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SCIENCE MEDICINES HEALTH

Variations Form for Human Medicinal Products

What will happen at Go-Live?

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

Agenda

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1	**Welcome / Introduction** 10:00 – 10:10	**Joris Wiemer** *Change Management Lead, EMA*
2	**Web forms as part of the Data-centric Target Operating Model** 10:10 – 10:20	**Karl Hamilton** *Product Lifecycle Management Value Stream Owner, EMA*
3	**Human Variations Form Timeline** 10:20 – 10:30	**Hannes Kulovits** *Product Lifecycle Management Value Stream Manager, EMA*
4	➢ **Impact for Applicants and Regulators** ➢ **Process at Go-live of DADI Variations Form** ○ 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*
6	**Closing** 11:55 – 12:00	**Joris Wiemer** *Change Management Lead, EMA*

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Welcome

Joris Wiemer, *Change Management Lead, EMA*

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DADI Overview

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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)** 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**

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PMS Overview

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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**

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

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

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Product Lifecycle Management

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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**

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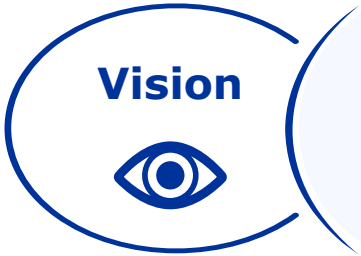
Product Lifecycle Management Vision



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

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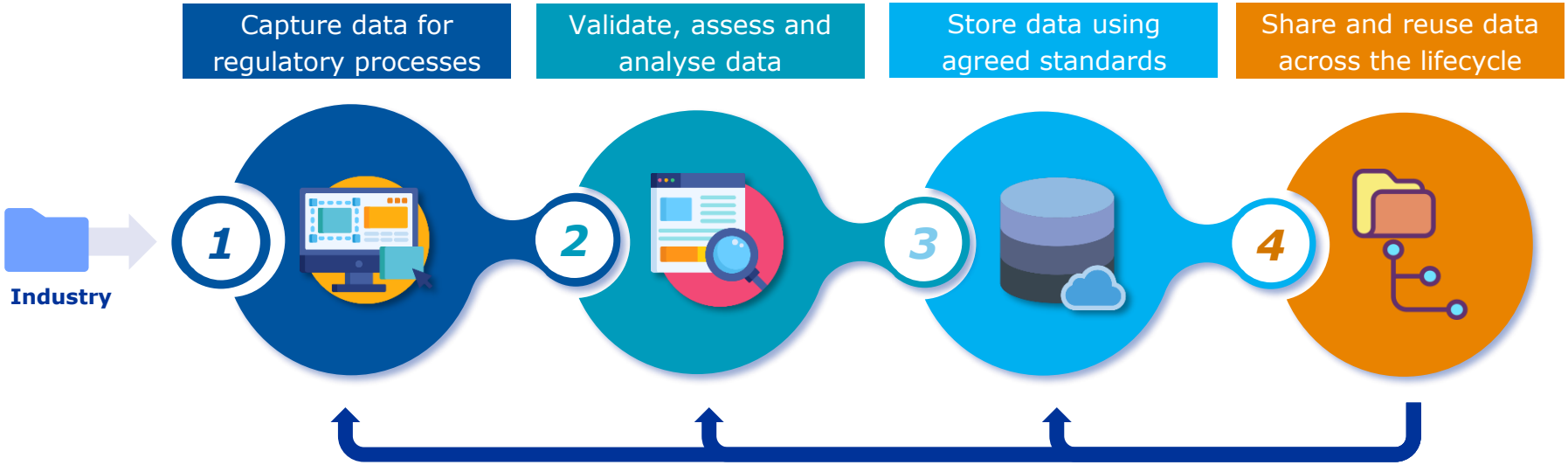
Moving to a Data-Centric Target Operating Model



Customer Centricity

Citizens

EMA and National Regulators

Healthcare Providers

Industry

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Human Variations Form Timeline

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

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DADI Human Variations Form Timeline

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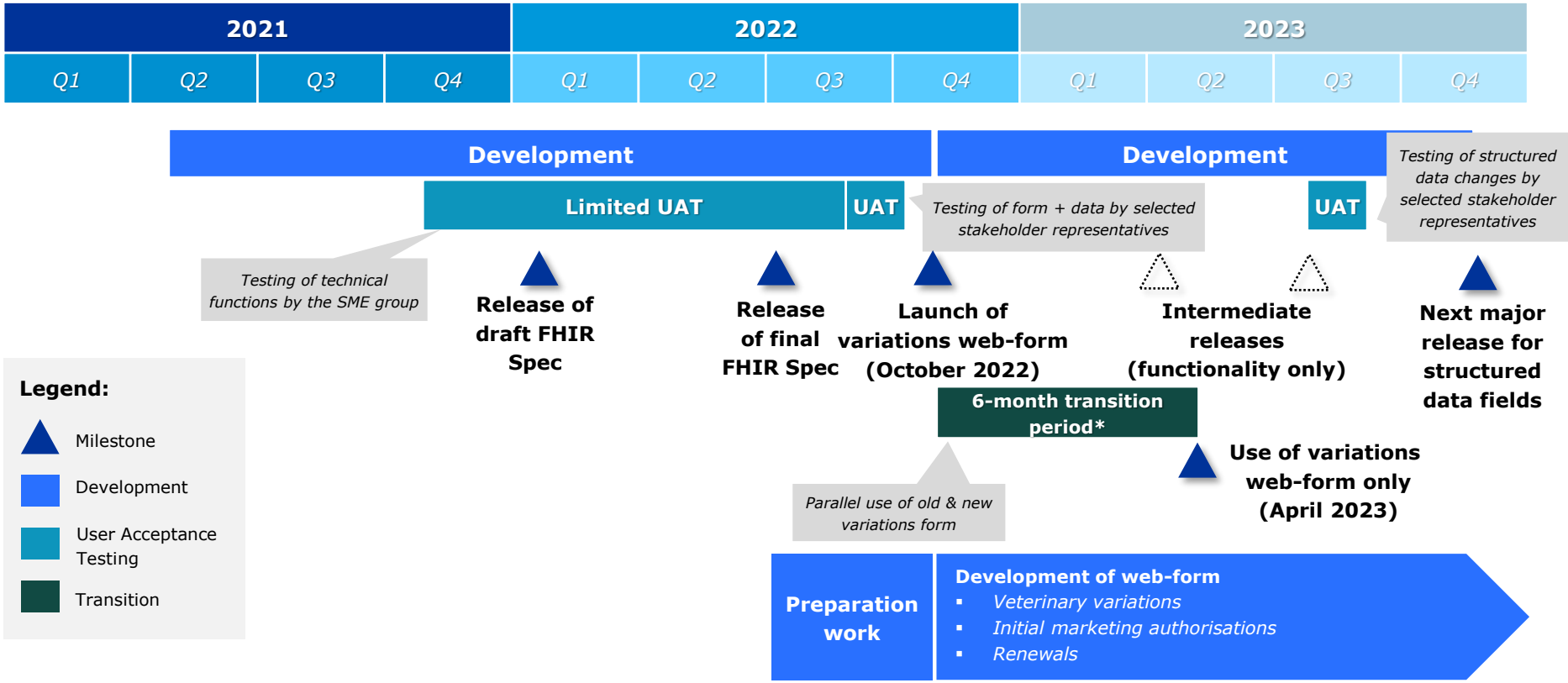

* Any extension to transition periods to be agreed through consultation

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

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Key Points

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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

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Impact for Applicants and Regulators

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*

*The UNICOM Innovation Action has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875299.

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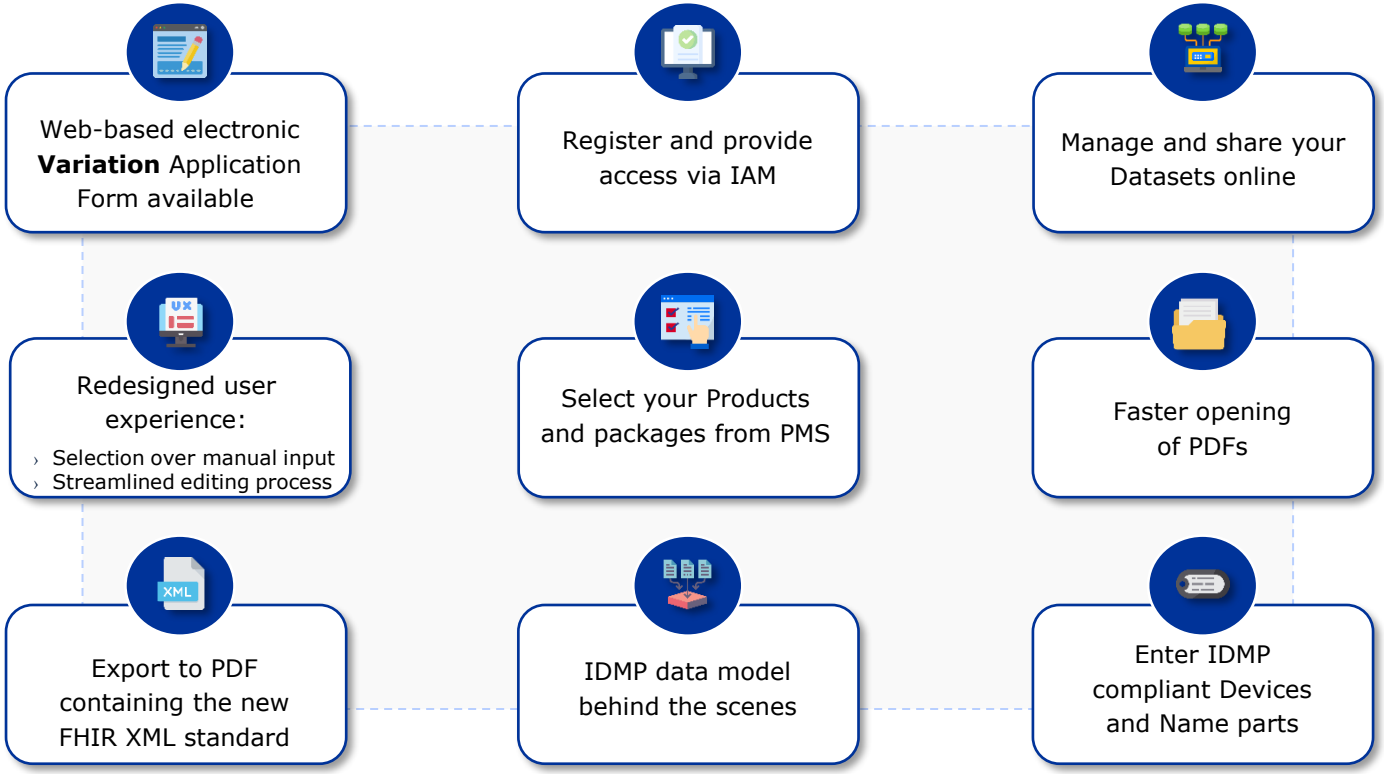
What's new at Go-live?



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Impacts for applicants at Go-live (2022)

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	Applicants	Consultancies
Ways of working	› Need to register to access application forms › Need to choose level of access for users	› Need to 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	**In order to use the eAF, all medicinal products must be registered in xEVMPD** › **Users of an MAH may only select products of their respective organisation**	**Consultancies must be associated to all MAHs in EMA IAM with an appropriate role in order to draft applications for them**

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Applicants gains & pains

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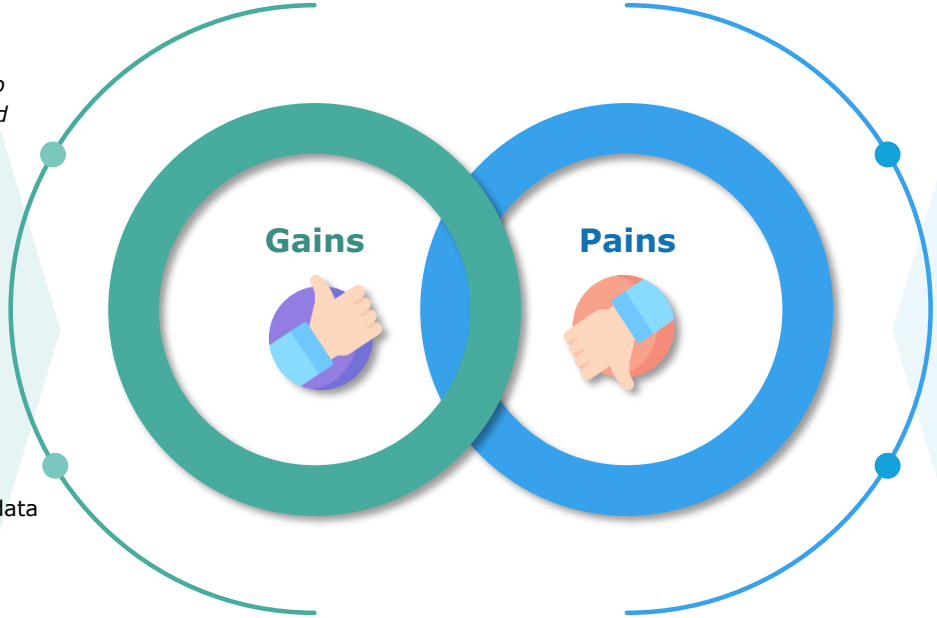
Short term:

- Usability improvement of forms *(e.g. less time waiting for lists to load, available data prepopulated from EMA system)*

Long term:

- Streamlined application interface
- Use of predictable, standardised data
- Less errors
- Faster processing of applications
- Machine-to-machine solutions based on IDMP & FHIR will facilitate the application data exchange



Short term:

- Different tools used until all PDF-based forms have been transitioned
- Change process requires knowledge ramp-up and trainings
- Registration and access management in the EMA portal

Long term:

- IDMP requires more structured input instead of free text to increase data quality

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Impacts for regulators at Go-live (2022)

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	Users	IT Directors
Ways of working	› PDFs opening faster › Changes to versions are possible during ongoing procedures	› Need to follow EMA's agile methodology to adapt to new FHIR releases
Training	› Supporting applicants in filling in variation forms requires training of the webform application functionalities	› Need to build knowledge on FHIR Standard
Technology	› No impact	› Change from DES to FHIR needs to be implemented to import data into regulatory IT-systems
Data	**Products in section 2 are selected from PMS; Data quality is dependent on xEVMPD**	› Data structures have been refactored to be IDMP compliant

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Regulators gains & pains

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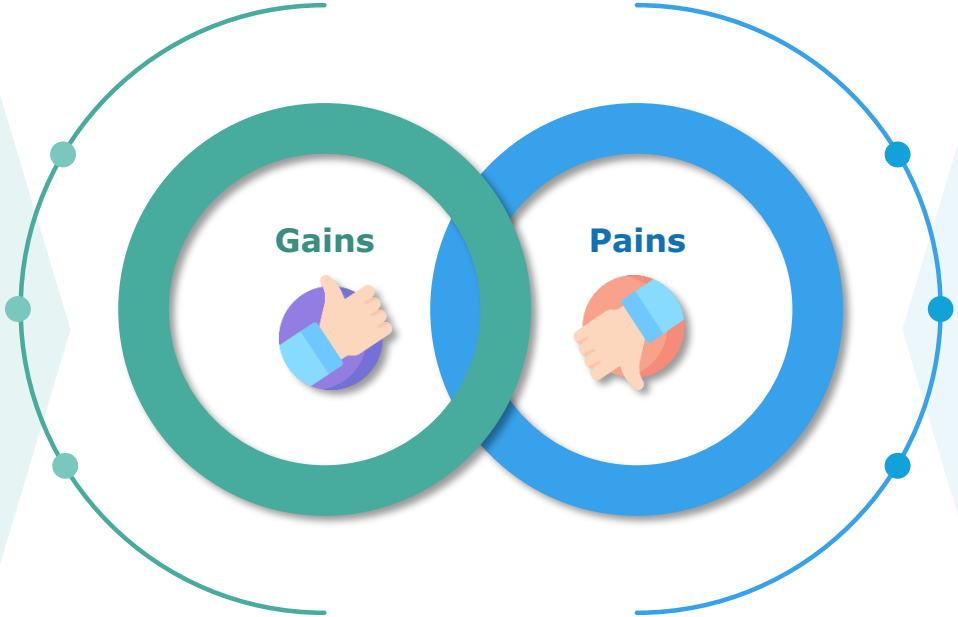
- Enabling more efficient processing, reducing errors and discrepancies
- Easier systems interoperability and data sharing among regulators
- Ensuring standardised data entry, thus making forms easier to process, validate, transmit and re-use
- Implementation fulfills the legal requirement according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

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Process at Go-live of DADI Variations Form

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

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

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

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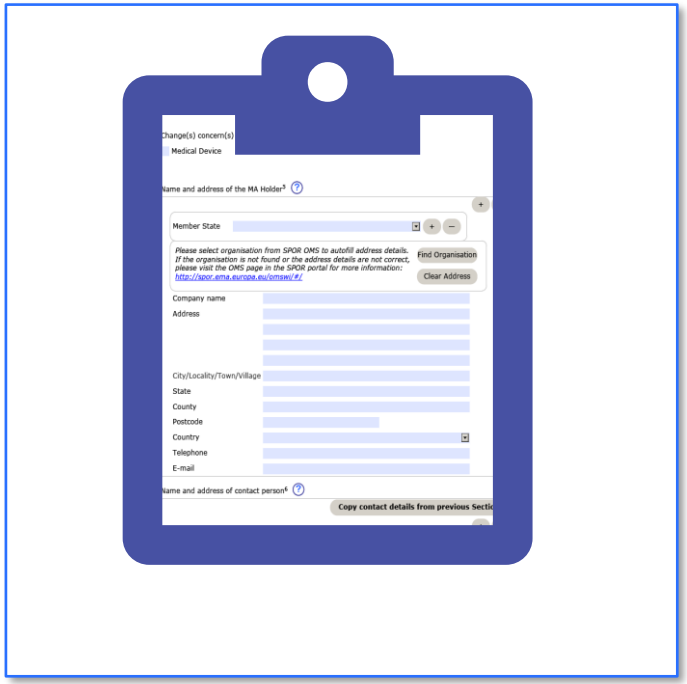
Process at the moment after Go-live



No change to the business process:

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

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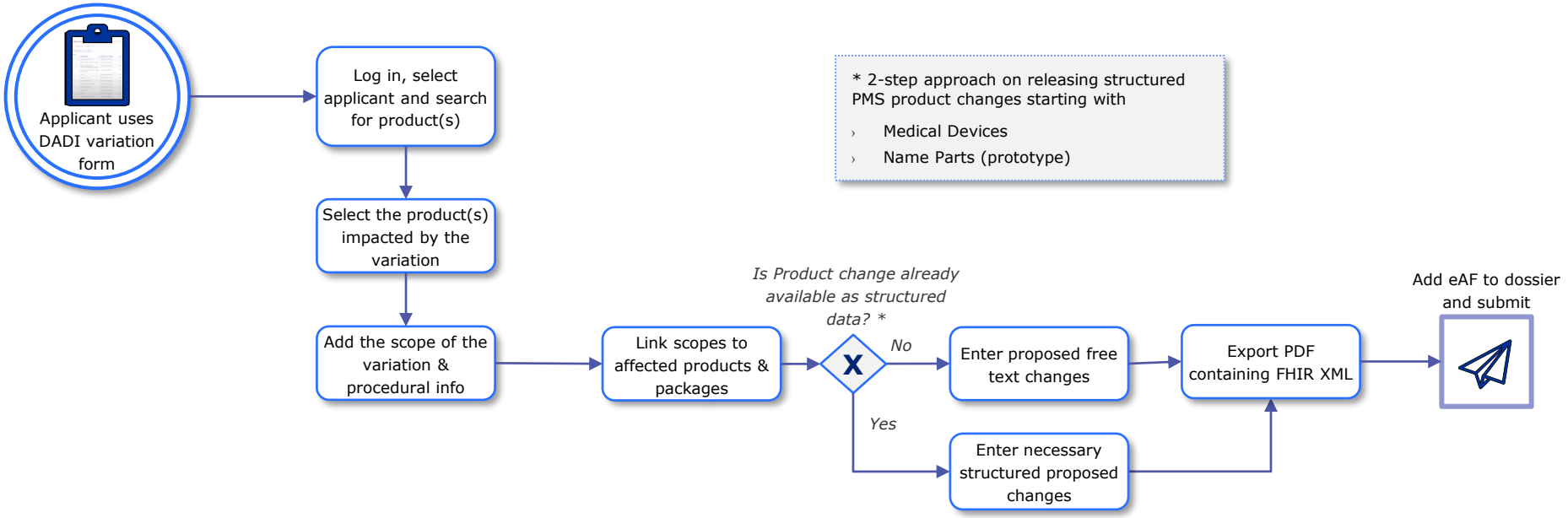
Scenario: Drafting the new web-based **eAF**



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How to select a Product?

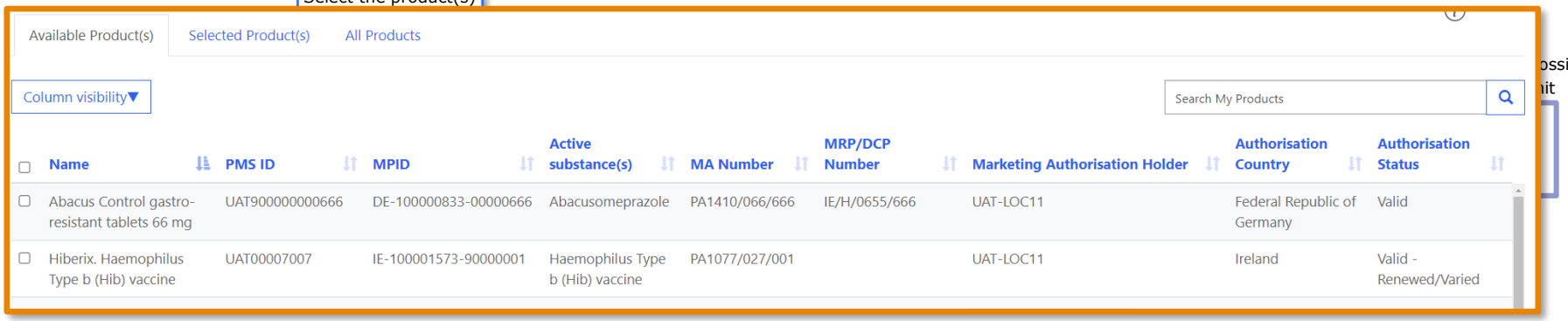
Applicant uses DADI variation form

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)



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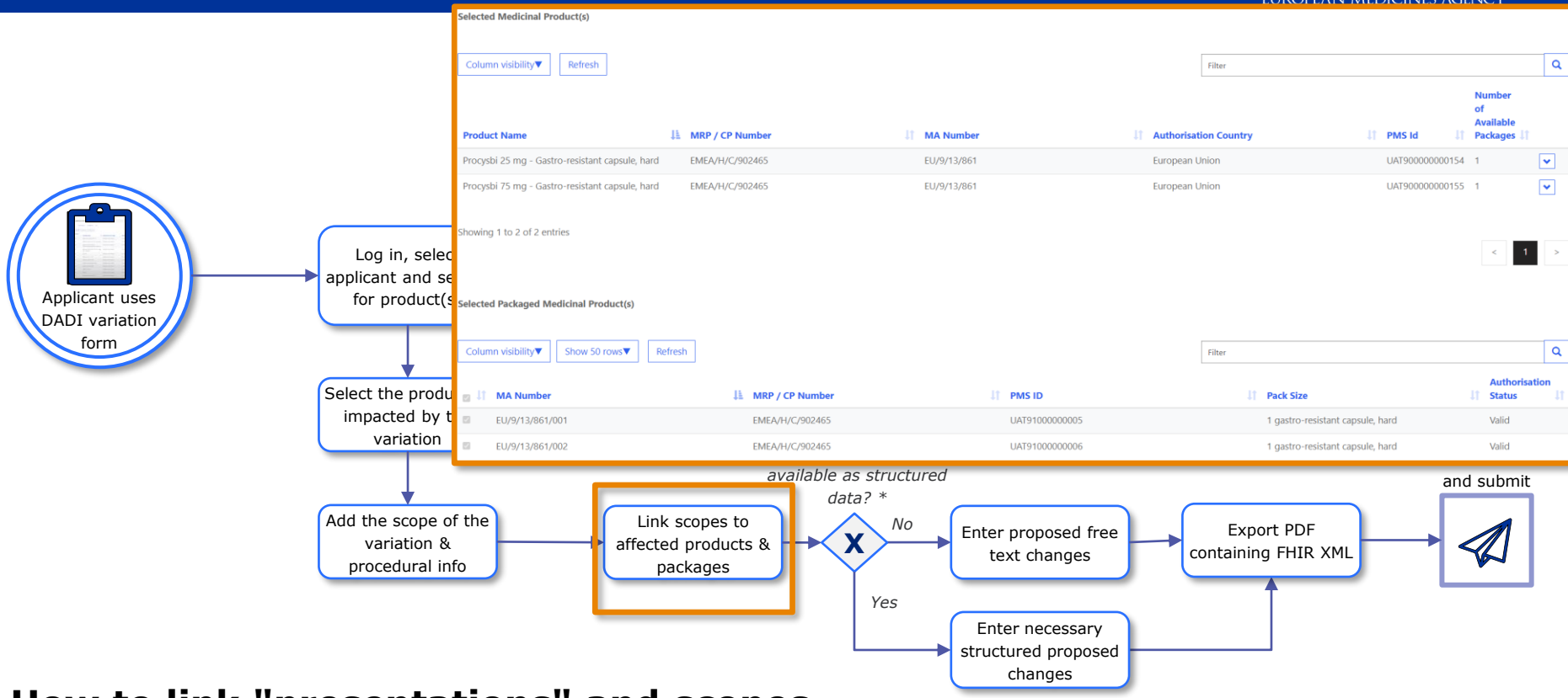
Drafting a variation after Go-live



How to link "presentations" and scopes

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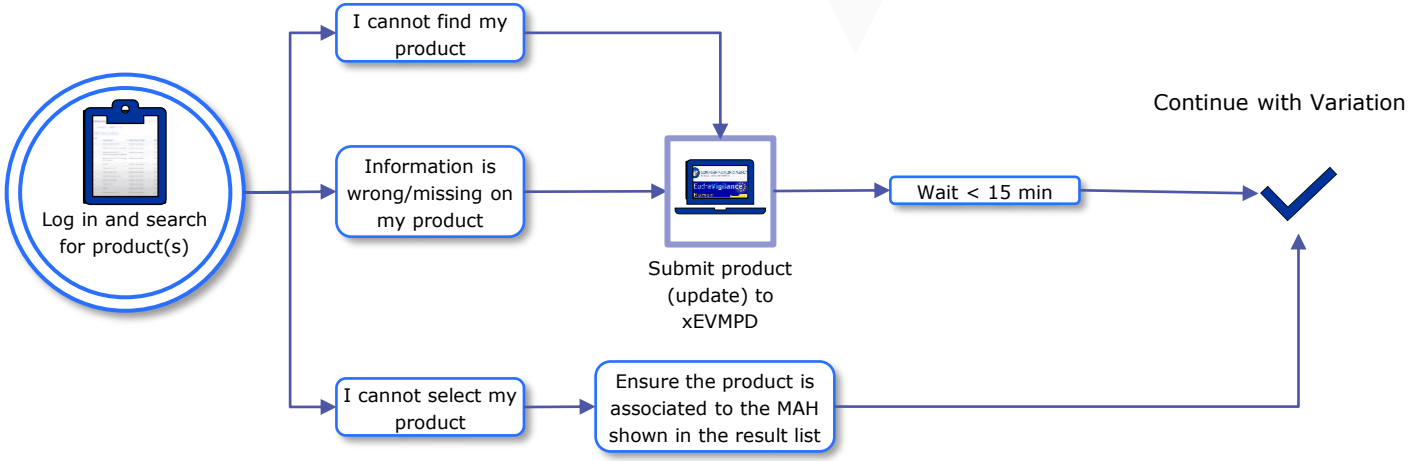
Special case: I cannot select my product

- 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



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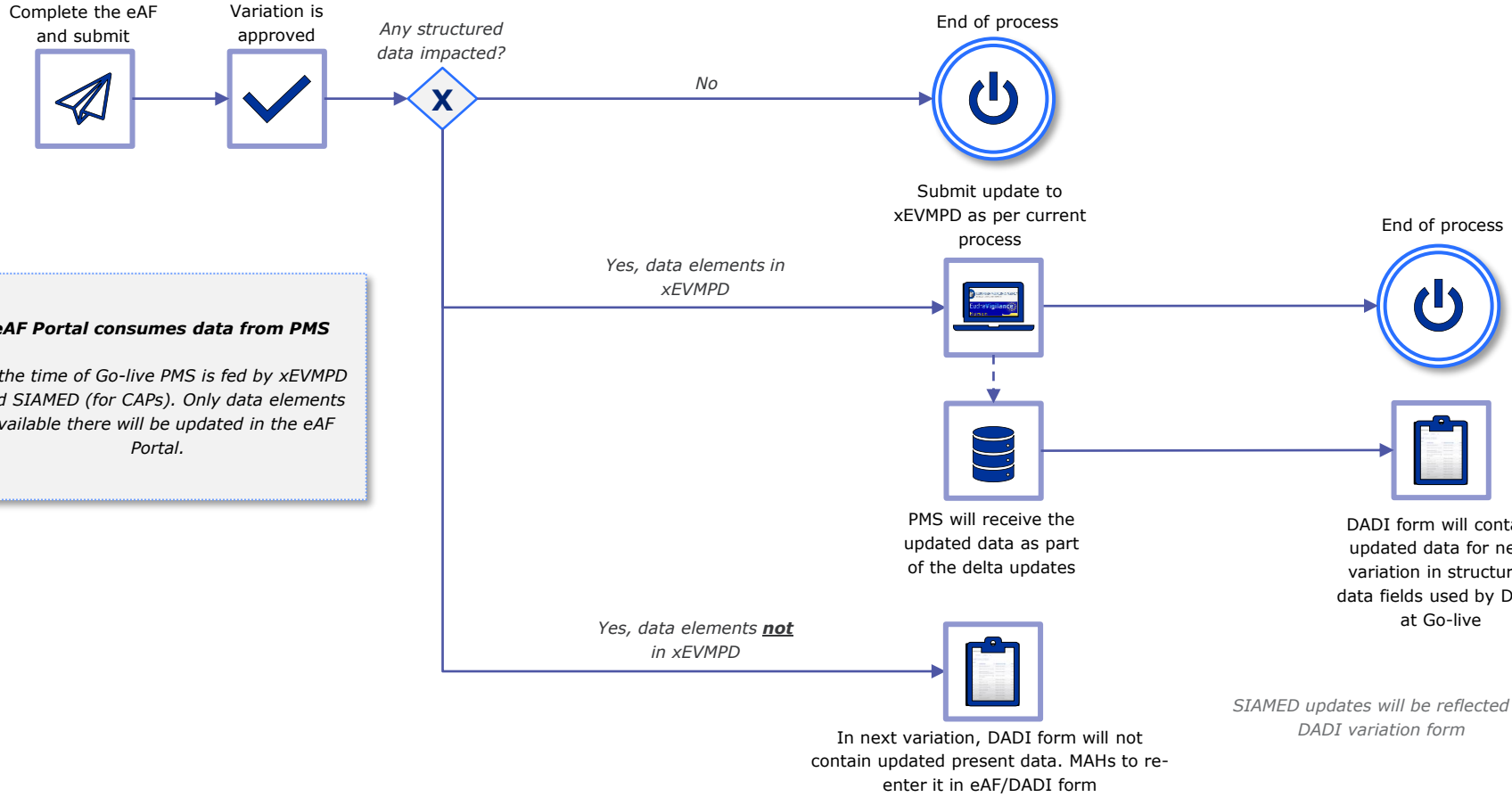
Data provisioning from PMS to eAF at Go-live



eAF Portal consumes data from PMS

At the time of Go-live PMS is fed by xEVMPD and SIAMED (for CAPs). Only data elements available there will be updated in the eAF Portal.

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Data used from PMS (1/2)

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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

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Data used from PMS (2/2)

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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

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Conclusions

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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

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Useful links

- '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)

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Q&A Slido Live Session

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

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Closing

Joris Wiemer, *Change Management Lead, EMA*

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Further information

http://esubmission.ema.europa.eu/cessp/cessp.htm
Substance and product data management services | European Medicines Agency

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