



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DADI eAF Training session

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

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



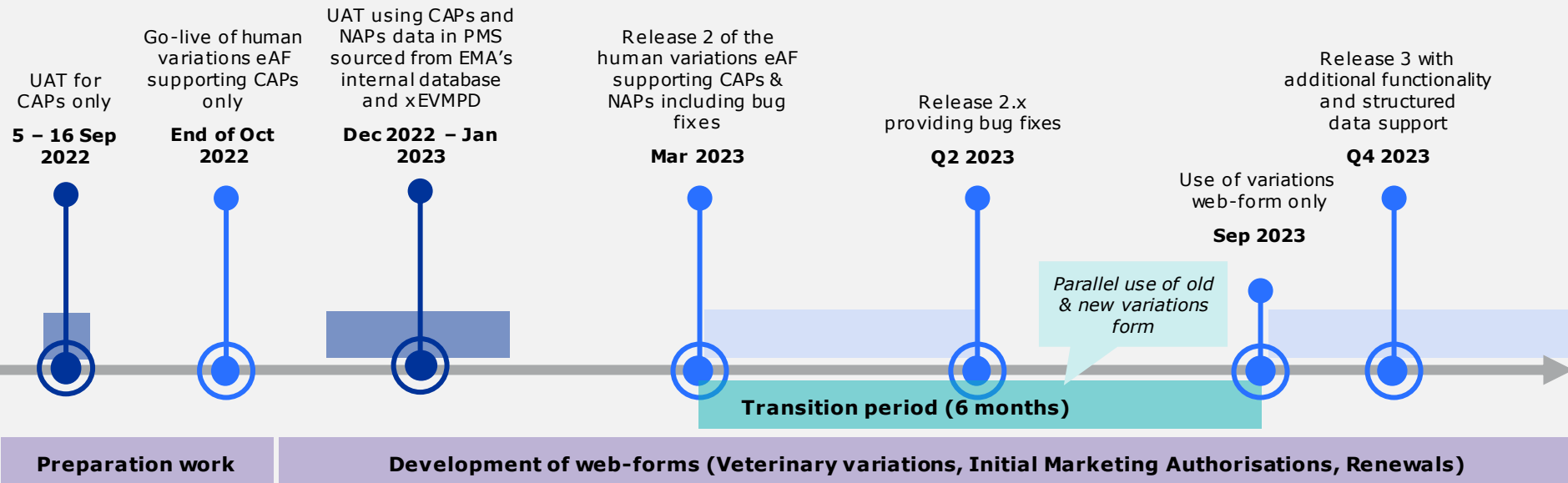
Scope

- > 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





Impacts for Applicants at Go-live

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

João Costa, *DADI Product Manager, EMA*



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

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*)

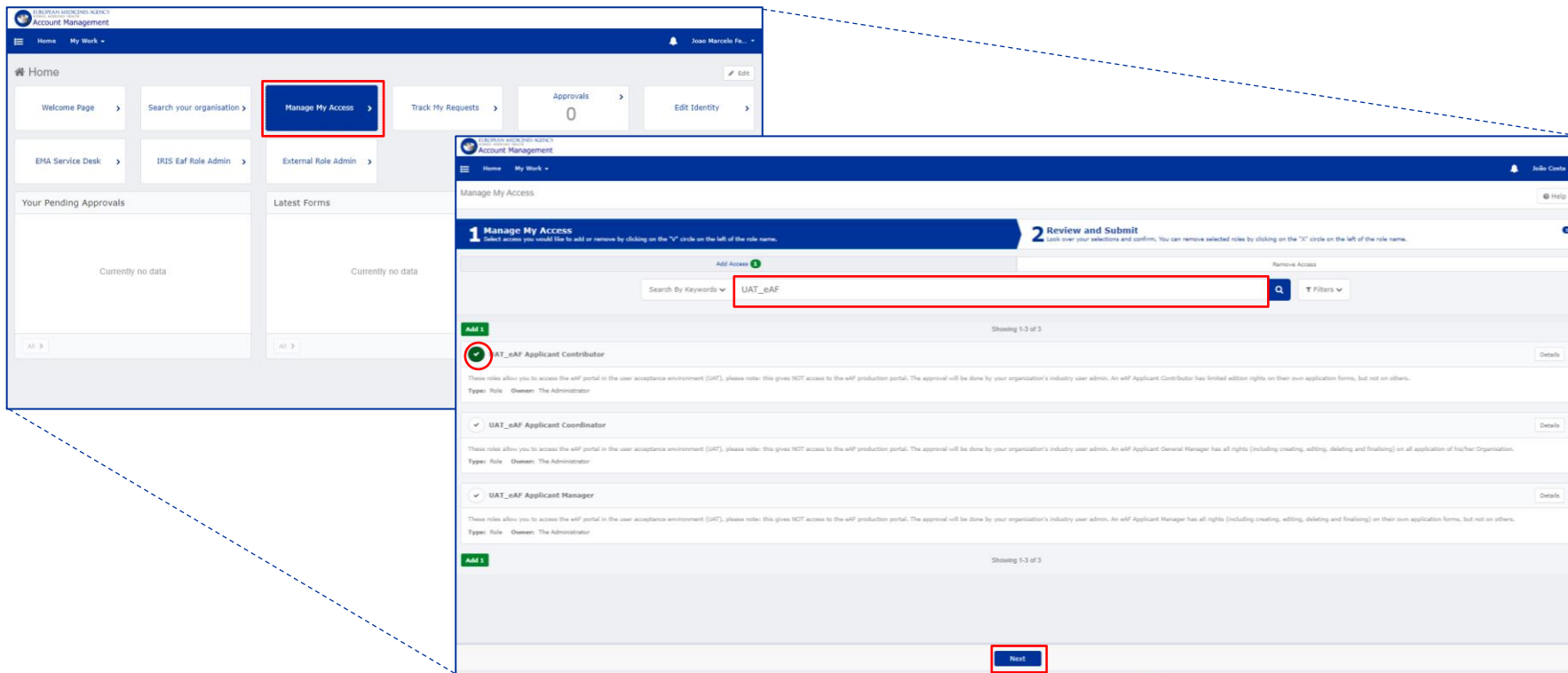
 **role(s)** assigned to that account

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 image displays two screenshots of the EMA Account Management web application. The first screenshot shows the 'Home' dashboard with the 'Manage My Access' button highlighted in a red box. The second screenshot shows the 'Manage My Access' page with a search bar containing 'UAT_eAF' and a list of roles. The first role, 'UAT_eAF Applicant Contributor', is selected with a green checkmark in a red circle. A 'Next' button is highlighted in a red box at the bottom of the second screenshot.

1 Manage My Access
Select access you would like to add or remove by clicking on the "X" 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.

Search By Keywords: UAT_eAF

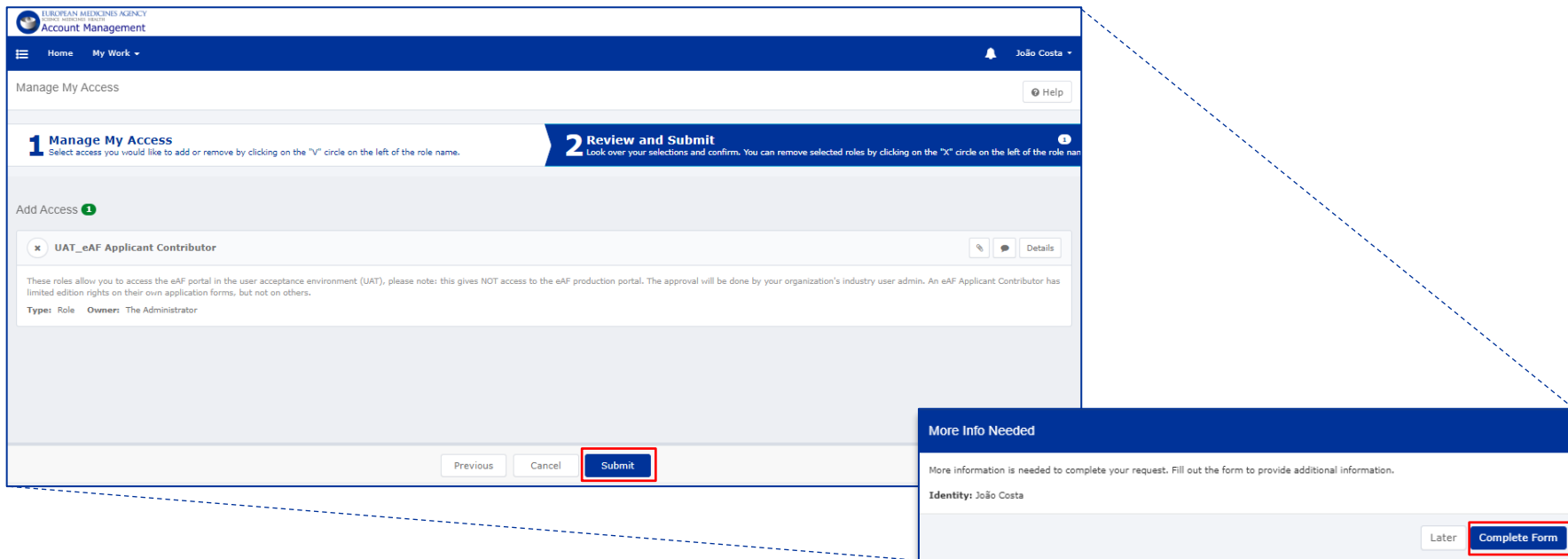
Showing 1-3 of 3

- 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 Owsen: The Administrator
- UAT_eAF Applicant Coordinator
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 General Manager has all rights (including creating, editing, deleting and finalising) on all application of his/her Organization.
Type: Role Owsen: The Administrator
- UAT_eAF Applicant Manager
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 Manager has all rights (including creating, editing, deleting and finalising) on their own application forms, but not on others.
Type: Role Owsen: The Administrator

Showing 1-3 of 3

Next

- 'Submit' > 'Complete Form'



The screenshot displays the 'Account Management' interface for 'Manage My Access'. It features two main steps: '1 Manage My Access' and '2 Review and Submit'. The 'Review and Submit' step is active, showing a list of roles with the 'UAT_eAF Applicant Contributor' role selected. Below the role list, there are 'Previous', 'Cancel', and 'Submit' buttons. The 'Submit' button is highlighted with a red box. A modal dialog titled 'More Info Needed' is open, displaying the message: 'More information is needed to complete your request. Fill out the form to provide additional information.' Below this message, the user's identity is shown as 'João Costa'. At the bottom of the modal, there are 'Later' and 'Complete Form' buttons, with the 'Complete Form' button highlighted with a red box.

- 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. Set a filter to search an organisation, you can use its ID or its name
2. Select your organisation by clicking on the dropdown icon
3. If your organisation is not shown, scroll down, you can load more results with the "Load more" button

1. Search your Organisation

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

2. Select your Organisation *

ORG-10000 - [dropdown icon]

ORG-10000 - [dropdown icon]

ORG-10000 - [dropdown icon]

ORG-10000 - [dropdown icon]

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 *

[dropdown icon]

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/>

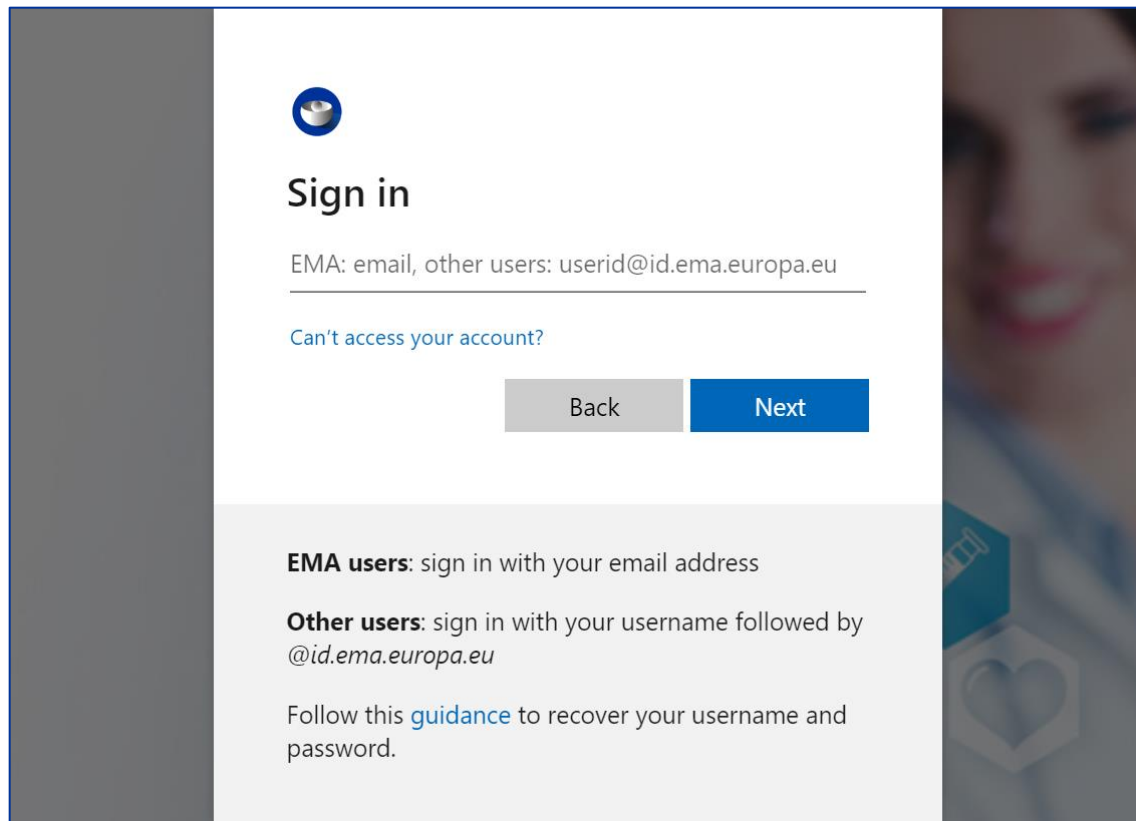
Save for later Cancel Request **Submit Request**

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 landing page of the eAF Portal. At the top left, there are logos for the European Medicines Agency (EMA) and the Health Medicines Agency (HMA). The top right navigation bar includes links for Home, Forum, SPOR, IAM, and Sign in. The main content area features a large heading "Welcome to the eAF Portal" and a sub-heading "Portal for applicants to fill in and generate electronic Application Forms for European Regulatory Procedures and to update Product Data". A prominent blue "Sign In" button is located below the text. To the right, there is an illustration of a computer monitor surrounded by various icons representing digital processes, security, and communication. Below the main content, there is a section titled "Quick links".



The screenshot shows the sign-in page for the eAF portal. At the top left is the EMA logo. Below it is the heading "Sign in". A text input field contains the instruction "EMA: email, other users: userid@id.ema.europa.eu". Below the input field is a link "Can't access your account?". At the bottom of the input area are two buttons: "Back" and "Next". Below the input area is a grey box containing instructions for EMA users and other users, and a link to guidance for recovering credentials.



Sign in

EMA: email, other users:

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

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](#)
- > 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



The screenshot displays the eAF portal interface. At the top left, there are logos for the European Medicines Agency and HMA. A navigation menu includes Home, Application Forms, Forum, SPOR, IAM, and Arturo Test. The main content area shows a breadcrumb trail 'Home > Application Forms' and a filter menu with 'Draft' selected. A search bar and a 'Create New Application Form' button are also present. Below this is a table of application forms with columns for ID, name, type, MAH, user, date, and status. Three entries are listed, all in 'Draft' status. The table includes interactive buttons for column visibility, refresh, and download. A footer note indicates 'Showing 1 to 3 of 3 entries'.

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



Demonstration of the User Interface

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/>



1 Select Application Details 2 Add Co-Author

Application Form Type * Variation Form Human	Friendly Name * DADI eAF session 26th July 2022
Reference MAH ⓘ European Medicines Agency	
Org ID ORG-100013412	LOC ID LOC-100020264
Address Domenico Scarlattilaan 6 Amsterdam 1083 HS Netherlands	Customer Account Number —
	Modified On 18/07/2022 12:38 AM

[Create & Next](#) [Cancel](#)

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

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	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 🔍

<input checked="" type="checkbox"/>	Name	PMS 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	600000000099	600000000099		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 5 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

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

Product Selection

Variation From Human / Application for variation to a marketing authorization

DADJ 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](#)

Search [Add Product](#)

	Invented Name	Strength	Pharmaceutical Form	Active Substance	Authorisation Country	MAH	MA Number	MRP / CP Number	PHS ID	MP ID	MRP 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	EME/H/C/000403	600000000044	600000000044		0	7
▼	Arixtra	1.5 mg/0.3 ml	Solution for injection		European Union	MYLAN IRE HEALTHCARE Limited	EU/1/02/206	EME/H/C/000403	600000000045	600000000045		0	7
▼	Arixtra	7.5 mg/0.6 ml	Solution for injection		European Union	MYLAN IRE HEALTHCARE Limited	EU/1/02/206	EME/H/C/000403	600000000098	600000000098		0	7
▼	Arixtra	10 mg/0.8 ml	Solution for injection		European Union	MYLAN IRE HEALTHCARE Limited	EU/1/02/206	EME/H/C/000403	600000000099	600000000099		0	7
▼	Arixtra	5 mg/0.4 ml	Solution for injection		European Union	MYLAN IRE HEALTHCARE Limited	EU/1/02/206	EME/H/C/000403	600000001026	600000001026		0	7

Showing 1 to 5 of 5 entries

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

Demonstration of the User Interface



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

Classification Level 1

Select Classification Level

Search

- A. ADMINISTRATIVE CHANGES
- B. QUALITY CHANGES
- C. SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES
- D. PNF / 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

Refresh

Search Add Scope

Scope	Selected	Description	
<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/> 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	<input checked="" type="checkbox"/>

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 Authorisation	Variation Procedure Number
Type of Application	Grouped Regulatory Activity	Name ↑ Centralised Procedure	Add
Including a line extension	<input type="checkbox"/>		Procedure Number ↑ EMEA/H/C/004985/IB/12/G ⌵
Worksharing ^①	<input type="checkbox"/>		
IG / Supergrouping ^①	<input type="checkbox"/>		
Procedure Type ^①		Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)	
Name ↑		<input type="checkbox"/> Name	
Variation Type IB		<input type="checkbox"/> Indication	
		<input type="checkbox"/> Paediatric requirements	
		<input type="checkbox"/> Safety	
		<input checked="" type="checkbox"/> Quality	
		<input type="checkbox"/> Annual variation for human influenza vaccines	
		<input type="checkbox"/> Other	
		<input type="checkbox"/> Medical Devices	

Name and Address of MA Holder (Applicant) ⓘ

Reference MAH ⓘ

European Medicines Agency

Org ID

ORG-100013412

Address

Domenico Scarlattilaan 6
Amsterdam 1083 HS
Netherlands

Phone Number

+31887818404

LOC ID

LOC-100020264

Customer Account Number

—

Modified On

18/07/2022 12:38 AM

Email

kristiina.puusaari@ema.europa.eu

Contact Person ⓘ

Selected Contacts

Add

Member State	Title	First name	Surname	Telephone	E-Mail	Company ↑
	Mrs	Kristiina	Puusaari	+31887818404	kristiina.puusaari@ema.europa.eu	European Medicines Agency



Save Validate Cancel Export

Demonstration of the User Interface



Completed

Type(s) of change(s)
Completed

Procedural Information
Completed

Proposed Changes
Incomplete

Finalisation
Completed

Proposed Changes Details

Precise Scope for Change

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

Background for Change

There are no other changes

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) [↑]	Scope(s)	Product Area
EU/1/19/1368	A.5.a - Variation Type IB - 1	Unstructured <input type="button" value="v"/>
EU/1/19/1368	A.5.b - Variation Type IB - 1	Unstructured <input type="button" value="v"/>

Other Applications



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



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](#)

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 to the request section of the EUPTR for the active ATX within the request submission.

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			
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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)¹:

Type of application (thick all applicable options)

Single variation
 Grouping of variations
 Including a line extension³
 Worksharing

Type IA_{IN}
 Type IA
 Type IB unforeseen²
 Type IB
 Type II
 Type II Art. 29⁴

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

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



Closing

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



2nd **eAF training session** on 2 September 2022



Further information

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

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