6  
Amsterdam 1083 HS  
Netherlands

### LOC ID

LOC-100020264

### Customer Account Number

—

### Modified On

18/07/2022 12:38 AM

### Phone Number

+31887818404

### Email

[kristiina.puusaari@ema.europa.eu](mailto:kristiina.puusaari@ema.europa.eu)

## Contact Person ⓘ

### Selected Contacts

Add

Member State	Title	First name	Surname	Telephone	E-Mail	Company ↑
	Mrs	Kristiina	Puusaari	+31887818404	<a href="mailto:kristiina.puusaari@ema.europa.eu">kristiina.puusaari@ema.europa.eu</a>	European Medicines Agency



Save Validate Cancel Export

# Demonstration of the User Interface



EUROPEAN MEDICINES AGENCY

Completed

Type(s) of change(s)

Completed

Procedural Information

Completed

Proposed Changes

Incompleted

Finalisation

Completed

## Proposed Changes Details<sup>①</sup>

### Precise Scope for Change

A.5.a Change of the manufacturer of the active substance from Churchill Place to Orly Plein for 5mg  
A.5.b Change of the manufacturer of the active substance from Churchill Place to Scariatslaan for 10mg

Font Size B I U

### Background for Change

There are no other changes

Font Size B I U

## Change(s) to the Product(s)

For Product changes please indicate all changes per row. All rows need to show completed to finalise the application form.

Search

### Product MA Number(s) <sup>①</sup>

EU/1/19/1368

EU/1/19/1368

### Scope(s)

A.5.a - Variation Type IB - 1

A.5.b - Variation Type IB - 1

### Product Area

Unstructured

Unstructured

## Other Applications<sup>①</sup>



Scope

A.5.b - Variation Type IB - 1

## Text Details

Add

Name	Modified On	Created On ↓
A.5.b Unstructured Change 7/25/2022 9:05:04 PM	25/07/2022 11:05 PM	25/07/2022 11:05 PM



### View Scope Details

Edit

#### Present Value

Manufacturer of the active substance for 10mg

Churchill place deleted

#### Proposed Value

Manufacturer of the active substance for 10mg



Scarlattilaan added



## Organisation Details



Add



Organisation Name (Present Organisation)	Organisation Location (Present Organisation)	Organisation Id (Present Organisation)	Address 1 - composite (Present Organisation)	Parent Organisation ID (Present Organisation)	Modified On (Present Organisation)	Status (Present Organisation)	Organisation Name (Proposed Organisation)	Organisation Location (Proposed Organisation)	Organisation Id (Proposed Organisation)	Address 1 - composite (Proposed Organisation)	Parent Organisation ID (Proposed Organisation)	Modified On (Proposed Organisation)
European Medicines Agency	LOC-100010800	ORG-100006175	30 Churchill Place London E14 5EU United Kingdom	[ INACTIVE ] European Medicines Agency	17/07/2022 10:06 PM	Active	European Medicines Agency	LOC-100020264	ORG-100013412	Domenico Scarlattilaan 6 1083 HS Amsterdam Netherlands	European Medicines Agency	18/07/2022 12:38 AM




**Product Selection**  
Completed 

**Type(s) of change(s)**  
Completed 

**Procedural Information**  
Completed 

**Proposed Changes**  
Completed 

**Finalisation**  
Completed 

## Annexed documents (where appropriate)

The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable.

- ☒ Manufacturing Authorisation Holder responsible for batch release and conditions of the Marketing Authorisation (Annex II)
- ☒ Package Leaflet
- ☐ List of all authorised presentations (Annex A)
- ☐ Labelling
- ☐ Specimens
- ☐ Mock ups
- ☐ Summary of Product Characteristics
- ☐ Restrictions posed by member states (Annex 127a)

## Declaration

I hereby submit a notification/application for the above Marketing Authorisation(s) to be varied in accordance with the proposals given above. I declare that (Please tick appropriate declarations)

- ☒ For type IA notifications: the required documents as specified for the changes concerned have been submitted;
- ☒ I understand that EMA expressly disclaims any liability or accountability for the presence of unnecessary personal data in the annotated PI submitted by the marketing authorisation holder
- ☒ The individuals whose data is included consented to its sharing with EMA and its further sharing by EMA with third parties such as other marketing authorisation applicants, marketing authorisation holders and National Competent Authorities, as relevant
- ☒ Where applicable, national fees have been prepaid or will be paid in accordance with national requirements;
- ☒ This notification/application has been submitted simultaneously in RMS and all CMSs (for products within the Mutual Recognition Procedure and worksharing) or both to EMA and (Co-)Rapporteur (for products within the Centralised Procedure) or, in case of worksharing involving the EMA, to the relevant National Competent Authorities and/or RMS/ CMS (as applicable) and the EMA;
- ☒ All PIs (including annotated PIs are submitted in an anonymised format (i.e. names of the reviewers removed from the track-changes, no names in document properties and other parts of the documents)
- ☒ There are no other changes than those identified in this application (except for those addressed in other variations submitted in parallel);
- ☐ Where applicable, all conditions as set for the variation(s) concerned are fulfilled;
- ☐ For worksharing or grouped variations affecting more than one MA: the MAs concerned belong to the same MAH.

## Proof of payment

## Signatories

[Save](#) [Validate](#) [Cancel](#) [Export](#) [Finalise](#)

# Demonstration of the User Interface



EUROPEAN MEDICINES AGENCY

Product Selection  
Completed

Type(s) of change(s)  
Completed

Procedural Information  
Completed

Proposed Changes  
Completed

Finalisation  
Completed

PMS Update was successful. Please refresh the page to see the latest value.

**Annexed documents (where appropriate)**

The following annexed product information documents are provided in the document section of the EPAR for VAR/22/319.

### Prefilled syringe test VAR/22/319

25/07/2022 21:40:16 PM

Export typically takes less than a minute but can take longer to complete, depending on the size of your Application. You'll get an email to notify you when the process is complete and ready to download.

Completed

FHIR xml Validation Failed

Download

Column visibility

Show 10 rows

Search

Refresh

Modified On	Created On	Requestor	Status Reason	FHIR PDF	Validation XML	Export Message
25/07/2022 23:11:04 PM	25/07/2022 23:11:04 PM	Kristiina Puusaari	Active			
25/07/2022 21:41:13 PM	25/07/2022 21:40:50 PM	Kristiina Puusaari	Completed			

Showing 1 to 2 of 2 entries

Close



4 / 20 99.9%

Bookmarks

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- 2. PRODUCTS CONCERNED BY THIS APPLICATION<sup>7</sup>
- 3. TYPES OF CHANGE(S)
- 4.a Type IB and Type II variation - new indication - orphan medicinal product information
- 4.b Type IB and Type II variation - Paediatric requirements
- 4.d Change to the design or intended purpose of the medical device component, or introduction of a new
- ANNEXED DOCUMENTS (WHERE APPROPRIATE)
- DECLARATION OF THE APPLICANT
- SIGNATURE
- NOTES
- FORM VALIDATION

## 1. APPLICATION FOR VARIATION TO A MARKETING AUTHORIZATION

☒ Human ☐ Veterinary

Type of authorization:

☐ National Authorization in MRP/DCP  
☒ EU Authorization  
☐ National Authorization

Variation procedure number(s)<sup>1</sup>:

Type of application (tick all applicable options)

☐ Single variation  
☒ Grouping of variations  
☐ Including a line extension<sup>3</sup>  
☐ Worksharing

☐ Type IA<sub>IN</sub>  
☐ Type IA  
☐ Type IB unforeseen<sup>2</sup>  
☒ Type IB  
☐ Type II  
☐ Type II Art. 29<sup>4</sup>

Change(s) concern(s)

☒ Medical Device

Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)

☐ Indication  
☐ Paediatric requirements  
☐ Safety  
☒ Quality  
☐ Annual variation for human influenza vaccines



## Q&A session

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



## Closing

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Cristina Pepato, *DADI & PMS Change Manager*



**EU Implementation Guide v2.1.1** release



Publication of the **Q&A Document** from the DADI Q&A Webinar on the revised Go-live scope held on 12 July 2022



2<sup>nd</sup> **eAF training session** on 2 September 2022



## Further information

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

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