EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DADI eAF Training session

2 September 2022, 11:00 – 12:25 Central European Time (CET)
Webinar: WebEx

Agenda

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1	**Introduction** 11:00 – 11:15	**Kristiina Puusaari** *DADI Product Owner, EMA*
2	**Access Management demonstration** 11:15 – 11:35	**Noel Diamant** *DADI Product Owner, AGES/UNICOM** **João Costa,** *DADI Product Manager, EMA*
3	**Demonstration of the User Interface** 11:35 – 11:55	**Kristiina Puusaari** *DADI Product Owner, EMA* **Noel Diamant** *DADI Product Owner, AGES/UNICOM**
4	**Q&A Session** 11:55 – 12:20	**Moderator:** **Cristina Pepato** *DADI & PMS Change Manager*
5	**Closing** 12:20 – 12:25	**Joris Wiemer** *EMA Change Management Lead*

*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.***

*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.*

Send your questions via Slido

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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, *DADI Product Owner, EMA*

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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**

DADI Variations Form revised Go-Live Scope

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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

DADI Human Variation Form Timeline (Sep 2022)

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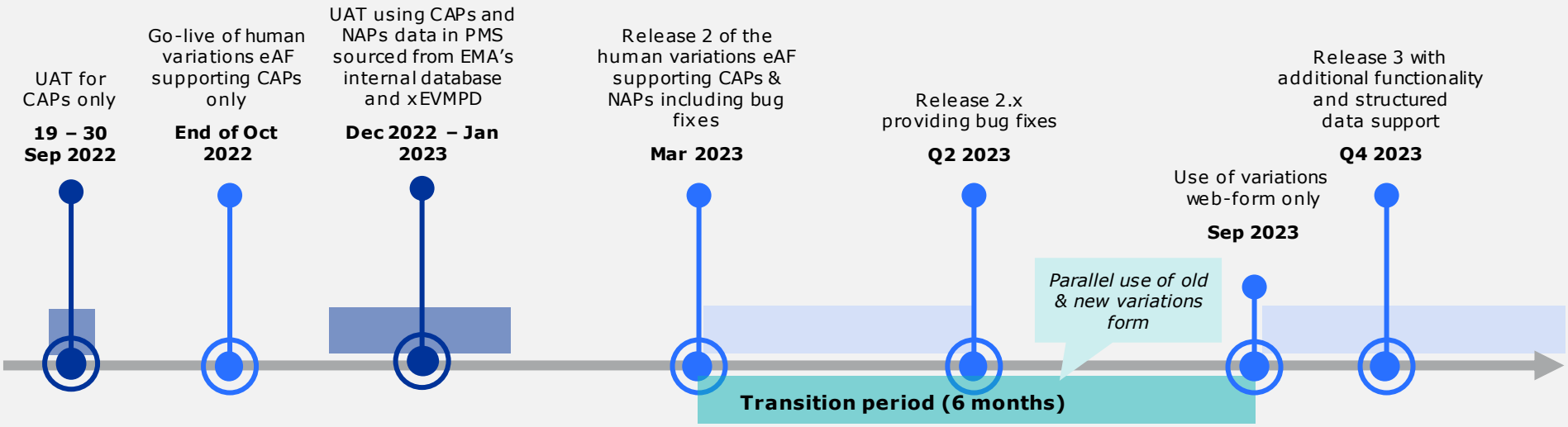

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Impacts at Go-Live for Applicants

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	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

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Access Management demonstration

Noel Diamant, *DADI Product Owner, AGES/UNICOM**

João Costa, *DADI Product Manager, EMA*

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eAF Roles Overview

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EMA

EMA User Admin

*Approve/Deny **Administrators** access requests*

Administrators

IRIS / eAF Industry User Admin

External Organisation Administrator *(optional)*

*Approve/Deny **Applicants** access requests*

Applicants

(UAT_) **eAF Applicant Contributor**

- Be added as co-author
- Edit applications
- Select classifications

(UAT_) **eAF Applicant Manager**

- Privileges of *eAF Applicant Contributor*
- Select products of my organisation
- Create, finalise and delete my applications
- Add co-authors

(UAT_) **eAF Applicant Coordinator**

- Privileges of *eAF Applicant Manager*
- Full access to all applications of my organisation

*Access to the **eAF Portal***
Create / access / edit / manage electronic Application Forms

Pre-requisites

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
Request now: IRIS - eAF Industry User Admin

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)**

Disclaimer: new way to request roles

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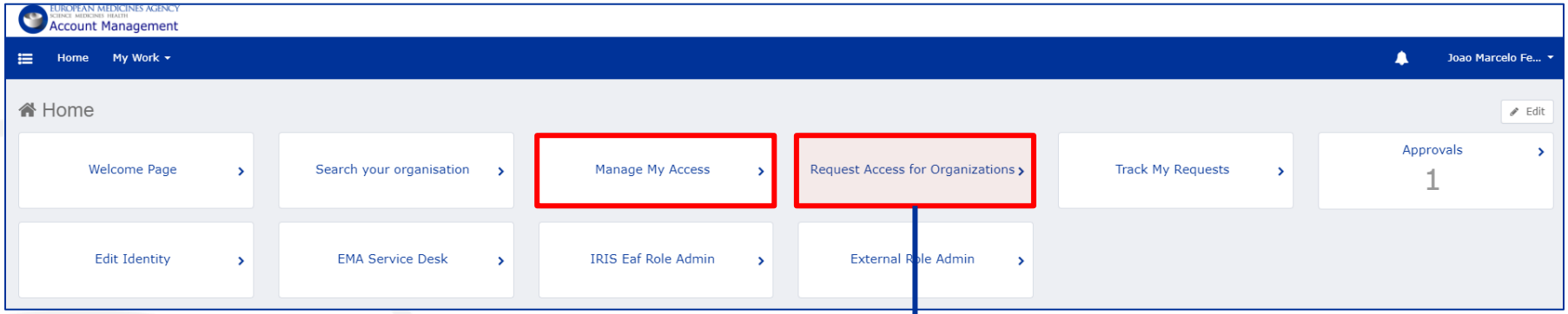
A new release of the EMA Account Management portal went recently live

- A new access request workflow has been deployed – **Request Access for Organisations** – allowing to submit in one go, user access role request(s) for more than one organisation



New access request workflow

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Disclaimer: new way to request roles

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- A new access request workflow has been deployed – **Request Access for Organisations** – allowing to submit in one go, user access role request(s) for more than one organisation

	Request:	**Manage My Access**	**Request Access for Organisations**
Up until end-September 2022	**1** or several role(s) for **1** Organisation	✓	✓
	1 or several role(s) for **n** Organisations	✗	✓
From October 2022 onwards	**1** or several role(s) for **1** Organisation	✗	✓
	1 or several role(s) for **n** Organisations	✗	✓

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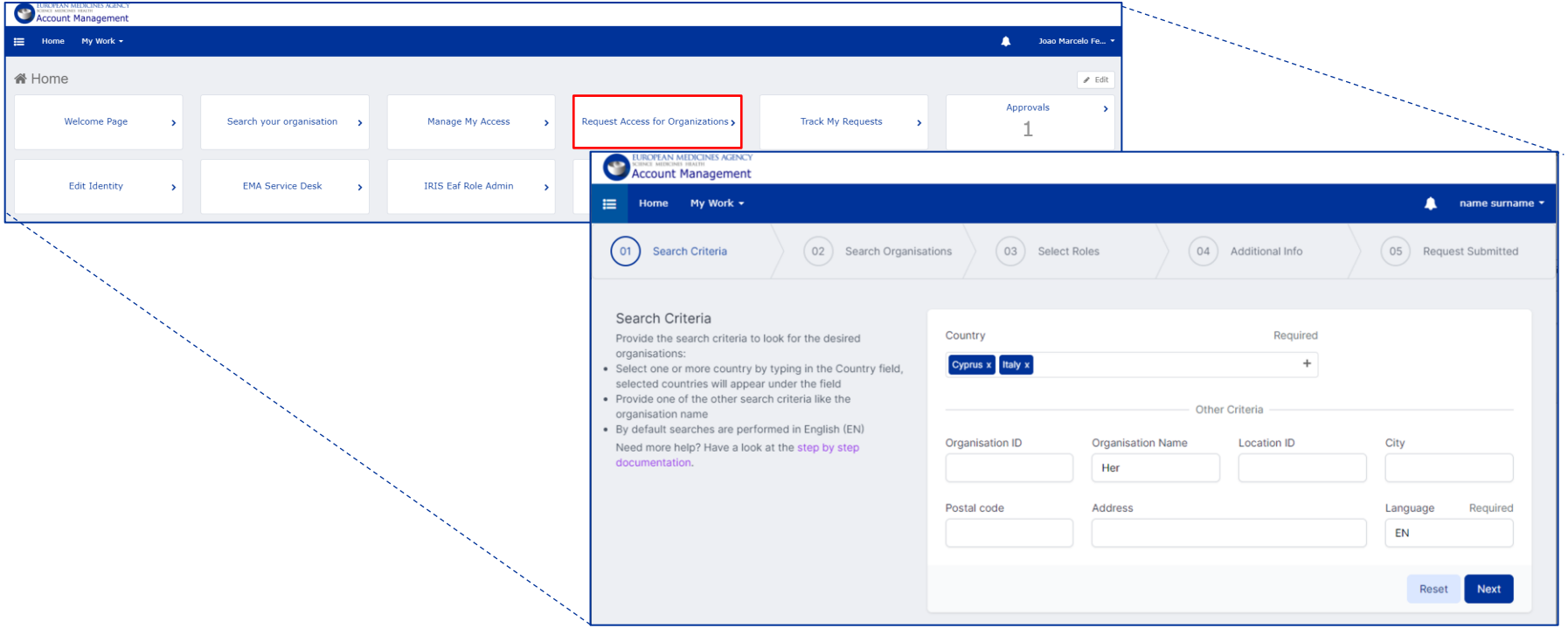
Steps to request a role

EMA Account Management > Login > 'Request Access for Organisations' >
01 Search Criteria (Add at least one *Country* and one *Other Criteria*) > 'Next'



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Steps to request a role

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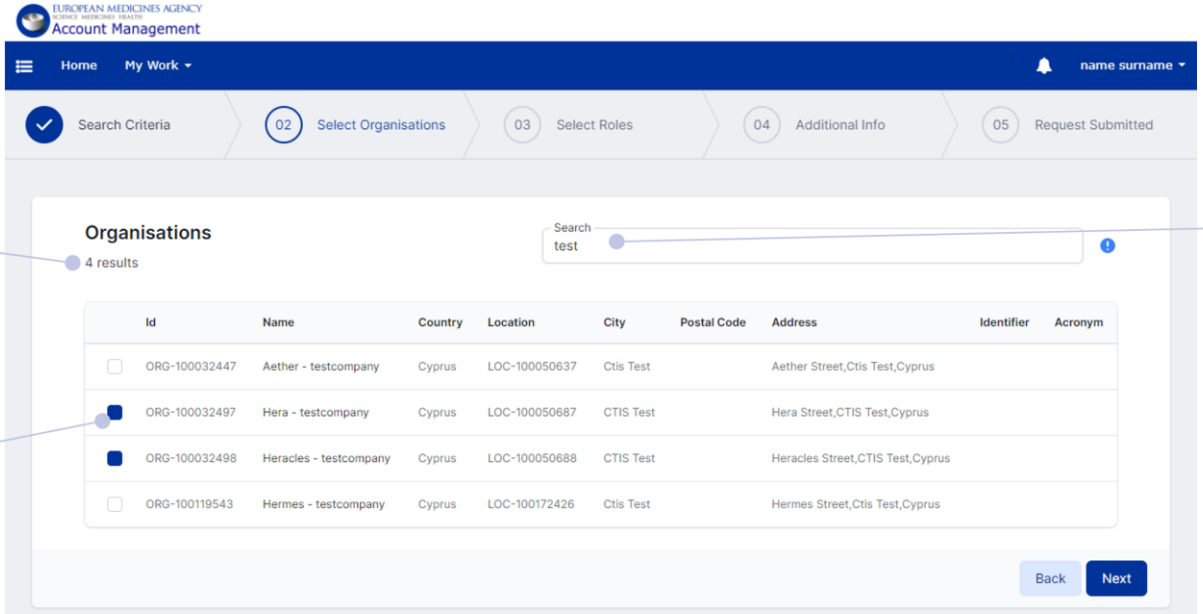
02 Select Organisations (Tick-mark the organisation(s) you want to select) **>** 'Next'

Up to **200 results** are shown, narrow down your research if you hit this limit

Use the **checkbox** close to each organisation to select them.



Use the Search field to restrict further your search

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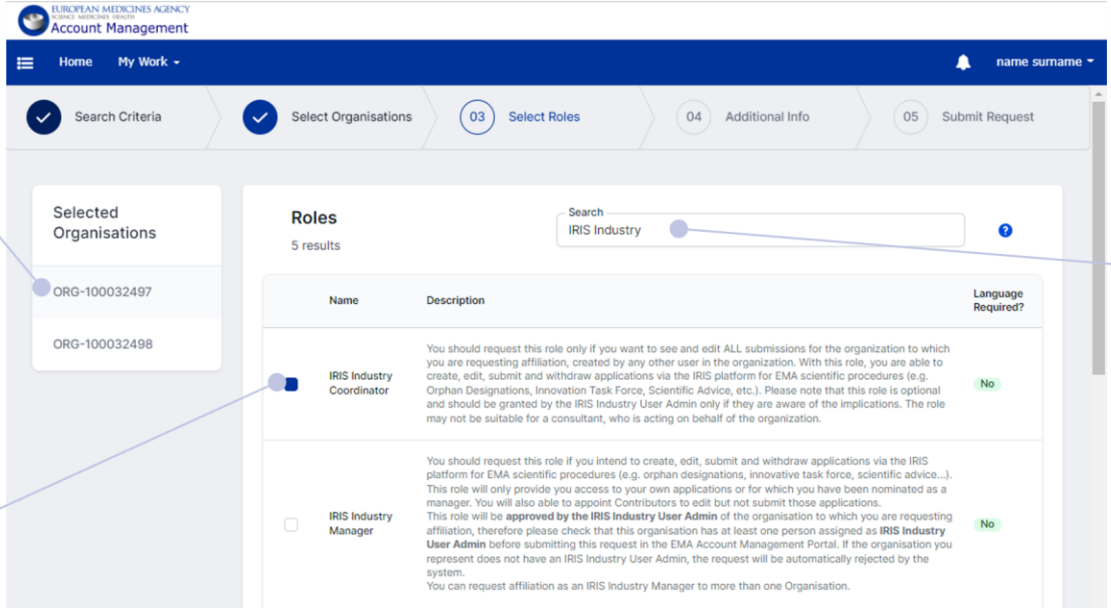
Steps to request a role

03 Select Roles (Tick-mark the roles(s) you want to select) **>** 'Next'

Selected **organisations** are shown here.
The **selected roles** will be requested **for all displayed organisations**

Use the **checkbox** close to each role to select them.



Use the **Search** field to look for desired roles

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Steps to request a role *(only applicable to Administrators)*

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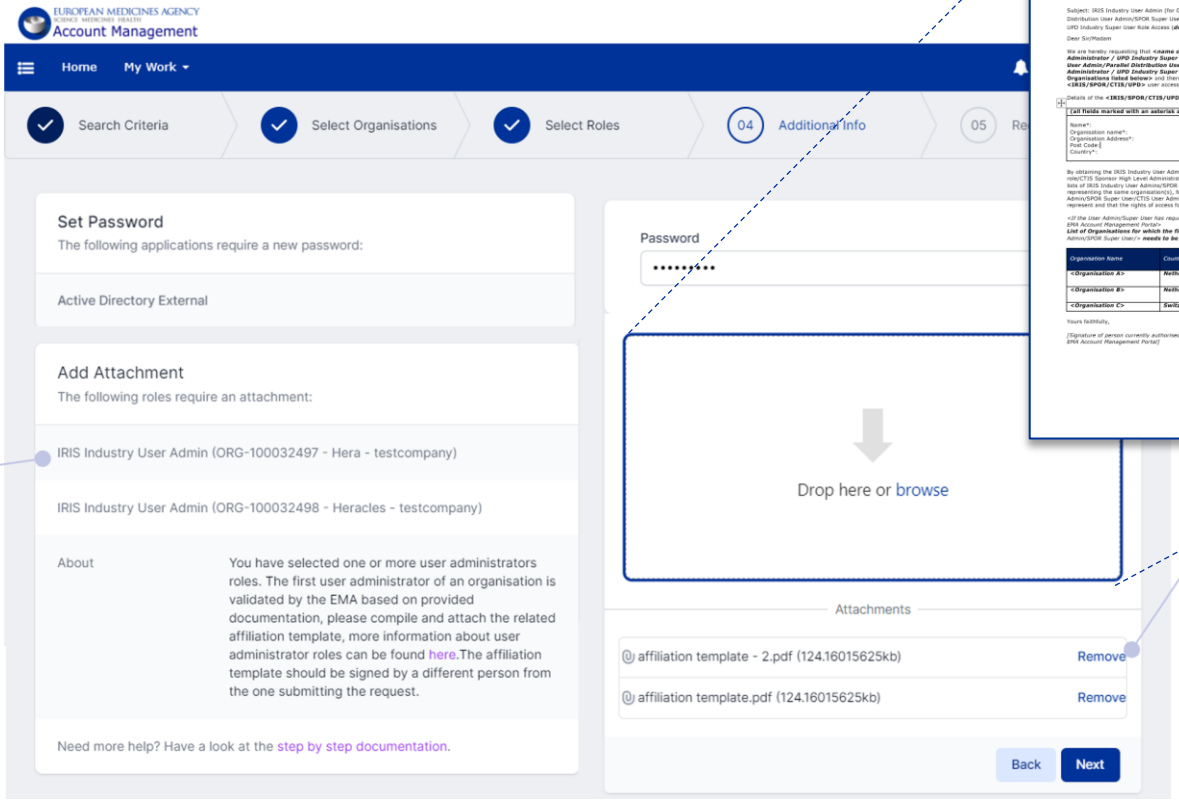
04 Additional Info (Attach signed affiliation letter) **>** 'Next'

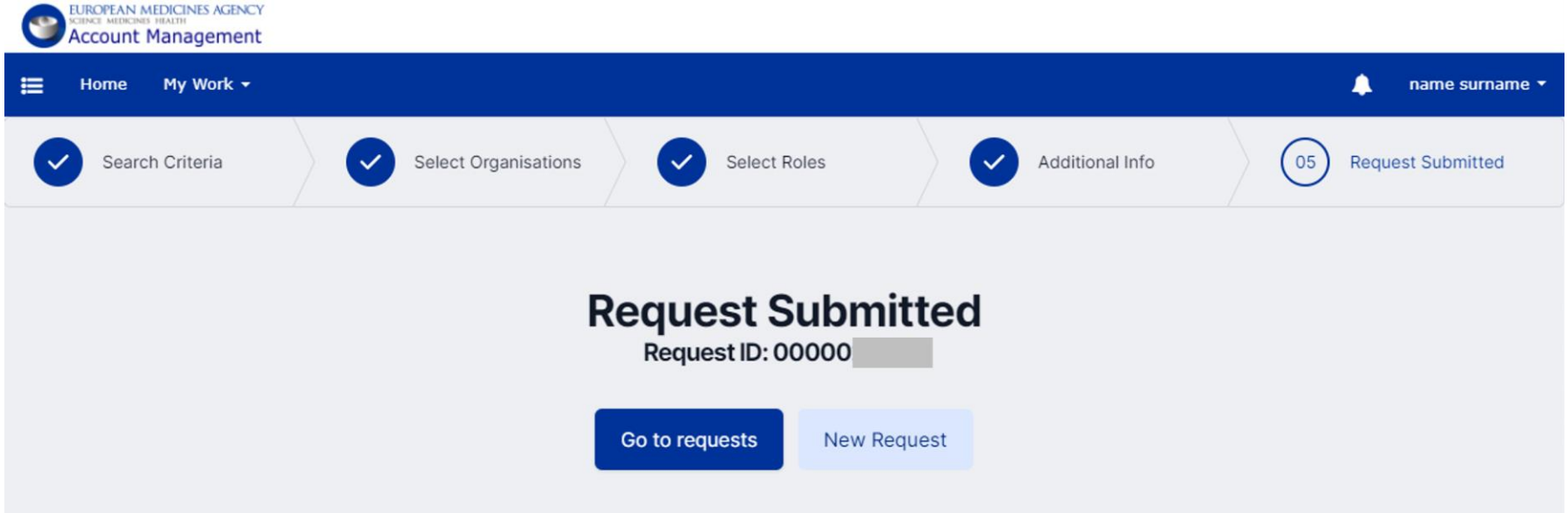


The role requiring additional information is displayed in the righthand panel

Multiple attachments can be provided but please note that the same affiliation letter can be re-used for multiple roles and multiple organisations.

Steps to request a role

05 Request Submitted (Window confirming that the request has been submitted)



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

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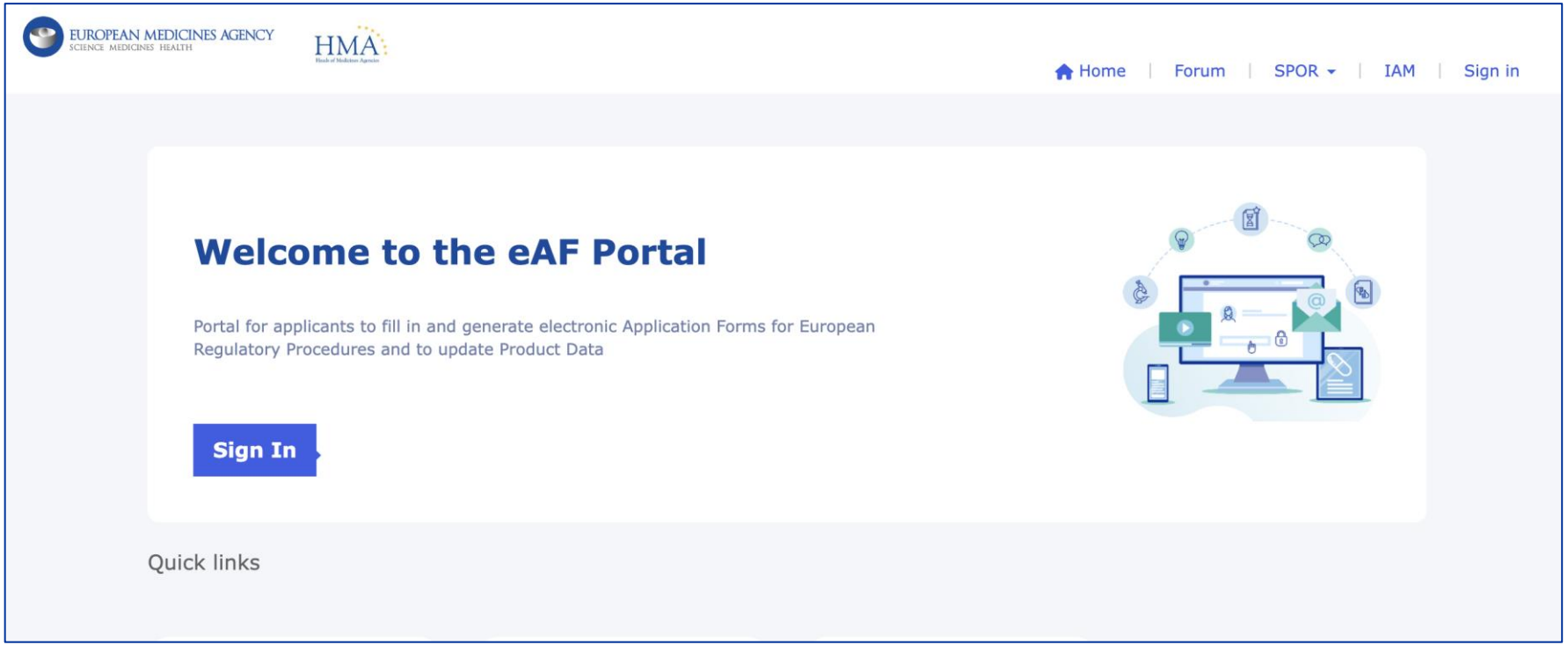
Signing in to the eAF portal

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



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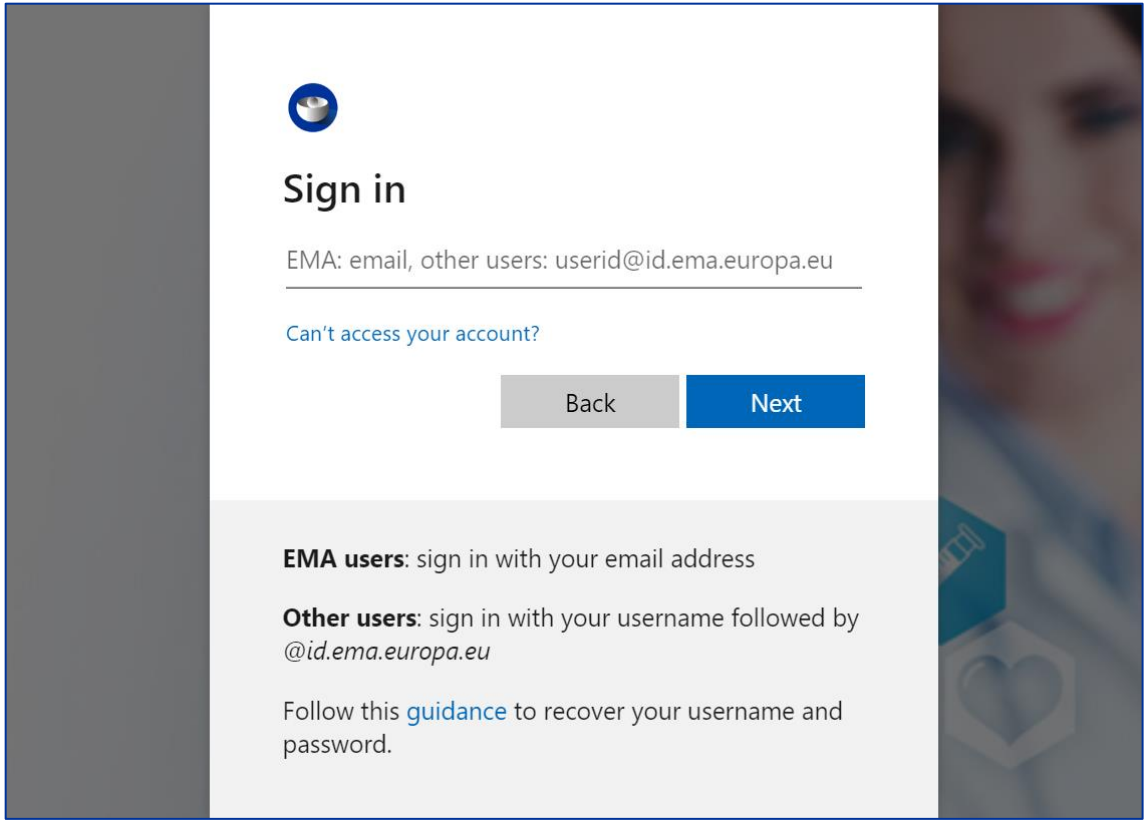
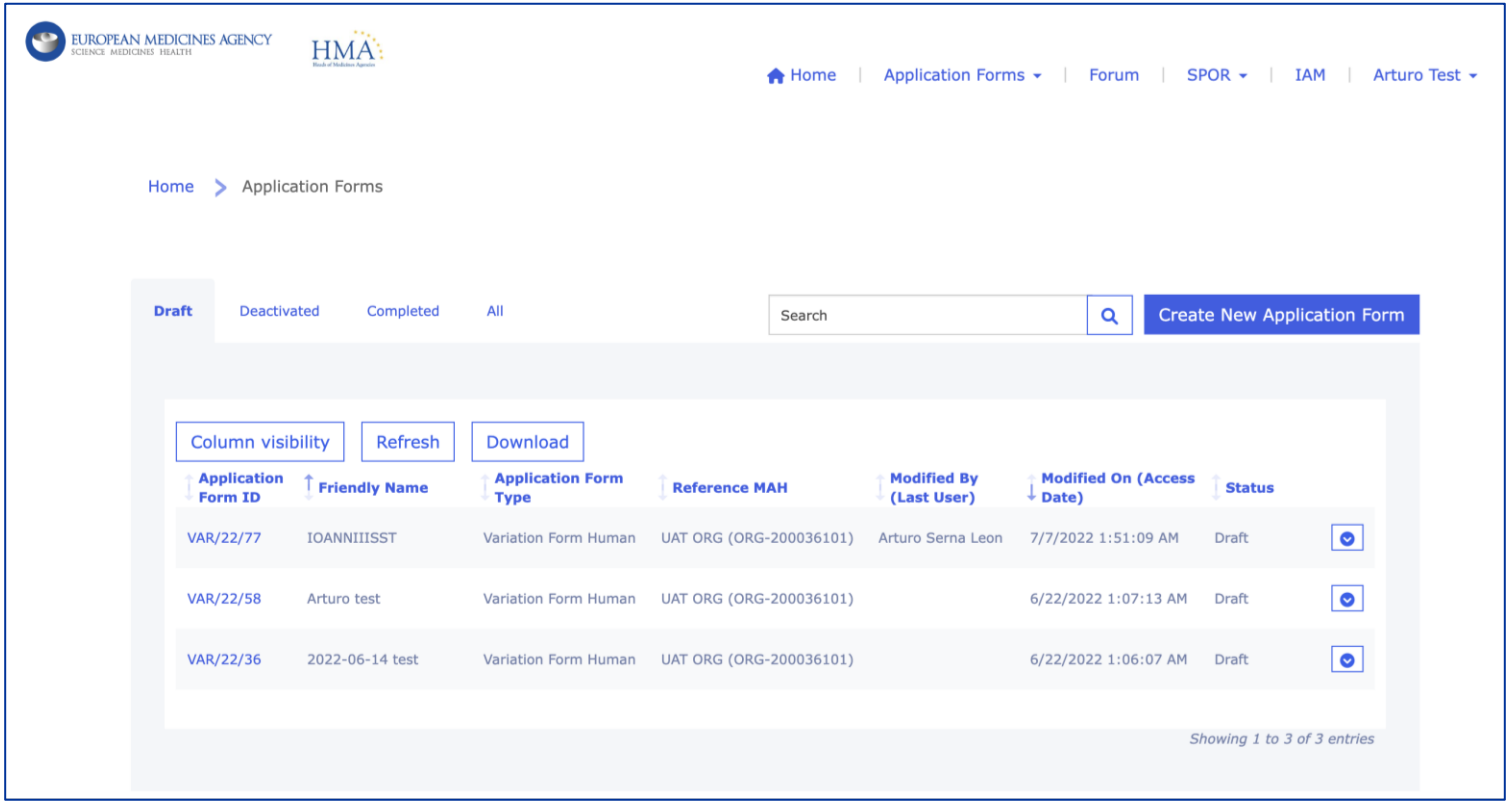


Please note that:

- 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



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Demonstration of the User Interface

Kristiina Puusaari, *DADI Product Owner, EMA*

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Demonstration of the User Interface

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To note:

- Although all features for the go-live are developed, 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
  - Additional bug-fix release(s) will be deployed prior to the UAT
  - Several bug fixes will be done after UAT – before go-live

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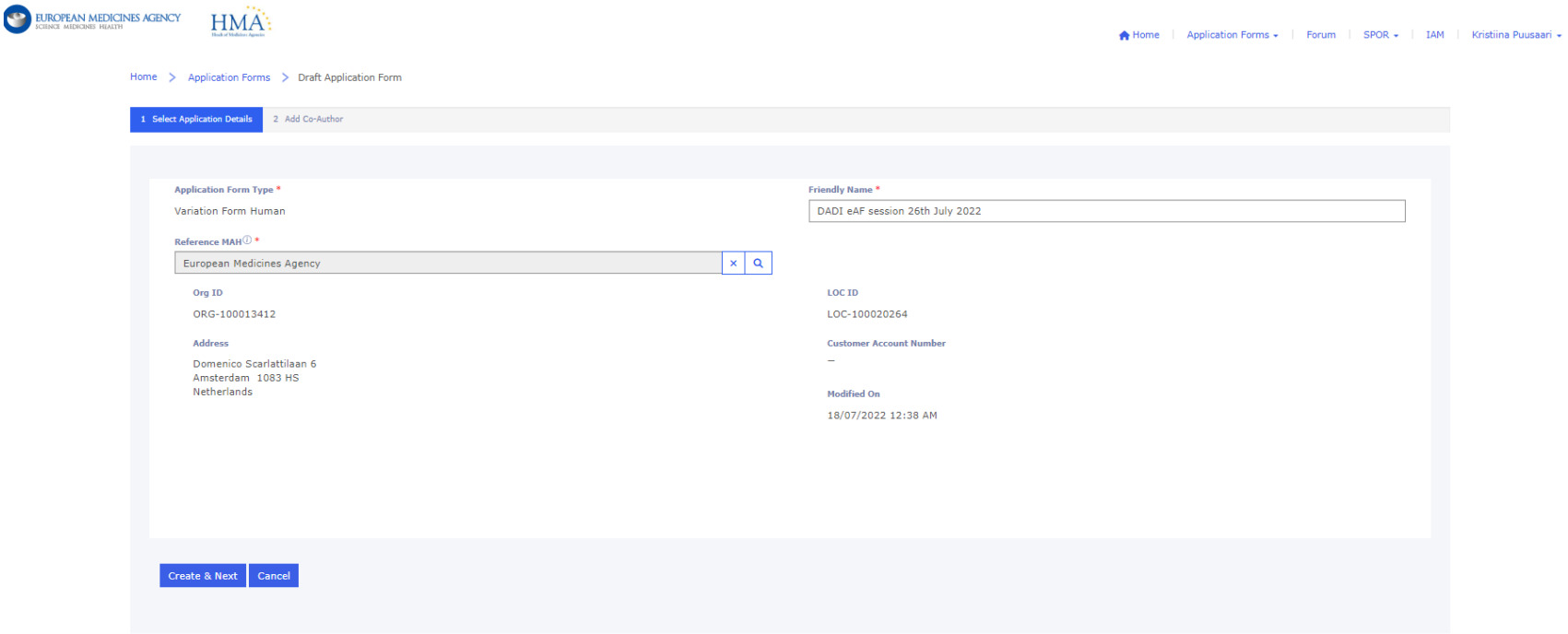

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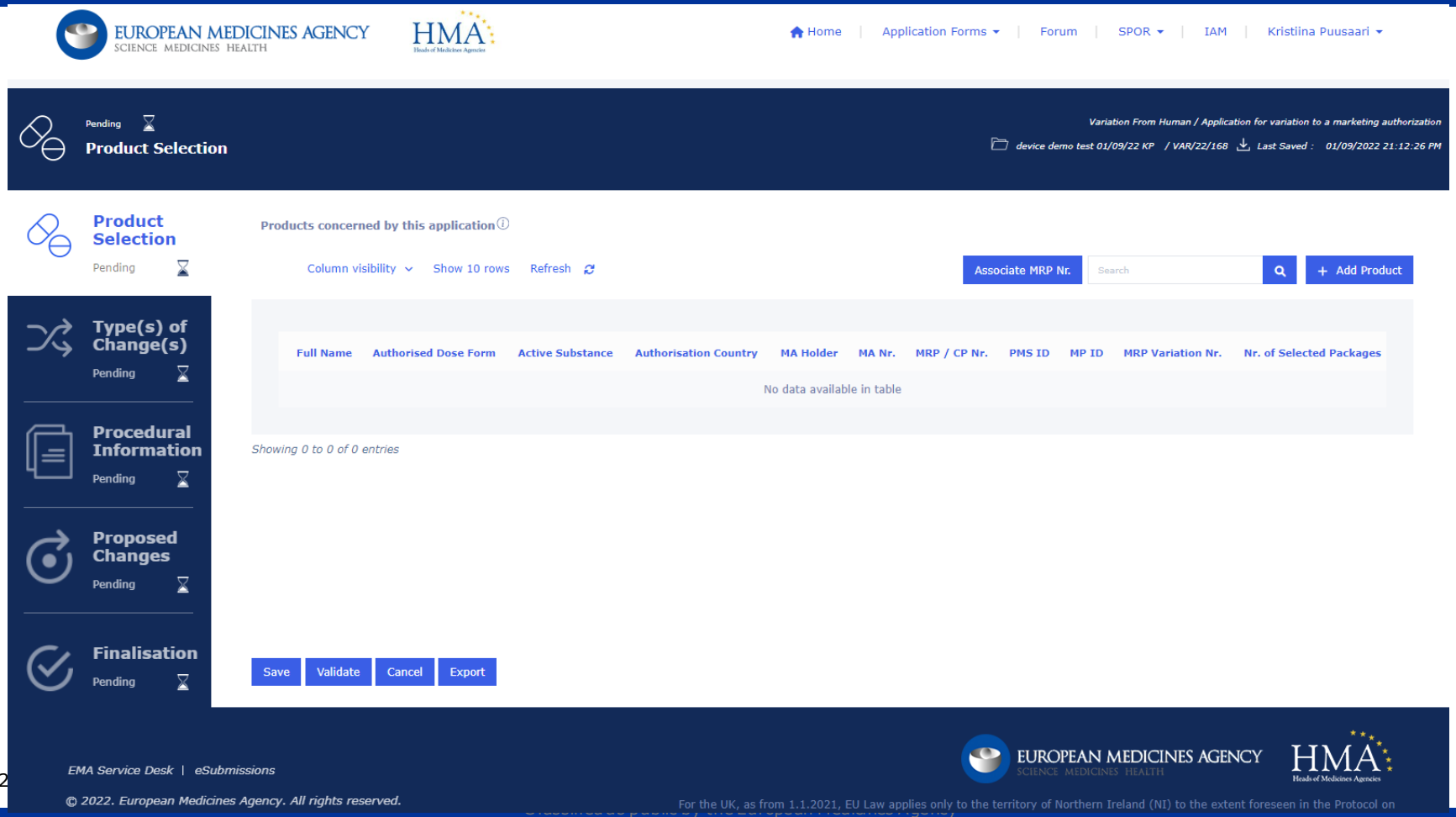

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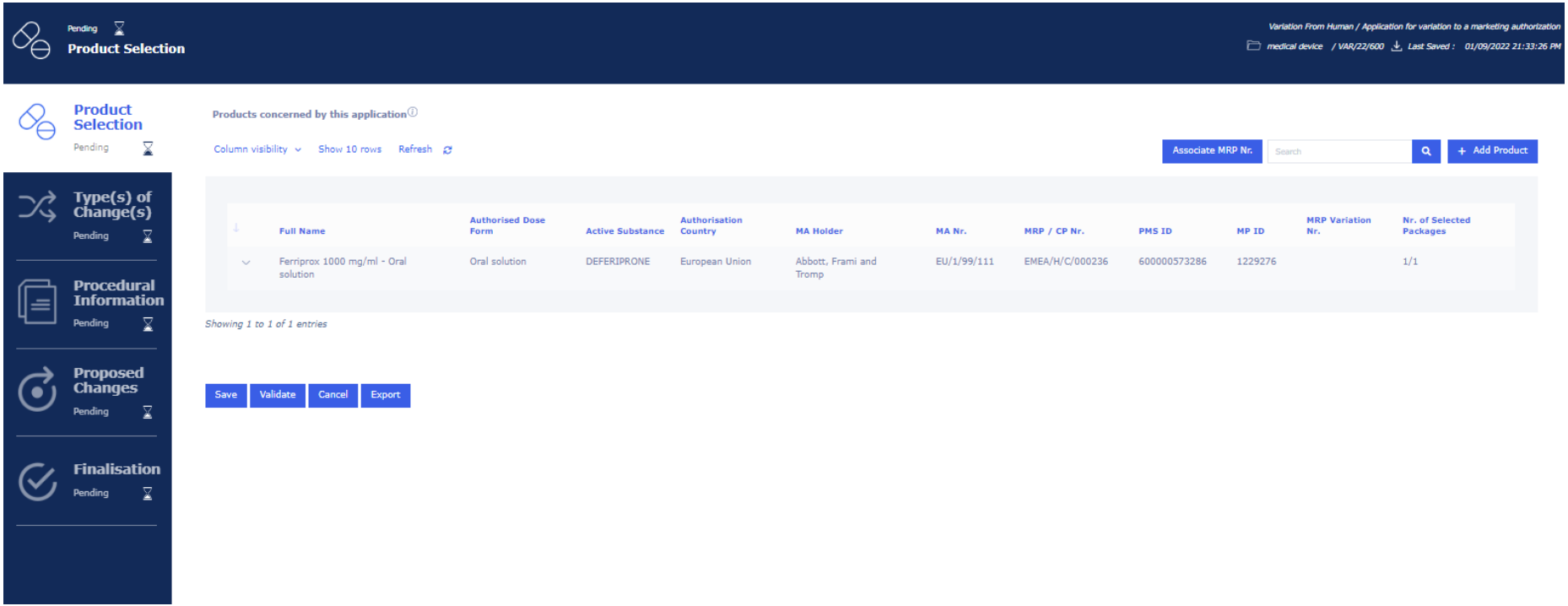

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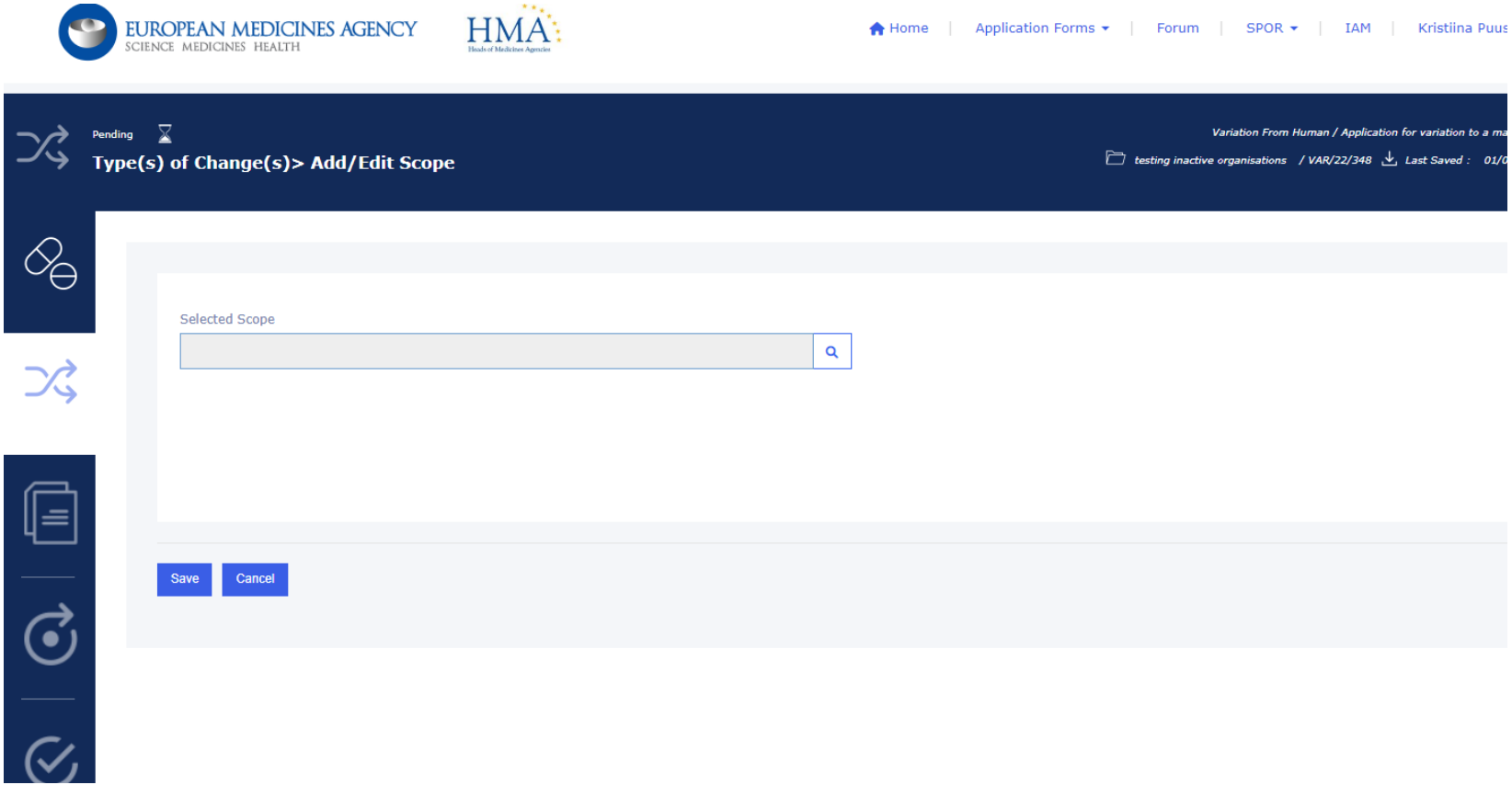

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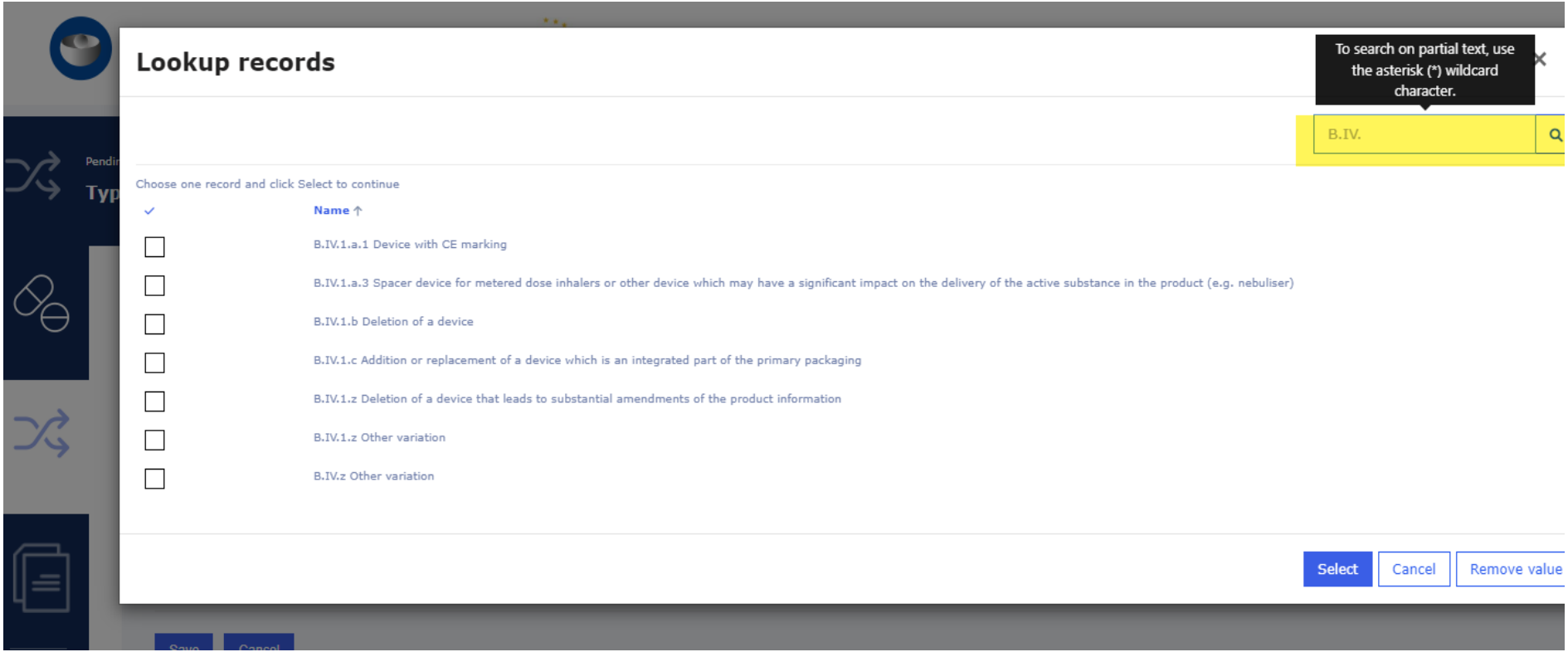

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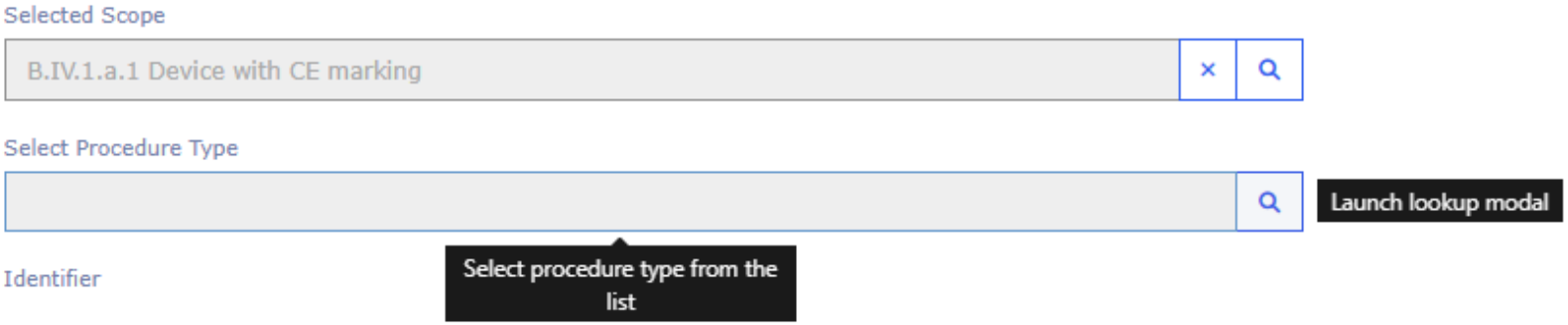

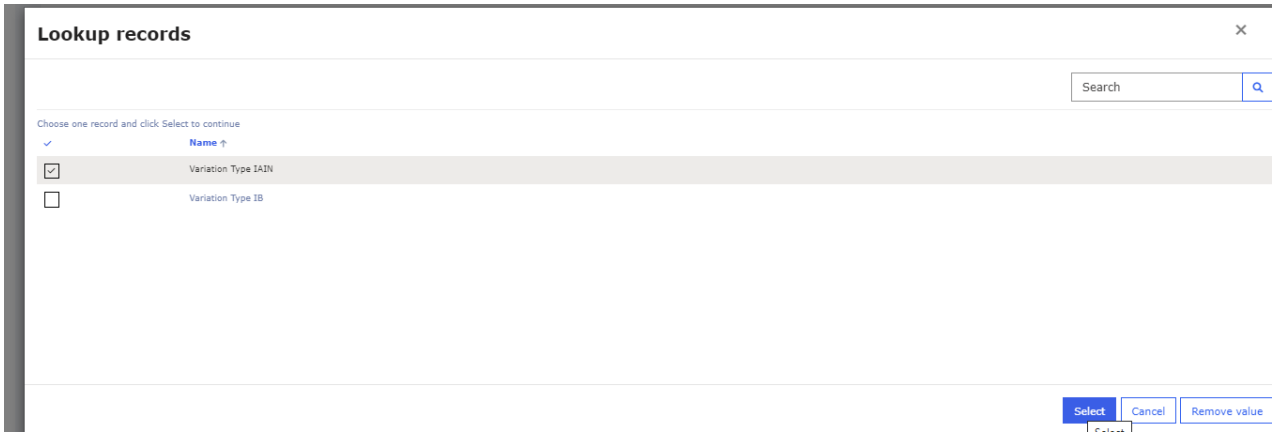

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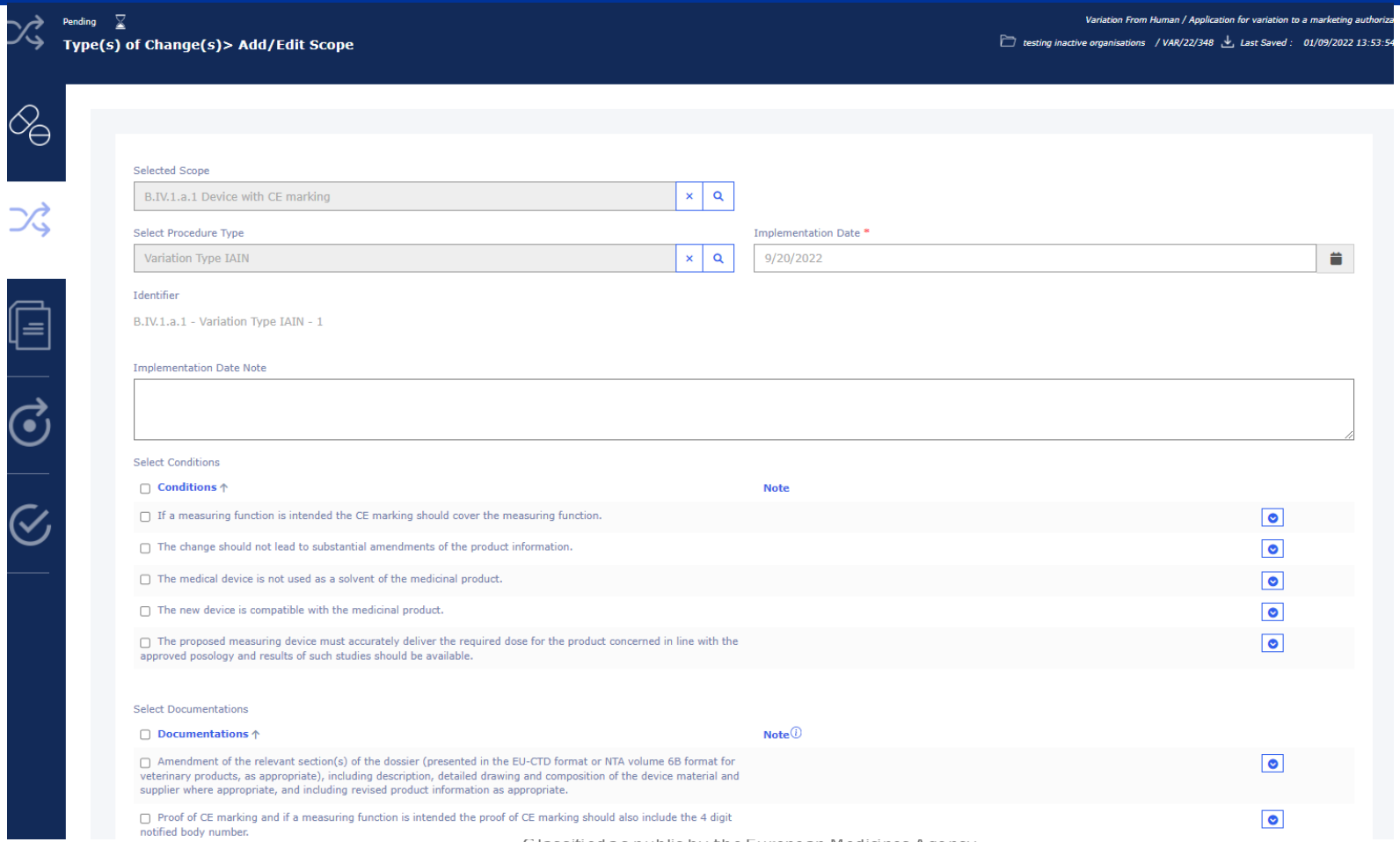

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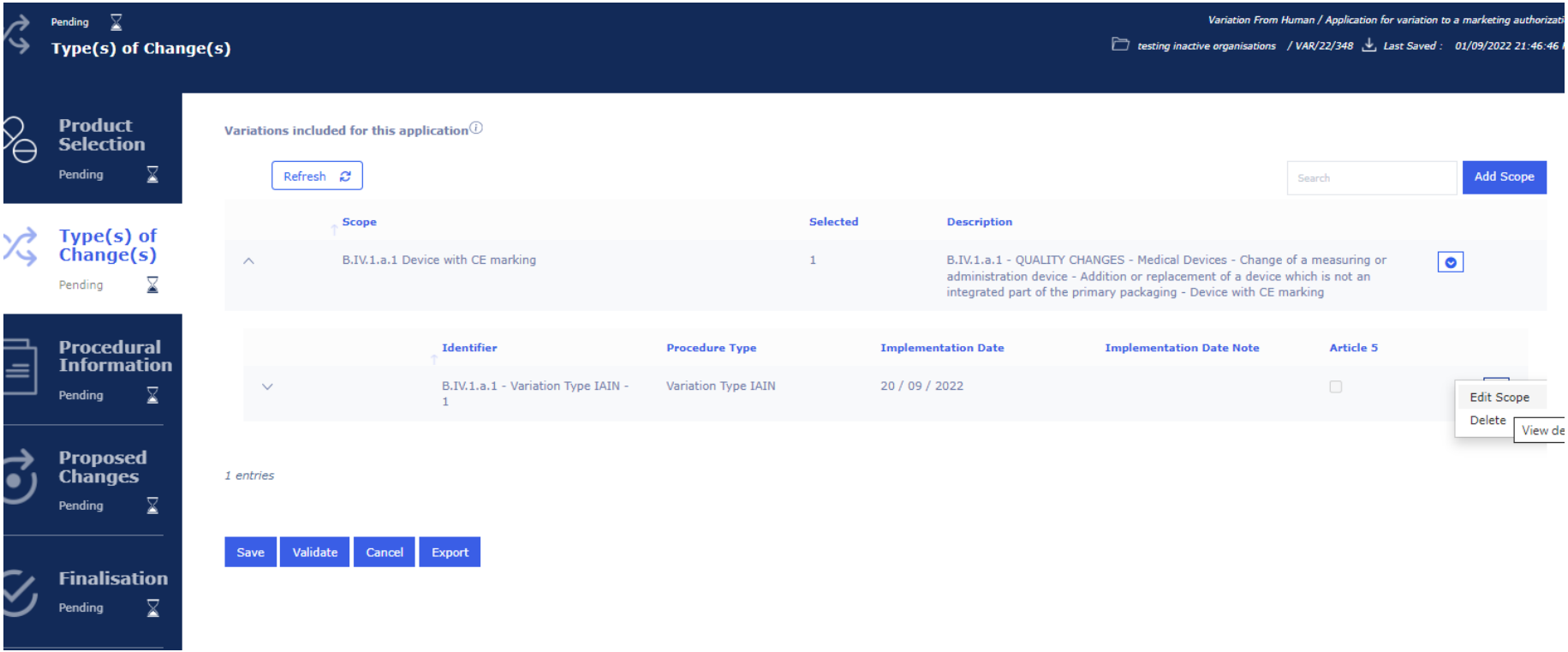

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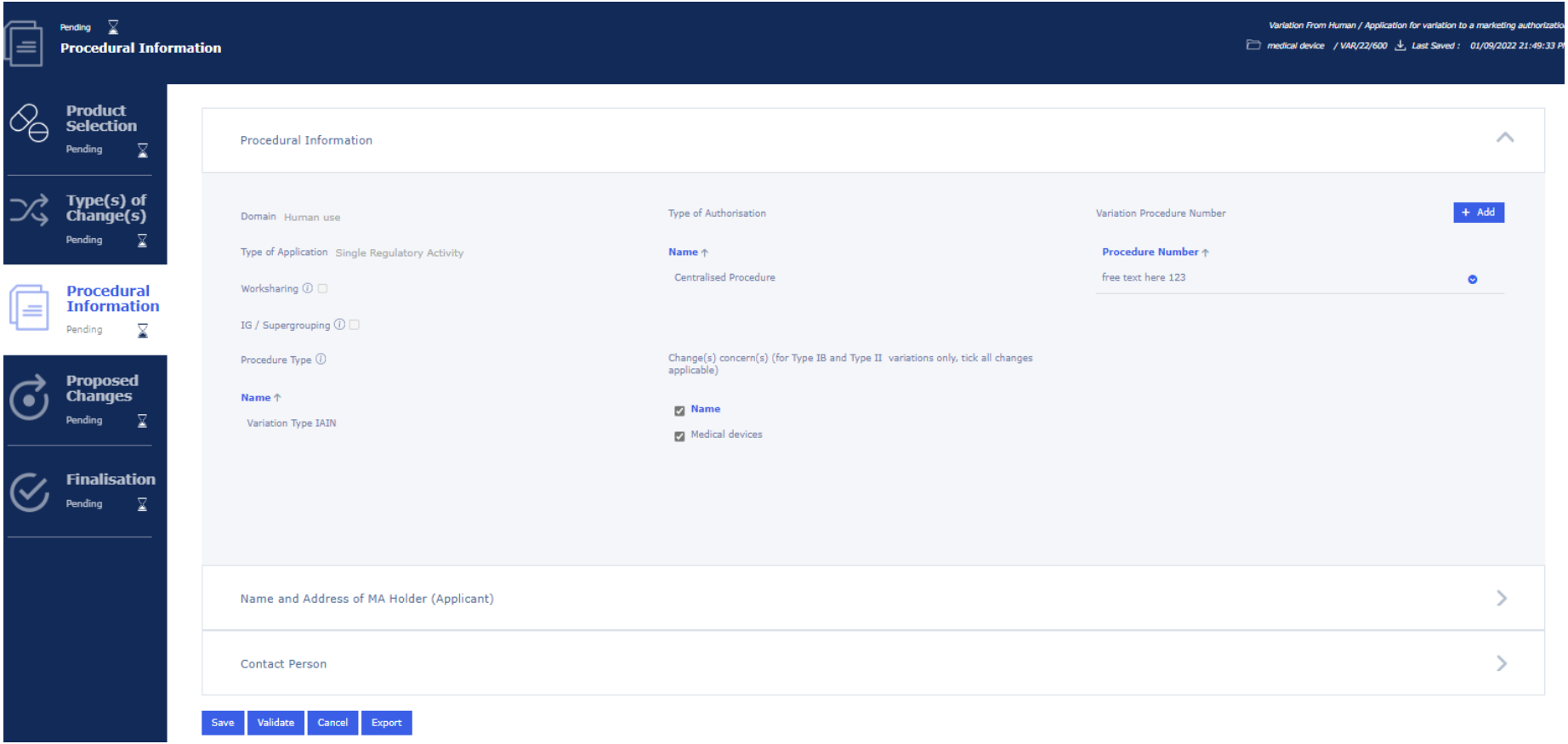

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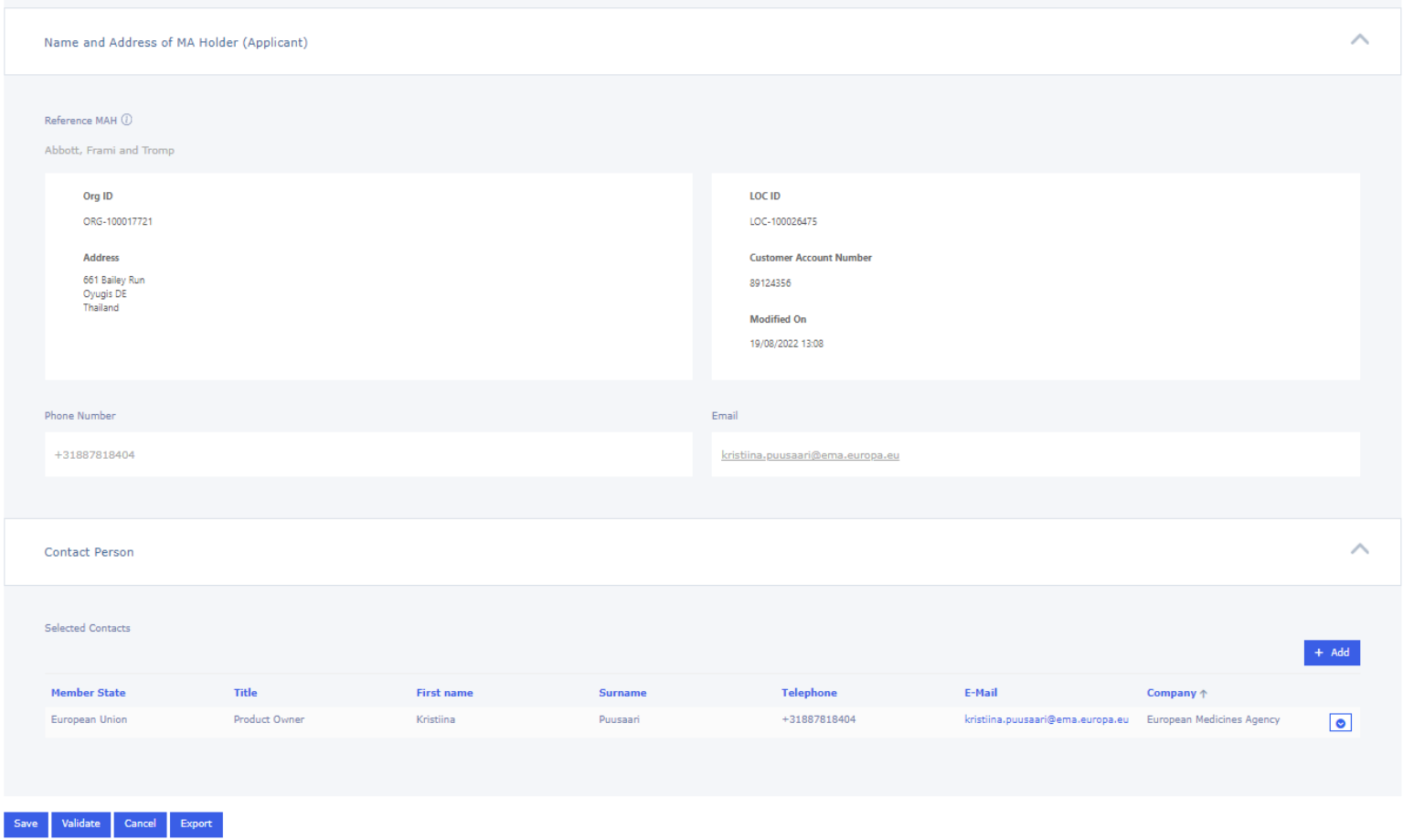

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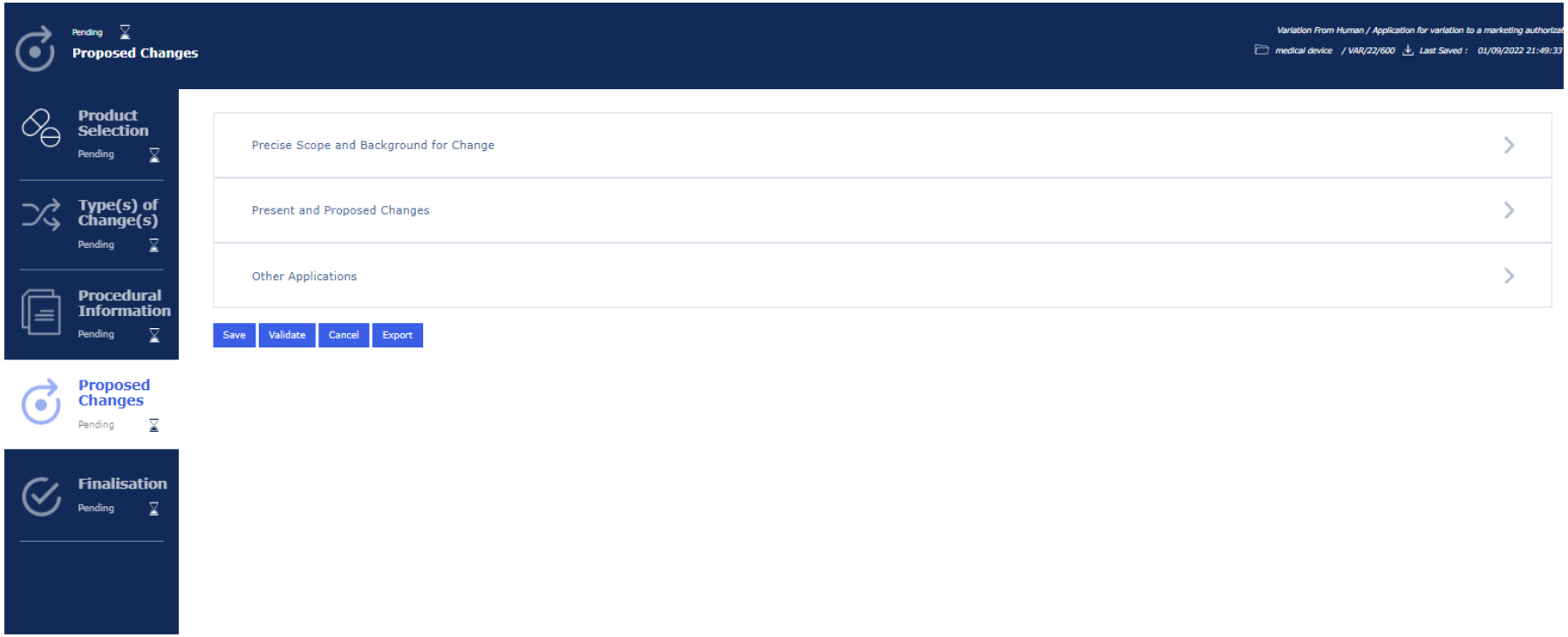

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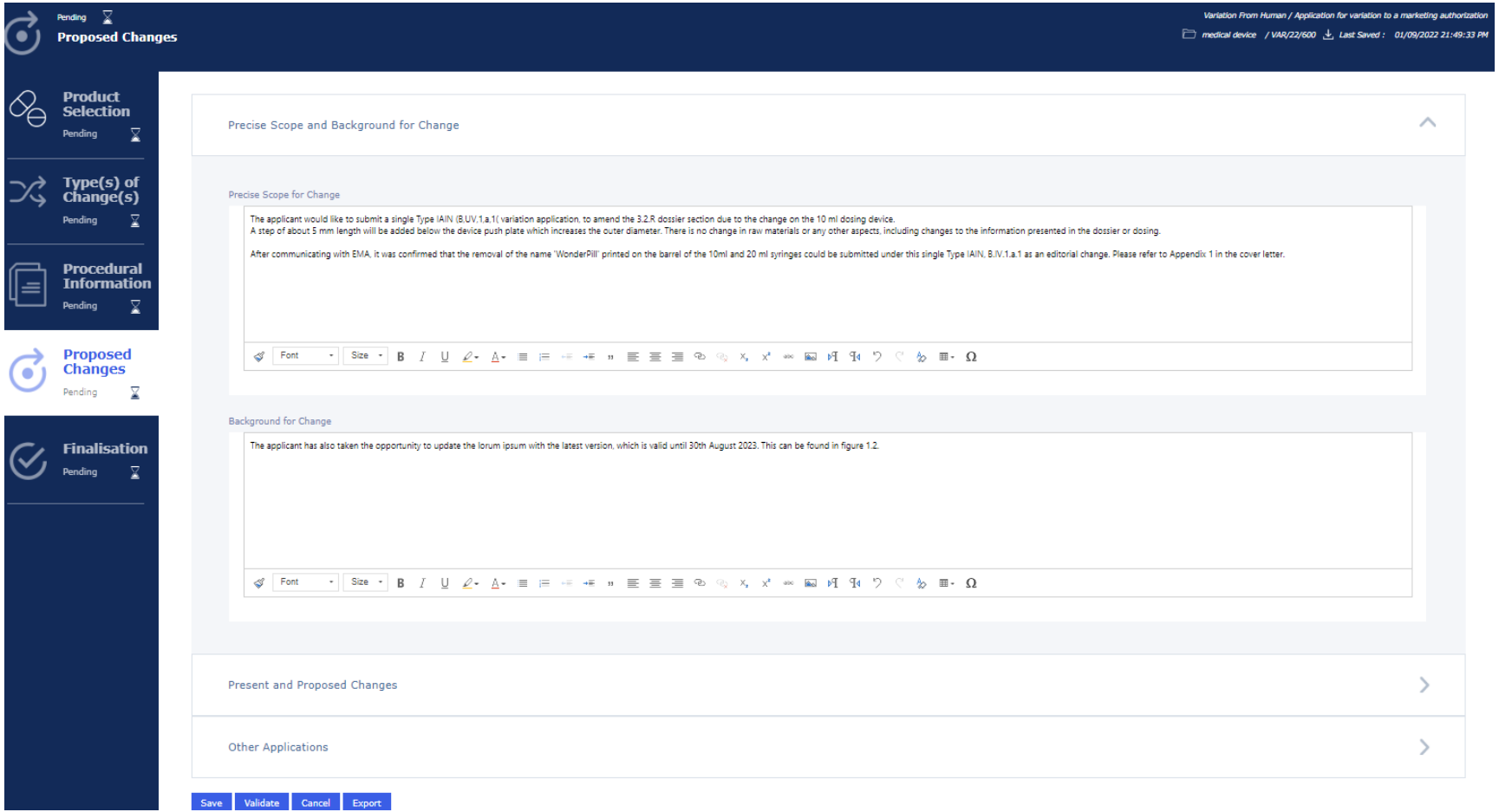

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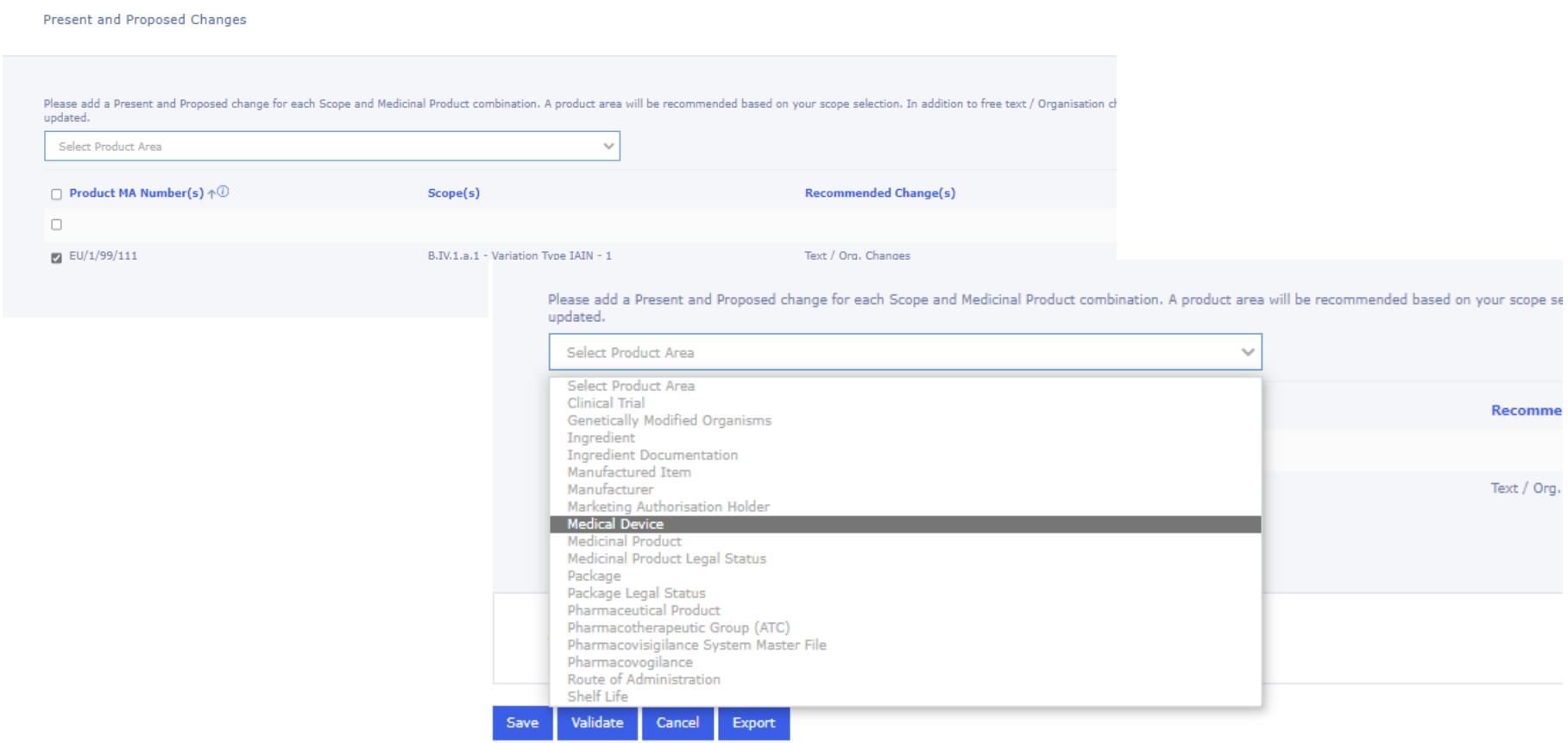

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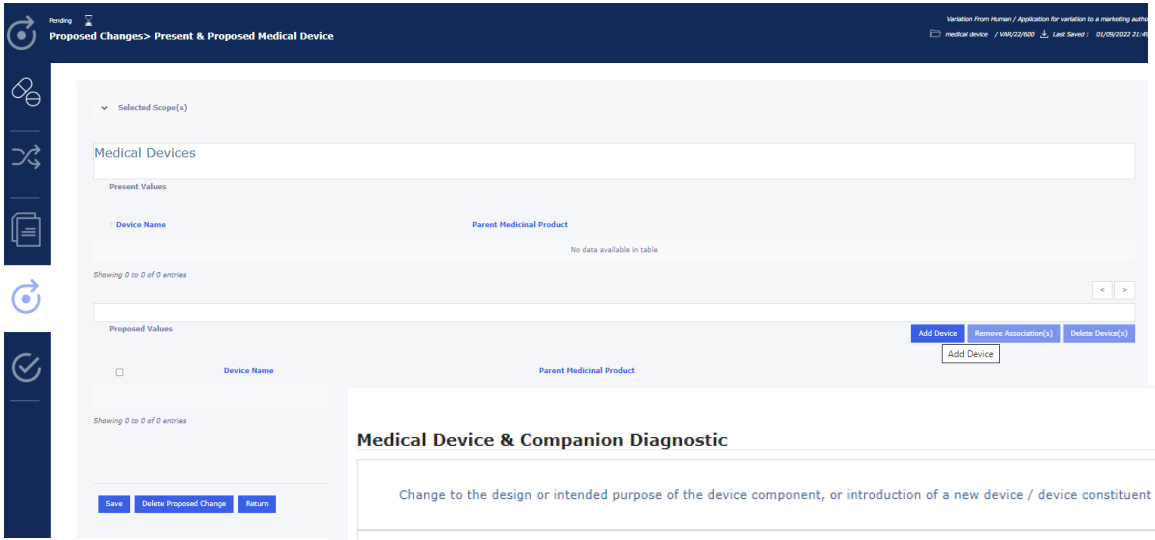

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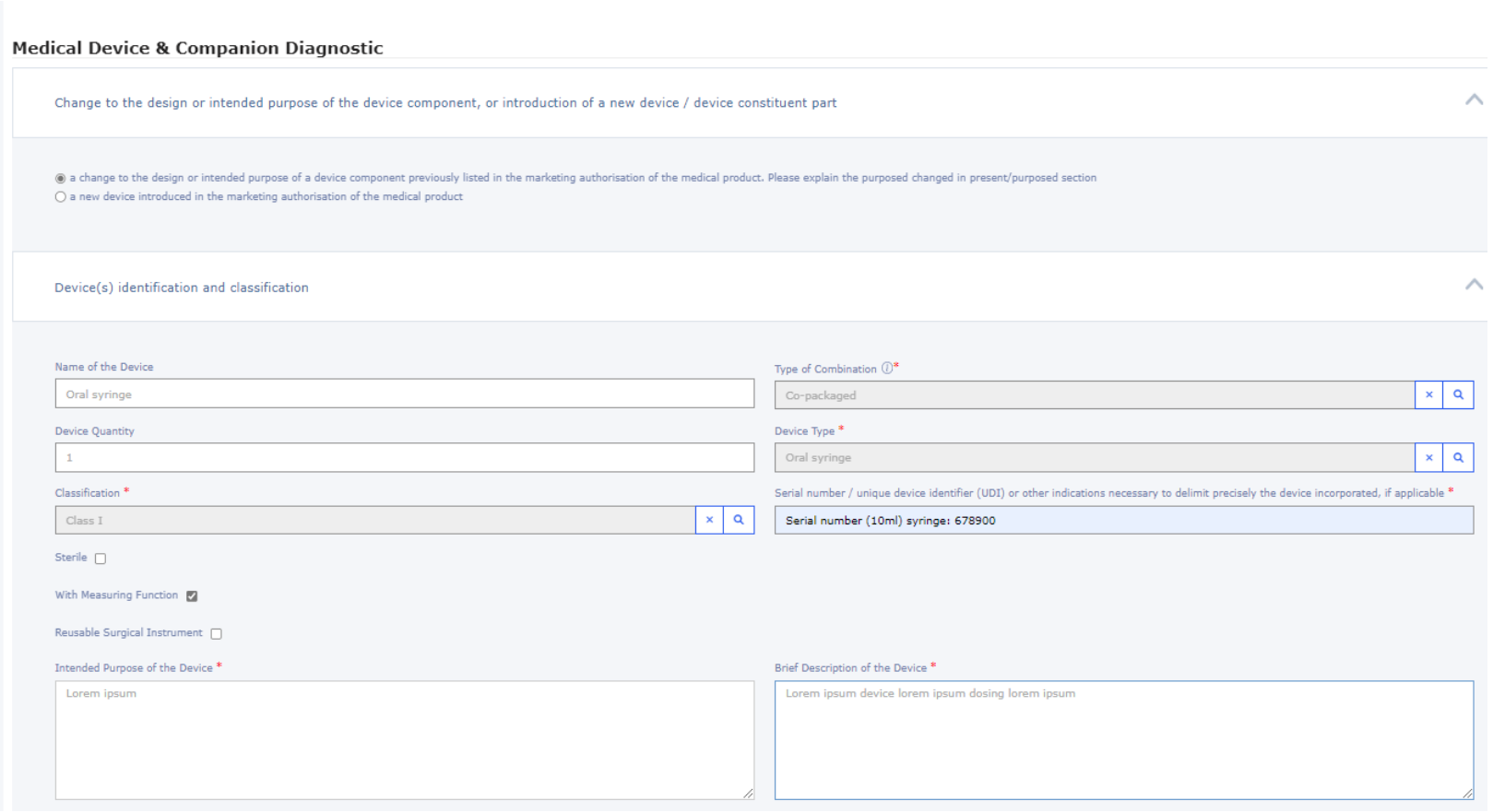

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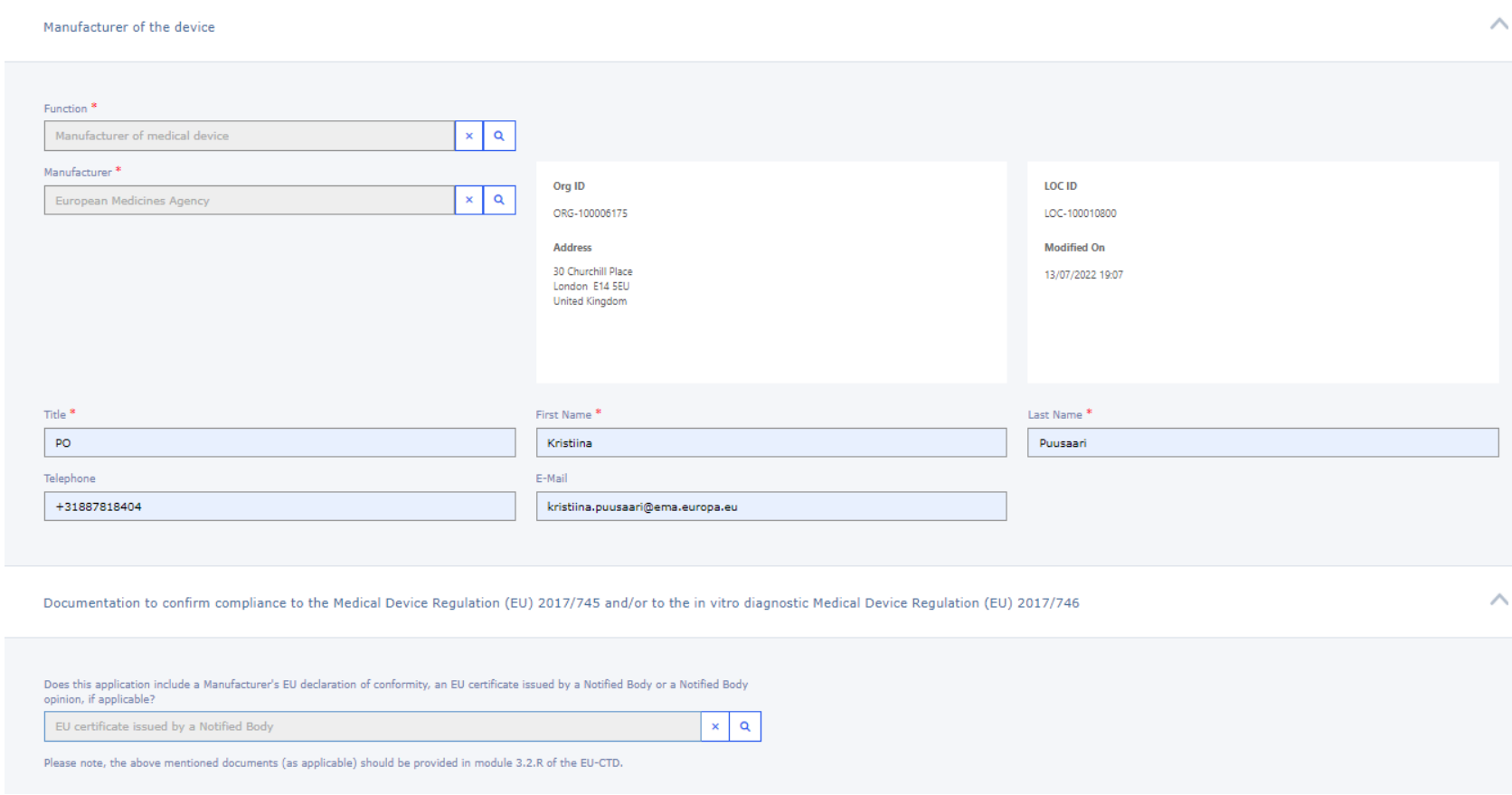

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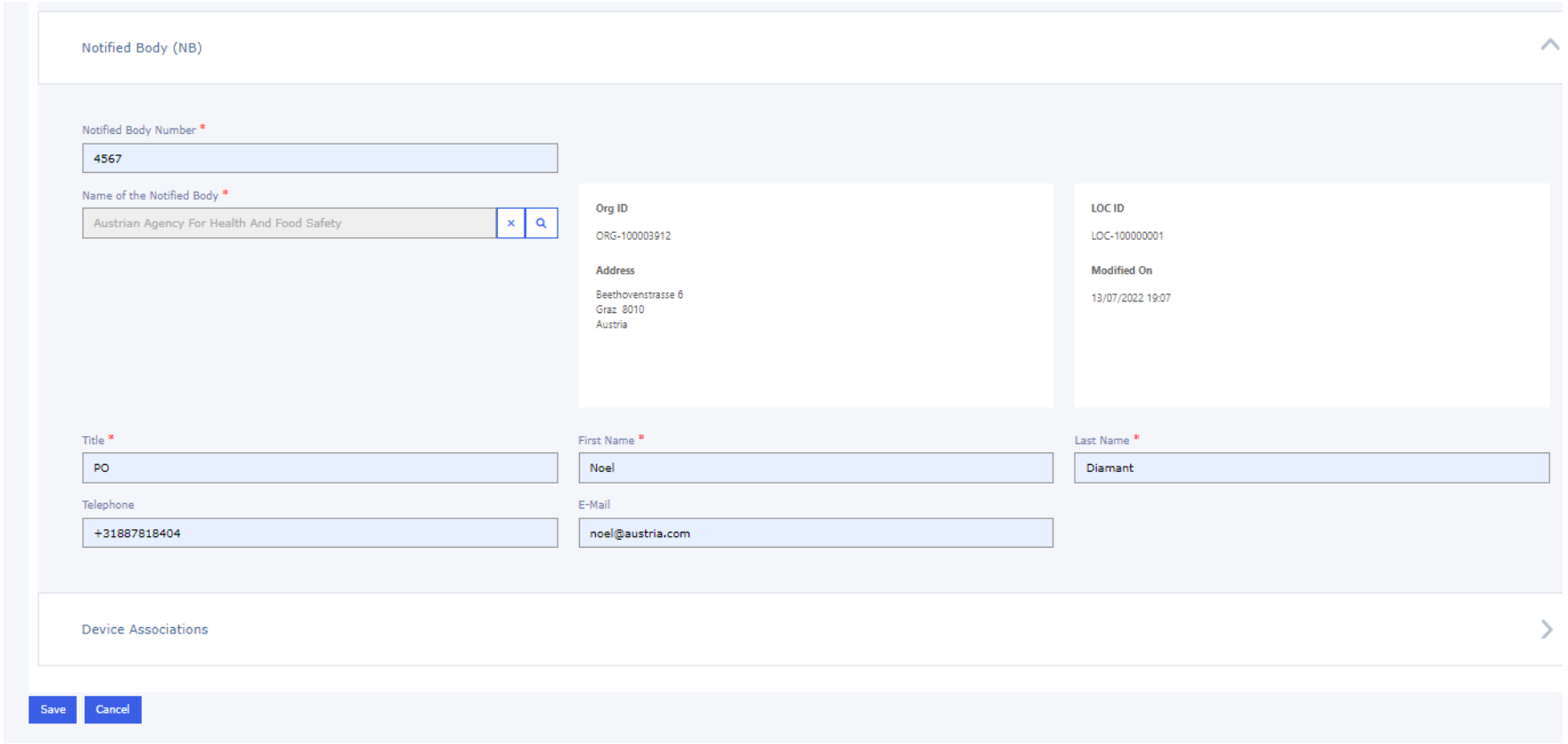

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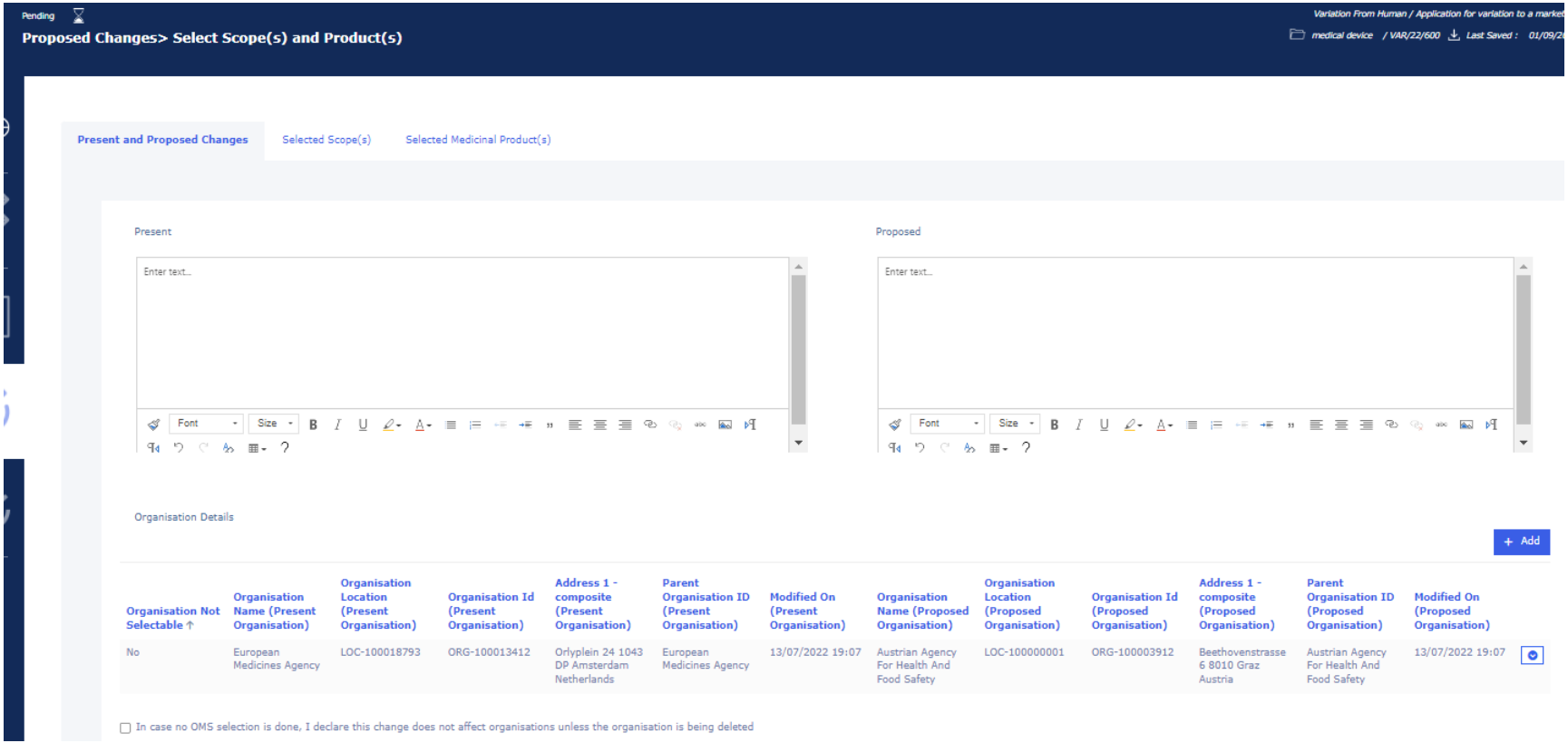

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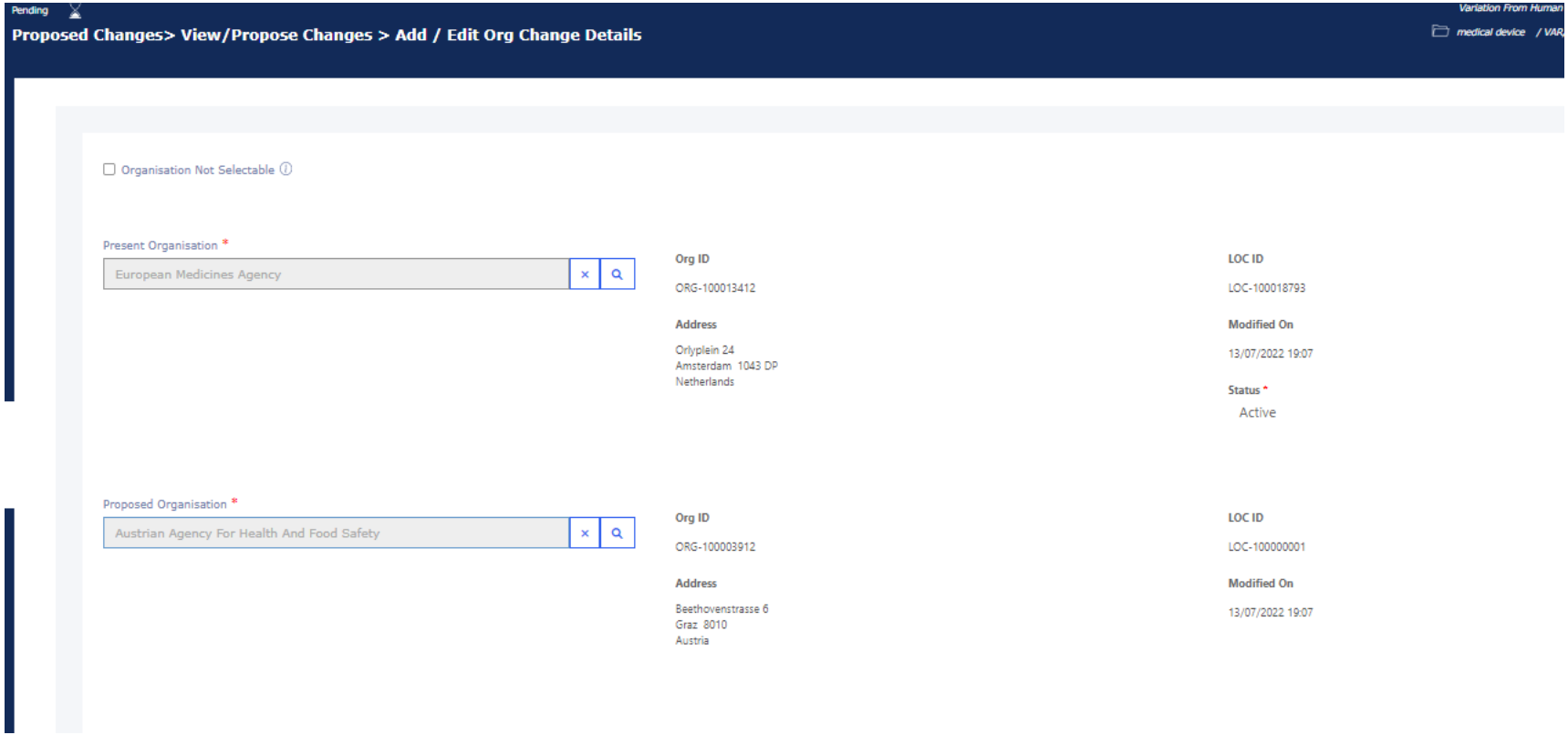

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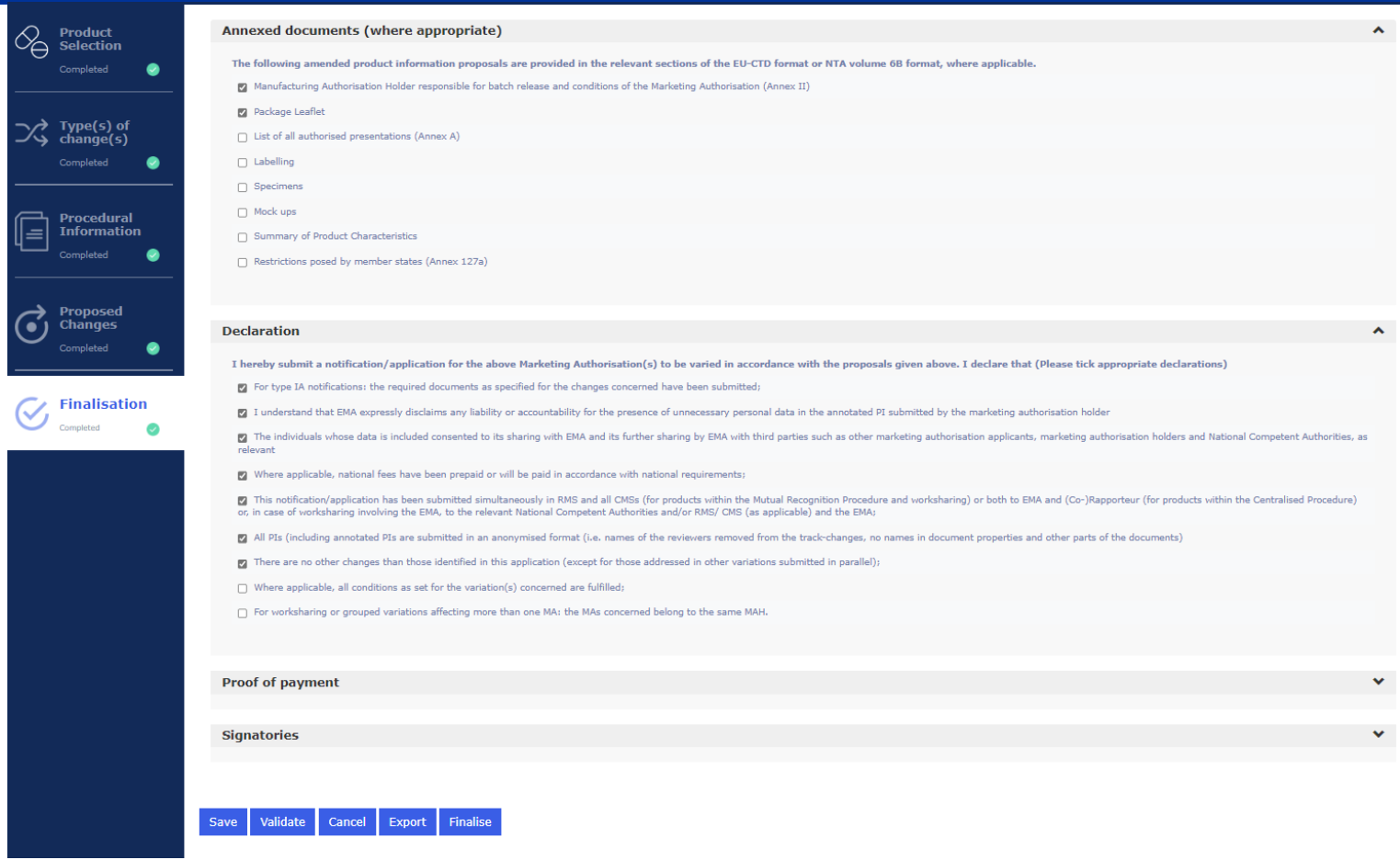

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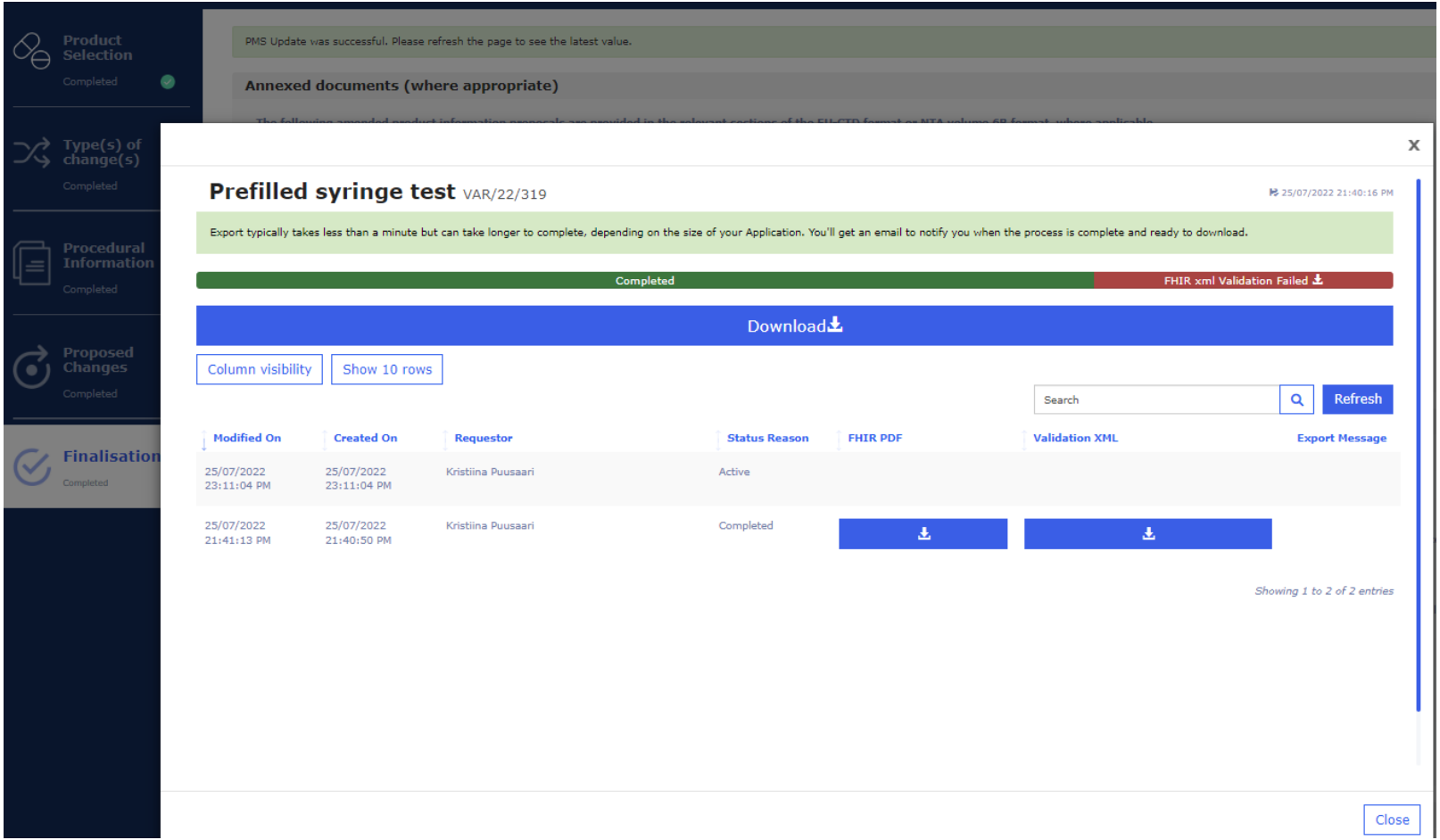
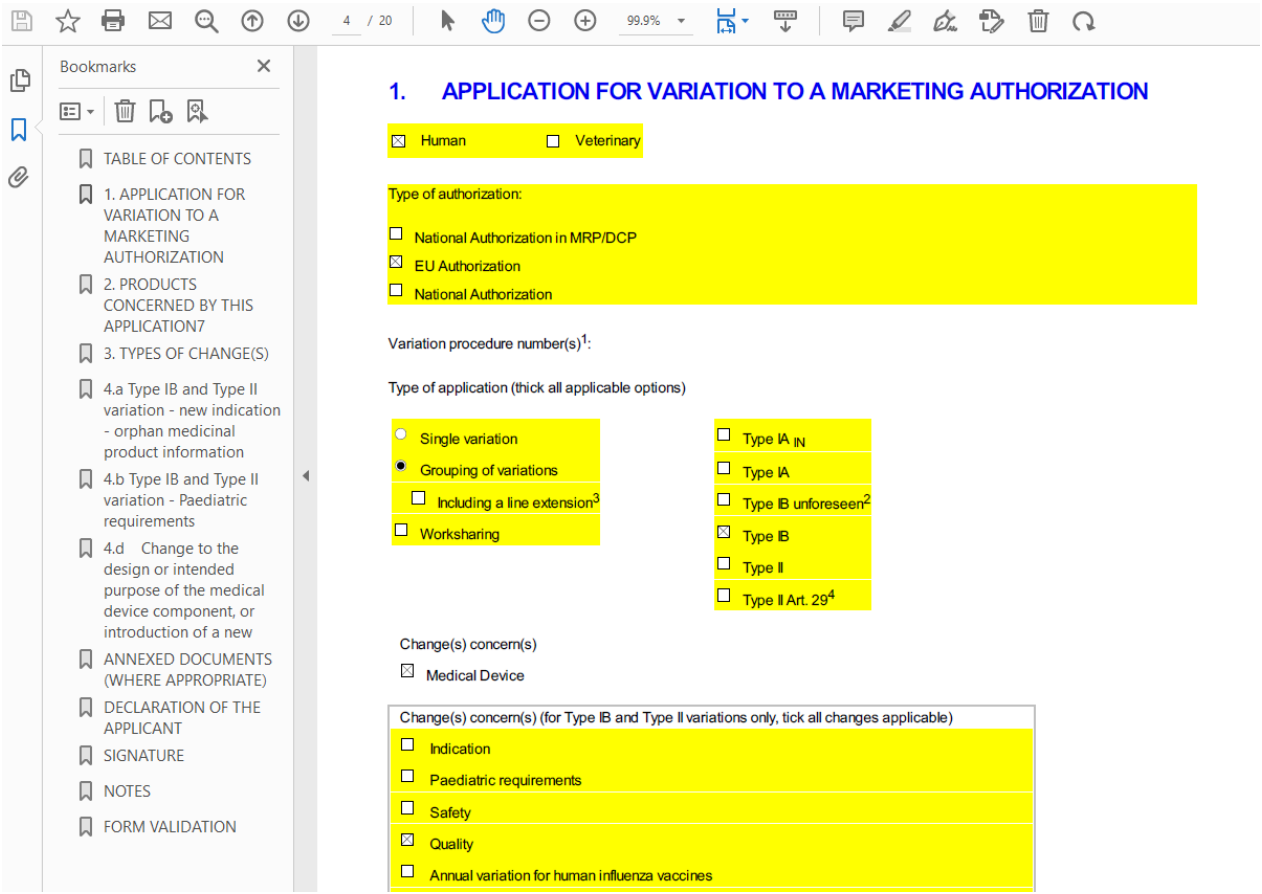


Demonstration of the User Interface



Q&A session

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

Closing

Joris Wiemer, *EMA Change Management Lead*

Next Steps

- Publication of the **Q&A Documents** from the 1st and 2nd eAF training webinars (26 July and 2 September 2022)
- Publication of the **Joint DADI-PMS Q&A Document**
- **UAT** between 19-30 September 2022
- **System demo** scheduled for September 2022

Further information

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

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