



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Variations Form for Human Medicinal Products What will happen at Go-Live?

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16 May 2022, 10:00 – 12:00 Central European Time (CET)  
Webinar: WebEx





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## Welcome / Introduction

10:00 – 10:10

**Joris Wiemer**

*Change Management Lead, EMA*

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## Web forms as part of the Data-centric Target Operating Model

10:10 – 10:20

**Karl Hamilton**

*Product Lifecycle Management Value Stream Owner, EMA*

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## Human Variations Form Timeline

10:20 – 10:30

**Hannes Kulovits**

*Product Lifecycle Management Value Stream Manager, EMA*

- **Impact for Applicants and Regulators**
- **Process at Go-live of DADI Variations Form**

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- Selection of Products in the Variations Form
- PMS Data in the Form at Go-live
- Submission of Variations Form
- Process after approval of a Variation
- xEVMPD submissions

10:30 – 11:20

**Kristiina Puusaari**

*DADI Product Owner, EMA*

**Noel Diamant**

*DADI Product Owner, UNICOM/Austrian Medicines Agency*

**Marcos Fernandez**

*PMS Product Owner, EMA*

**Veronica Lipucci Di Paola**

*PMS Product Owner, EMA*

5

## Q&A Session

11:20 – 11:55

**Moderator:**

**Cristina Pepato**

*DADI & PMS Change Manager*

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## Closing

11:55 – 12:00

**Joris Wiemer**

*Change Management Lead, EMA*



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**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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Joris Wiemer, *Change Management Lead, 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)** and **Nationally authorised product (NAPS)** applications



### 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**

## Context

- › The **Product Management Services (PMS)** is part of the **SPOR Programme**, and is a **Network project** led by the **EMA** in cooperation with the **European medicines regulatory network** and **industry**
- › PMS aims to:
  - enable the implementation of globally recognised ISO standards for the **identification of medicinal products (IDMP)**, allowing everyone to align to one standard set of rules
  - deliver **comprehensive and consolidated** medicinal product data (CAP and Non-CAPs) from different sources which will be re-used by DADI and throughout regulatory processes
  - deliver a **trusted and good quality** source of product data by enabling data use and assessment to become an integral part of the regulatory procedure
  - support the implementation of the **target operating model (TOM)** for managing medicinal product data
  - **Replace Art. 57 submission process, data format and data content**



### PMS will change:



- › Enable **IDMP implementation**
- › **Content and format** of authorised medicinal product data used in **DADI web-forms, Art 57 submissions and any other systems** which require product data
- › **Process for Art 57 submission** (*timelines and process to be defined*)



### PMS will NOT change:

- › The process to apply for, submit or approve **Marketing authorisation applications** e.g. eCTD
- › The **legal requirements for Art 57 submission**



# Web forms as part of the Data-centric Target Operating Model

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Karl Hamilton, *Product Lifecycle Management Value Stream Owner, EMA*





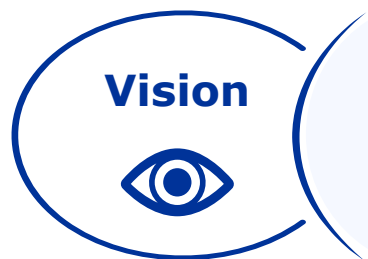
## DADI & PMS

- › Key **enablers** for the implementation of more **digital** and **improved core regulatory procedure management** as part of EMA's digital transformation
- › Both part of **the Product Lifecycle Management (PLM) Value Stream**



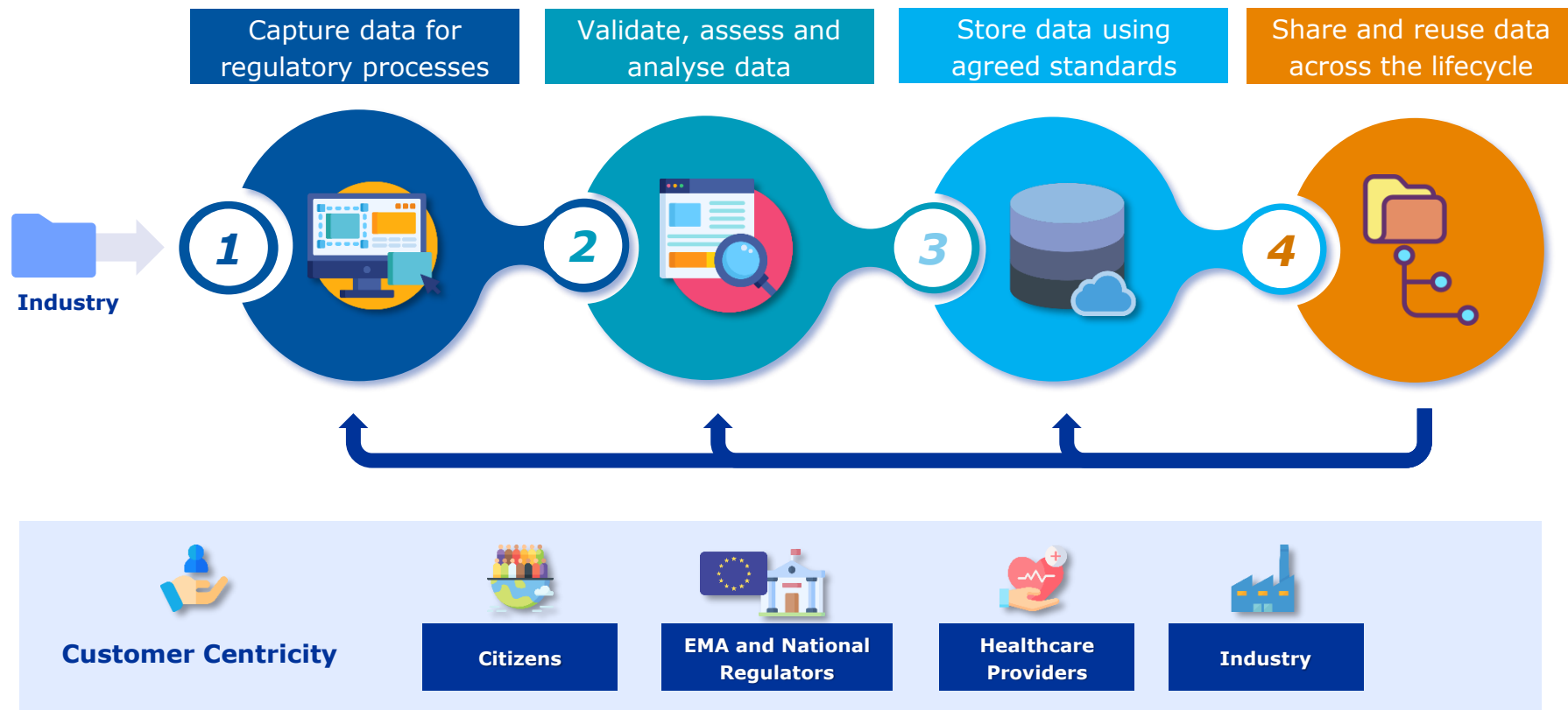
## PLM Value Stream

- › **Single coordination framework** facilitating **improved business** and **IT alignment** on digital transformation of core regulatory processes
- › Fostering strong **collaboration** between **DADI** and **PMS**, in light of the significant **dependencies** between **master data implementation** and **procedure management** and **form implementation**



EMA's aim is to **transform and optimise regulatory procedure management across the product lifecycle**,  
unlocking more value together with our partners and  
stakeholders, for the benefit of public and animal health in the EU

# Moving to a Data-Centric Target Operating Model



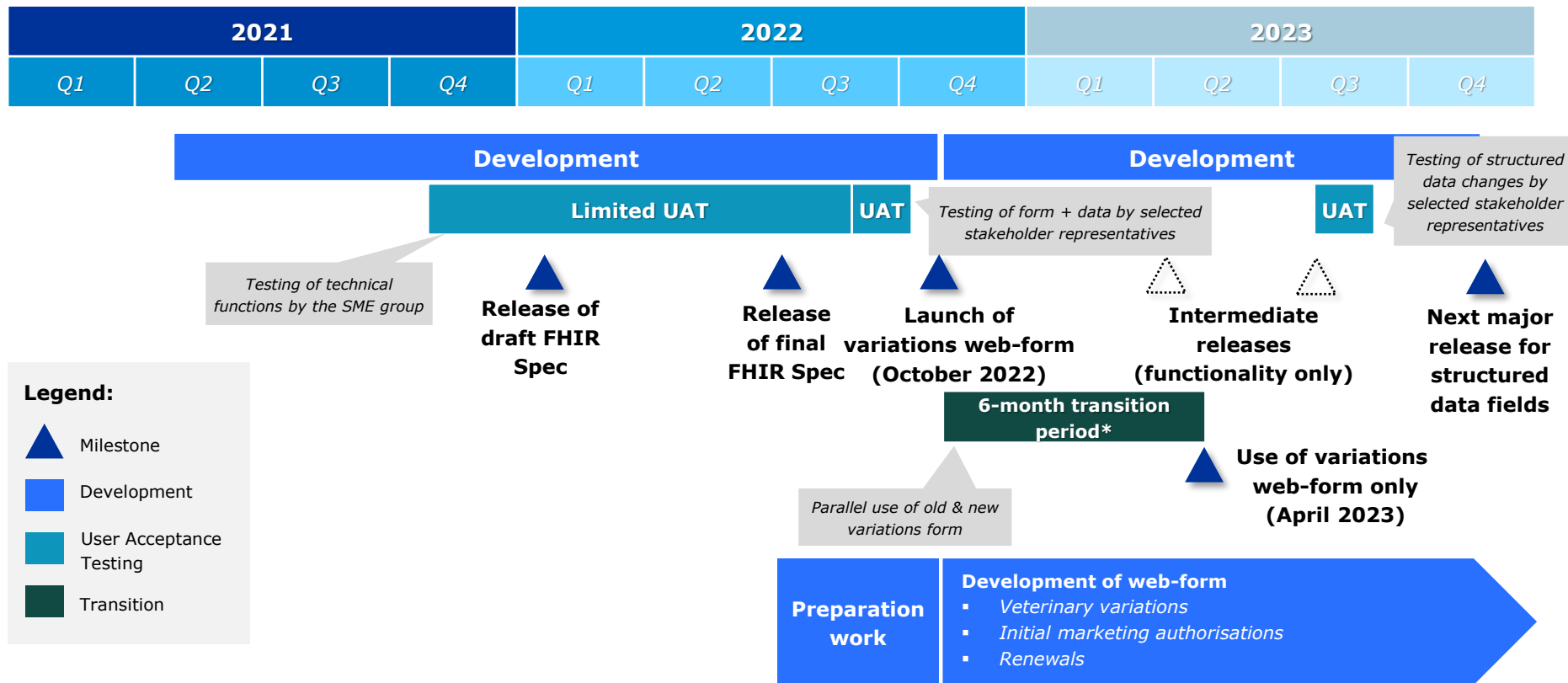


## Human Variations Form Timeline

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Hannes Kulovits, *Product Lifecycle Management Value Stream Manager, EMA*

# DADI Human Variations Form Timeline



\* Any extension to transition periods to be agreed through consultation

\*\* Data cleansing is not part of this timeline as it is not a precondition for the use of H Var form at go-live

## 2022



### Go-Live

- › DADI variations form release/go-live planned for **October 2022**
  - › Create variation forms in a new Web application and export to PDF & IDMP FHIR standard



### Transition

- › **6-month transition period** including early-life support releases i.e., until April 2023 users can use the old electronic Application Forms (eAF) PDF form for variations and/or web-based DADI variations form

## 2023



### Future (+2023)

- › A **second major release eAF variation** before 2024 will allow:
  - › Updating data elements of your products as part of the variation
  - › Reuse variation forms to submit product data to PMS



### Data Cleansing

- › Correction/completing product data previously submitted to xEVMPD is **not required** for the **successful use of the DADI variations forms** delivered in October
- › Capabilities for data cleansing/completion in PMS will be released together with structured product updates within the eAF in 2023



### xEVMPD

- › In the future electronic Application Forms (eAFs) can be used to update Art 57
- › In October 2022 **xEVMPD submissions** will still be required



## Impact for Applicants and Regulators

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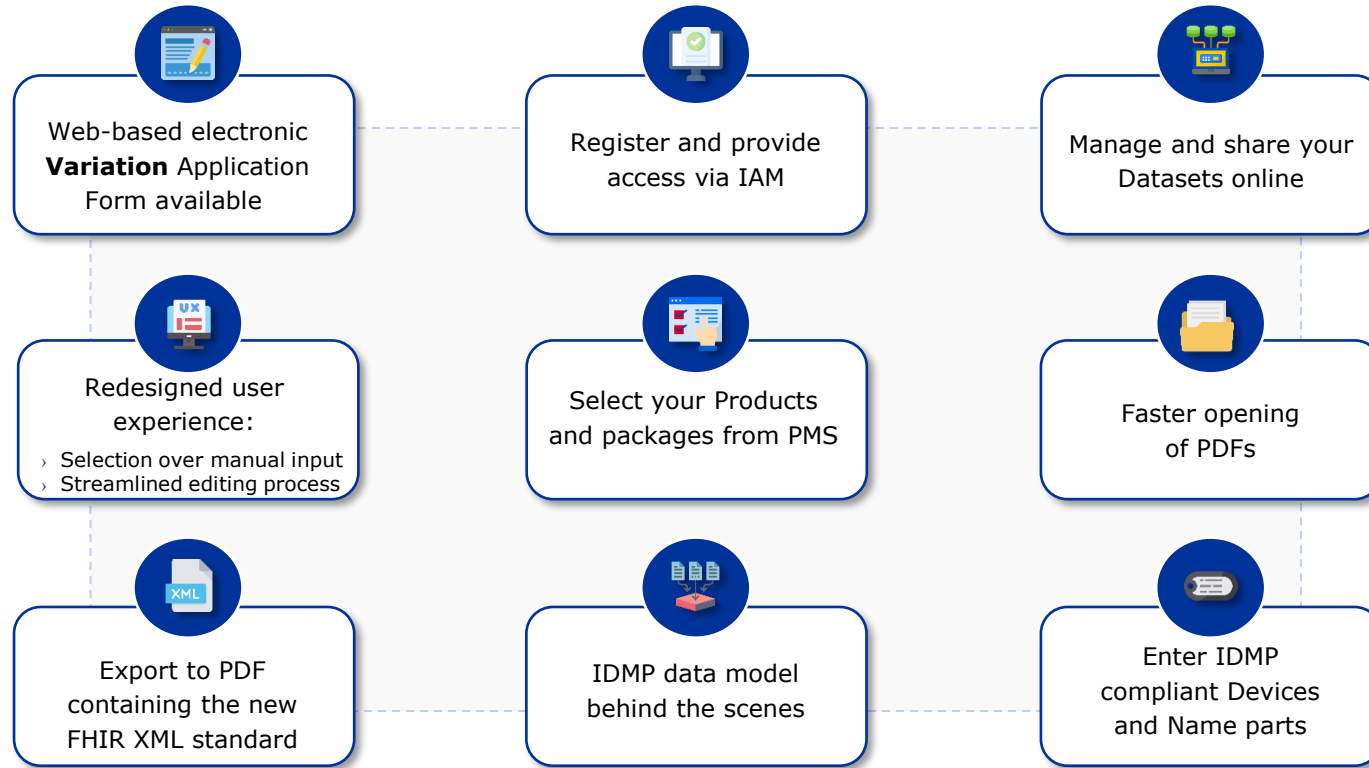
Kristiina Puusaari, *DADI Product Co-Owner, EMA*

Noel Diamant, *DADI Product Co-Owner, AGES/UNICOM\**









Marcos Fernandez, *PMS Product Co-Owner, EMA*

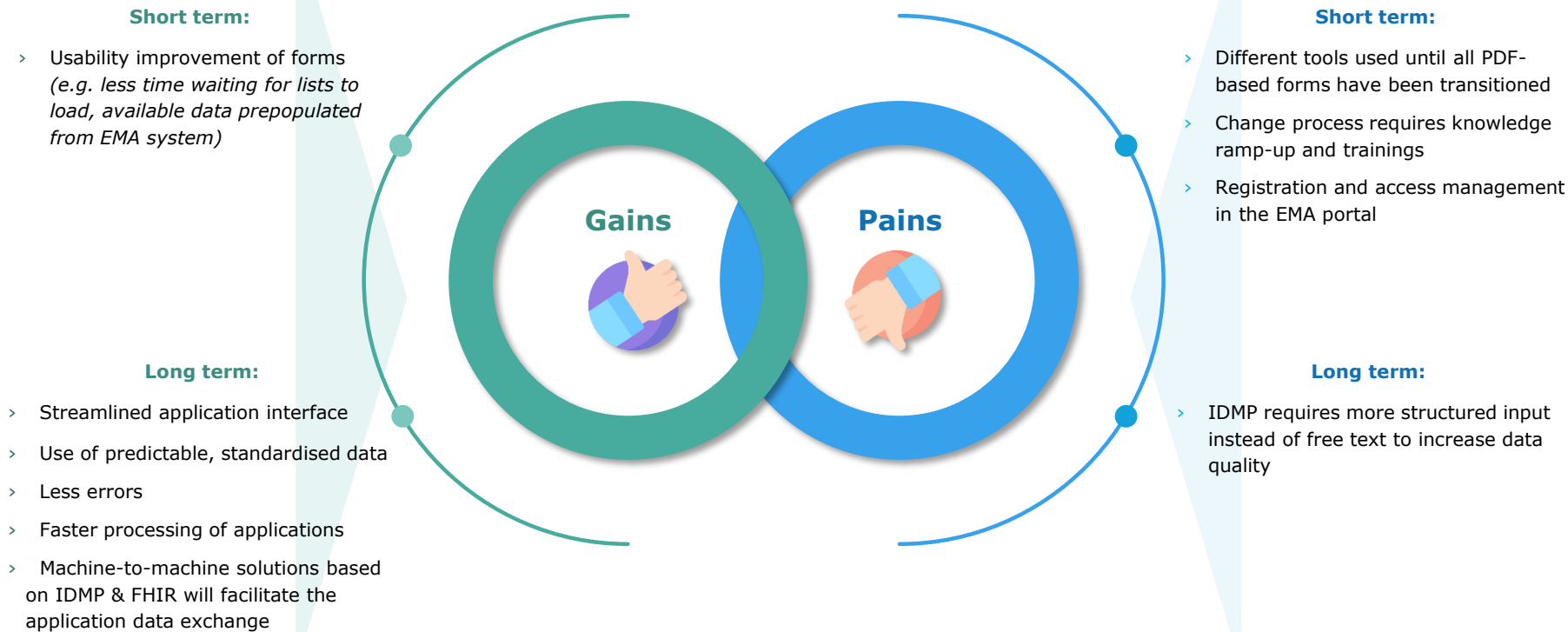
Veronica Lipucci Di Paola, *PMS Product Co-Owner, EMA*












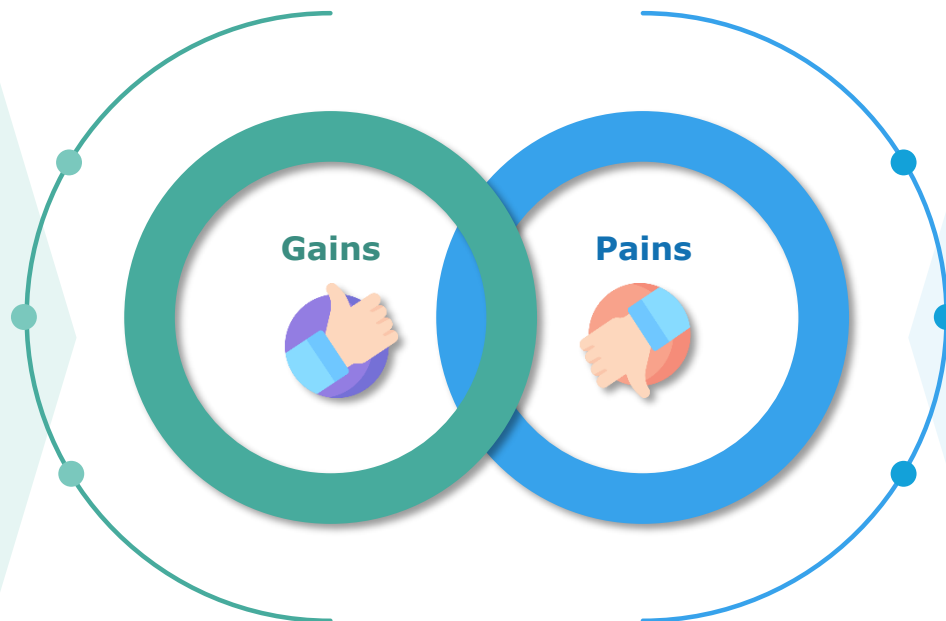


	Applicants 	Consultancies 
Ways of working 	<ul style="list-style-type: none"><li>› Need to register to access application forms</li><li>› Need to choose level of access for users</li></ul>	<ul style="list-style-type: none"><li>› Need to engage with MAH to ensure access is provided to necessary medicinal products</li></ul>
Training 	<ul style="list-style-type: none"><li>› New web application functionalities</li></ul>	<ul style="list-style-type: none"><li>› New web application functionalities</li></ul>
Technology 	<ul style="list-style-type: none"><li>› Compliant web browsers &amp; optional quality of life plugins</li><li>› Manage webforms online instead of document management systems &amp; email</li></ul>	<ul style="list-style-type: none"><li>› Compliant web browsers &amp; optional quality of life plugins</li><li>› Manage webforms online instead of document management systems &amp; email</li></ul>
Data 	<div> <b>In order to use the eAF, all medicinal products must be registered in xEVMPD</b></div> <ul style="list-style-type: none"><li>› <b>Users of an MAH may only select products of their respective organisation</b></li></ul>	<div> <b>Consultancies must be associated to all MAHs in EMA IAM with an appropriate role in order to draft applications for them</b></div>



	Users 	IT Directors 
Ways of working 	<ul style="list-style-type: none"><li>› PDFs opening faster</li><li>› Changes to versions are possible during ongoing procedures</li></ul>	<ul style="list-style-type: none"><li>› Need to follow EMA's agile methodology to adapt to new FHIR releases</li></ul>
Training 	<ul style="list-style-type: none"><li>› Supporting applicants in filling in variation forms requires training of the webform application functionalities</li></ul>	<ul style="list-style-type: none"><li>› Need to build knowledge on FHIR Standard</li></ul>
Technology 	<ul style="list-style-type: none"><li>› No impact</li></ul>	<ul style="list-style-type: none"><li>› Change from DES to FHIR needs to be implemented to import data into regulatory IT-systems</li></ul>
Data 	 <b>Products in section 2 are selected from PMS; Data quality is dependent on xEVMPD</b>	<ul style="list-style-type: none"><li>› Data structures have been refactored to be IDMP compliant</li></ul>

- Enabling more efficient processing, reducing errors and discrepancies
- Easier systems interoperability and data sharing among regulators
- Ensuring standardised data entry, thus making forms easier to process, validate, transmit and re-use
- Implementation fulfills the legal requirement according to pharmacovigilance and extended EMA mandate for IDMP



- Change effort to migrate from DES to FHIR XML standards
- Parallel data standards during transition from legacy DES to FHIR
- Multiple changes expected due to FHIR being a “young” standard
- Full benefits of data import reached only once all form elements are structured and fed back to PMS



## Process at Go-live of DADI Variations Form

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Kristiina Puusaari, *DADI Product Co-Owner, EMA*

Noel Diamant, *DADI Product Co-Owner, AGES/UNICOM\**

Marcos Fernandez, *PMS Product Co-Owner, EMA*

Veronica Lipucci Di Paola, *PMS Product Co-Owner, EMA*





Change(s) concern(s)  
Medical Device

Name and address of the MA Holder<sup>8</sup> ⓘ

Member State

Please select organisation from SPOR QMS to autofill address details.  
If the organisation is not found or the address details are not correct,  
please visit the QMS page in the SPOR portal for more information:  
<http://spor.ema.europa.eu/qms/#/>

Company name

Address

City/Locality/Town/Village

State

County

Postcode

Country

Telephone

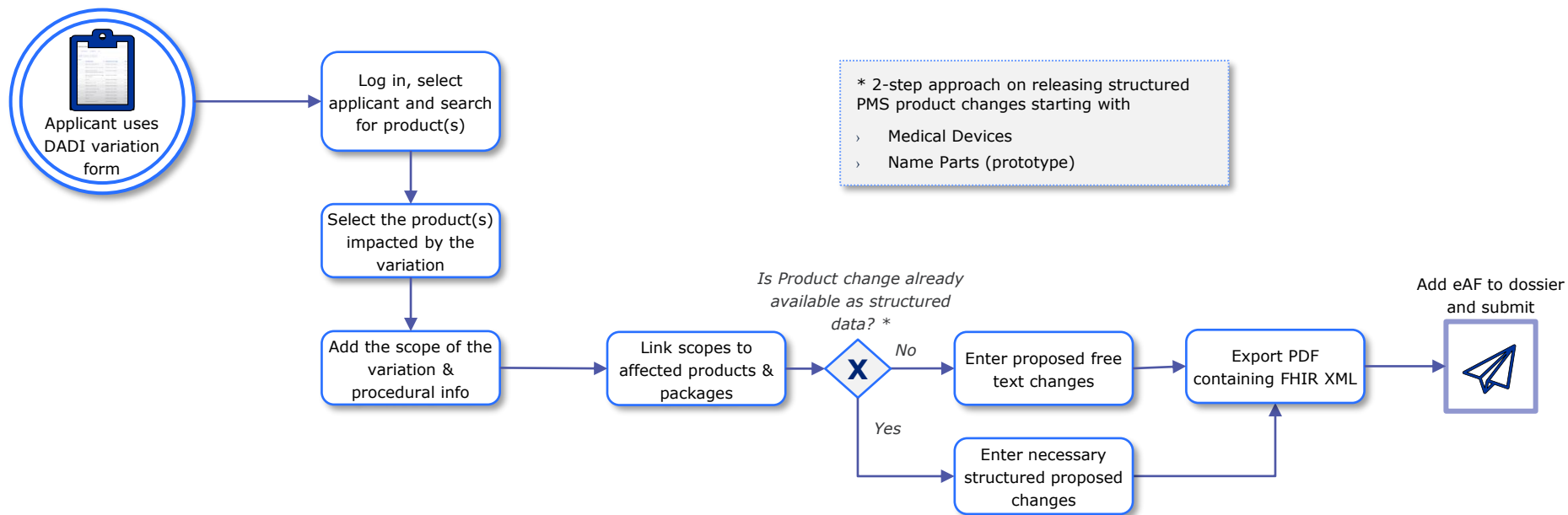
E-mail

Name and address of contact person<sup>8</sup> ⓘ

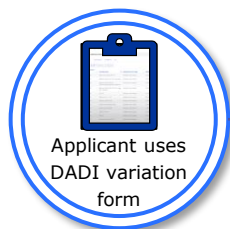
## No change to the business process:

- Submission of eAF
- Evaluation and approval
- Submission to xEVMPD

## Scenario: Drafting the new web-based eAF



## How to select a Product?



Log in, select applicant and search for product(s)

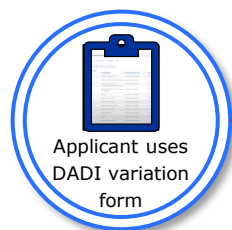
Select the product(s)

\* 2-step approach on releasing structured PMS product changes starting with

- › Medical Devices
- › Name Parts (prototype)

Available Product(s)   Selected Product(s)   All Products									
Column visibility ▾									
Search My Products 🔍									
<input type="checkbox"/>	Name	PMS ID	MPID	Active substance(s)	MA Number	MRP/DCP Number	Marketing Authorisation Holder	Authorisation Country	Authorisation Status
<input type="checkbox"/>	Abacus Control gastro-resistant tablets 66 mg	UAT900000000666	DE-100000833-00000666	Abacosomeprazole	PA1410/066/666	IE/H/0655/666	UAT-LOC11	Federal Republic of Germany	Valid
<input type="checkbox"/>	Hiberix. Haemophilus Type b (Hib) vaccine	UAT00007007	IE-100001573-90000001	Haemophilus Type b (Hib) vaccine	PA1077/027/001		UAT-LOC11	Ireland	Valid - Renewed/Varied





Log in, select applicant and select product(s) for product(s)

Select the product(s) impacted by the variation

Add the scope of the variation & procedural info

Selected Medicinal Product(s)

Column visibility Refresh

Filter

Product Name	MRP / CP Number	MA Number	Authorisation Country	PMS Id	Number of Available Packages
Procysbi 25 mg - Gastro-resistant capsule, hard	EME/H/C/902465	EU/9/13/861	European Union	UAT900000000154	1
Procysbi 75 mg - Gastro-resistant capsule, hard	EME/H/C/902465	EU/9/13/861	European Union	UAT900000000155	1

Showing 1 to 2 of 2 entries

Selected Packaged Medicinal Product(s)

Column visibility Show 50 rows Refresh

Filter

MA Number	MRP / CP Number	PMS ID	Pack Size	Authorisation Status
EU/9/13/861/001	EME/H/C/902465	UAT910000000005	1 gastro-resistant capsule, hard	Valid
EU/9/13/861/002	EME/H/C/902465	UAT910000000006	1 gastro-resistant capsule, hard	Valid

Link scopes to affected products & packages

available as structured data? \*

No

Yes

Enter proposed free text changes

Enter necessary structured proposed changes

Export PDF containing FHIR XML

and submit

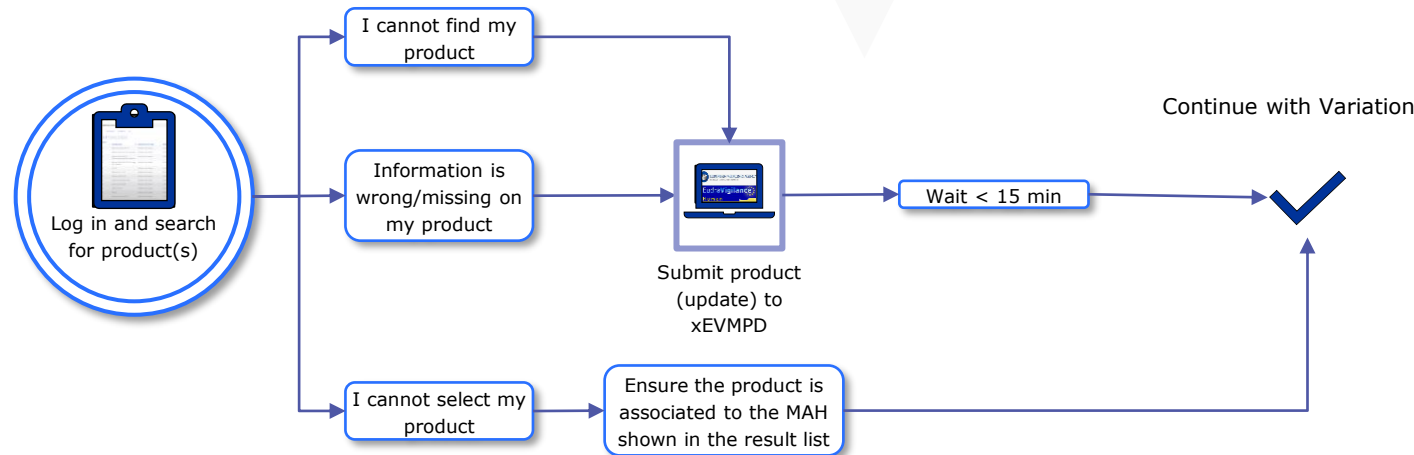


## How to link "presentations" and scopes

# Special case: I cannot select my product



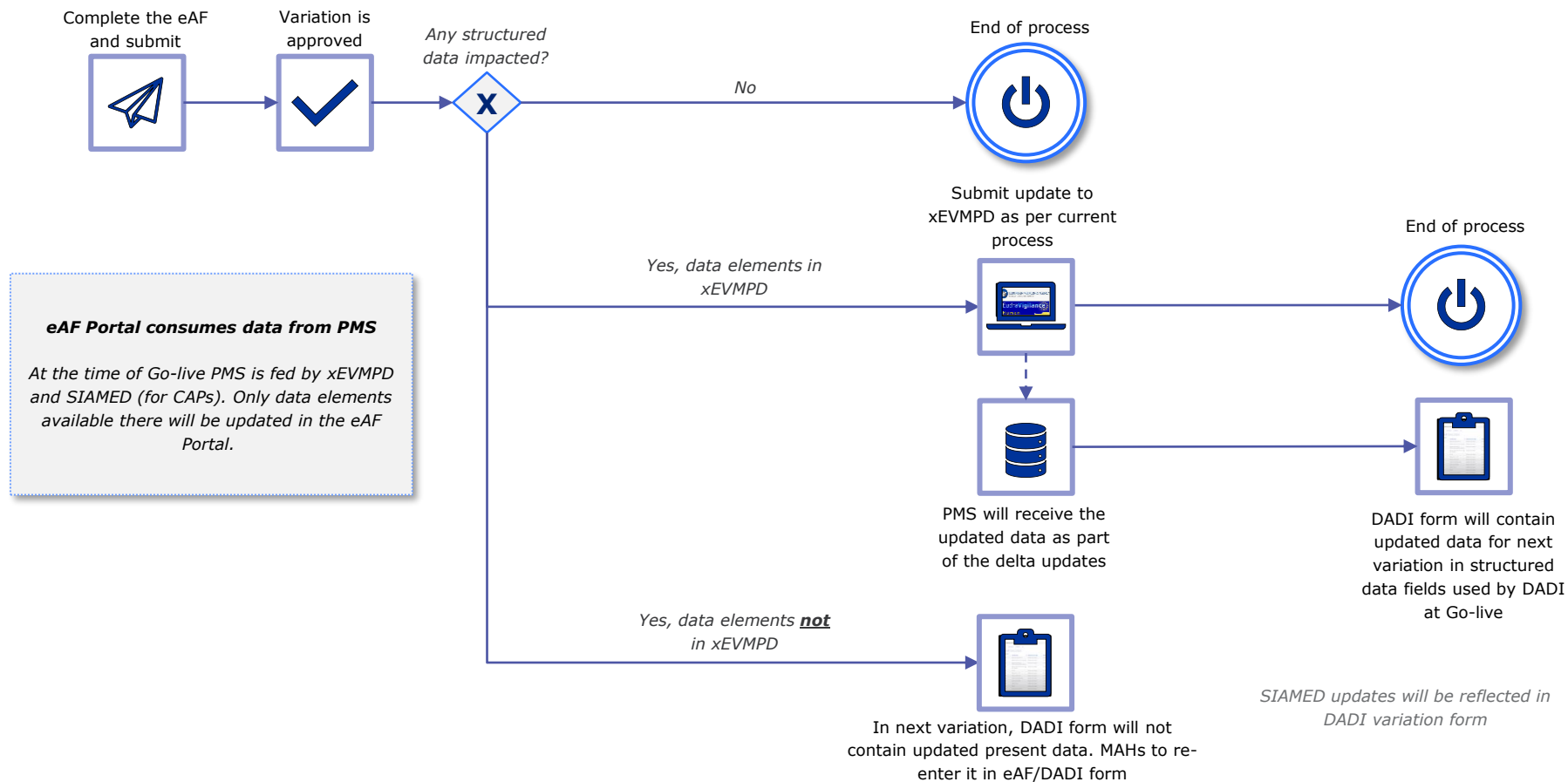
- > To use the eAF Webform the product must be submitted via the EVMPD process
- > Products out of scope today can be created (e.g. herbal, homeopathic, etc)
- > Packages subject to variation (i.e.: with an MA number) have been submitted to xEVMPD
- > MAHs that are already compliant with xEVMPD do not need to provide additional info



# Data provisioning from PMS to eAF at Go-live



EUROPEAN MEDICINES AGENCY





## Name

Invented Name Part as in Art 57. If it is empty the generic name will be used (INN & MAA). Full name of a CAP will be shown in English; MRP / NAP will be shown in the result list in one of the languages submitted to xEVMPD. Search by MA Nr is recommended



## Strength (Name part)

Might be empty as not all products have a strength name part



## Authorised Dose Form

Authorised dose form will be used instead of form name part to search for products



## Domain

Only human products will be shown



## PMS ID

In order to identify the product in PMS



## MPID

The MPID will be shown if available just for information



## Active substance(s)

A concatenated list of all active substances in the composition will be used to group products in the PDF export



## MA Number (product or package)

Often on product level, but where the authorisation number is assigned at Packaged Medicinal Product level and no stable "root number" common to all packaged medicinal products is assigned, the number will only be available at packaged medicinal product level



## MRP/DCP Number



## Marketing Authorisation Holder

Used for access management and prefilling the form



## Authorisation Country



## Authorisation Status

Either explicit or derived from the authorisation status of the packages



## Authorisation type (CP, MRP/DCP or NAP)

Other cases may be identified (e.g., Art 58)



## Nr of Packages

Data currently only available for CAPs and NAPs for specific countries where MA is granted at pack level



## Package size

Data currently only available for CAPs and some NAPs



## 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

## eAF



- > **Web-based variations form** is available
  - ➡ The Users will select the product from PMS and will have **limited number of "structured product data changes"** i.e. enforcing that product data changes are entered in a structured way as per IDMP structure and rules
  - ➡ For 6 months (i.e. until April 2023) users can use old eAF PDF form or web-based DADI form
  - ➡ **Implementation of further "structured product data changes" is planned for 2023**
- > For other procedures, the **existing interactive PDF forms** are in use

## PMS



- > PMS contains data migrated from xEVMPD and SIAMED
- > **No corrections or enrichments need to be submitted**
- > Updates to xEVMPD/SIAMED are reflected in PMS (deltas)

## xEVMPD



- > xEVMPD submissions still required following current process
- > All medicinal products and all packages which are **subject to variations** (have an authorisation number) should already be in xEVMPD to be compliant with Art 57 requirements.  
**Applicants do not need to do extra work if they are already Art 57 compliant.**
- > Some **new MP & packages** not yet in Art 57 scope may be required - all products need to be registered in xEVMPD even those out of scope for Art 57

- > **'Introducing DADI' Webinar presentation**
- > **'Common factors in the FHIR data standard for Art. 57(2) and eAF' Webinar presentation**



- > **Q&A Document**



- > **'Introducing DADI' Webinar recording**
- > **'Common factors in the FHIR data standard for Art. 57(2) and eAF' Webinar recording**



- > **FHIR draft specifications**



- > **System Demo Recording**



- > **Substance and product data management services | European Medicines Agency (europa.eu)**
- > **EU ISO IDMP IG, Chapter 2 Data elements for the electronic submission of information on medicinal products for human use (europa.eu)**







## Q&A Slido Live Session

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



## Closing

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Joris Wiemer, *Change Management Lead, EMA*



## Further information

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

[Substance and product data management services | European Medicines Agency](#)

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

**Telephone** +31 (0)88 781 6000

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