03 **Issue 3**
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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eAF-PMS NEWSLETTER

News, views and interviews for the informed stakeholder
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IN THIS ISSUE

eAF Updates

Human Variations electronic application form

This 3rd edition of the eAF-PMS Newsletter highlights the latest news, upcoming events and activities planned for the next months. An updated **timeline** of the web-based **Human Variations electronic application form** (eAF) accessible from the **Product Lifecycle Management (PLM) Portal** is now available to all interested stakeholders. The timeline highlights important milestones to be achieved in the upcoming months with regards to the release of new functionalities, User Acceptance Testing (UAT) and start of the transition period. A version of the timeline highlighting impacts on the eAF users in the different periods is also available for consultation.

If you are interested in the progress of national Identification of Medicinal Product (IDMP) implementation strategies, the **UNICOM* consortium** scheduled several webinars and events European National Competent Authorities (NCAs) can join to build the necessary competencies to take the appropriate decisions for the imminent IDMP implementation journey.

Regarding Product Management Services (PMS), a new Network Product Owner joined the team and will support the implementation of the product in cooperation with the previously appointed Network and Industry Subject Matter Experts (SMEs). You can find an overview of the priorities identified for the next quarter within this issue.

EMA (European Medicines Agency) has hosted several webinars and shared regular updates on the Human Variations eAF, as well as hosted a User Acceptance Testing and trainings. Many more will follow in the coming months. Furthermore, there are several resources such as Guidance and Q&A documents already available to help users familiarise themselves with the web-based form and the PLM portal.

In this newsletter you will find a summary of what has been shared so far and what you can expect in the coming period. In particular, the eAF and PMS product teams are pleased to announce a joint webinar on the NAPs release on the PLM Portal, scheduled for 8 June 2023. All business and technical audiences working for industry and national competent authorities that are interested in learning more are invited to attend the session.

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

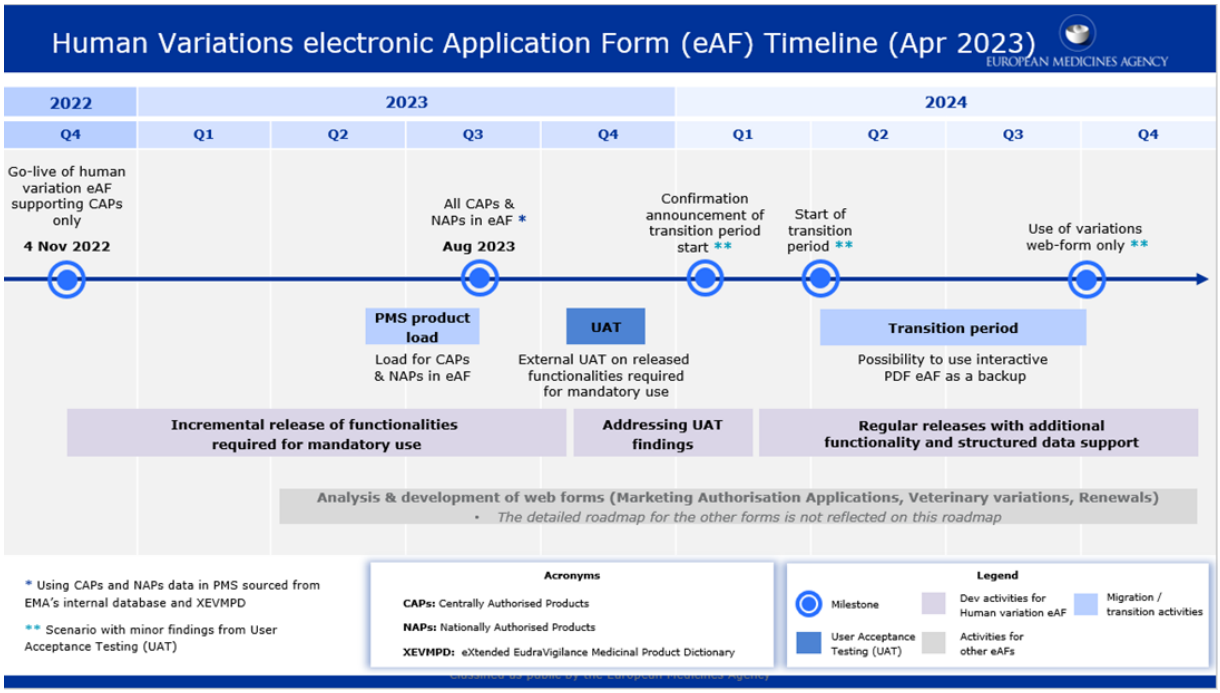
Human Variations eAF Updated Timeline

The timeline below details key milestones and activities towards eventual mandatory use of the **web-based Human Variations electronic application form** (eAF), expected in 2024.

Please note in particular the following periods and activities:

June 2023	Start of data transfer – Centrally Authorised Products (CAPs) and National Authorised Products (NAPs) for use in eAFs – the first NAPs products will appear in the eAF. This will allow users to start preparing web-based eAFs for NAPs as these products become gradually available on the PLM Portal;
August 2023	Expected completion of data transfer – all CAPs and NAPs available in eAF;
November 2023	UAT on the version of the web-based eAF intended to replace the PDF and
Q1 2024	Confirmation of transition period start date, approximately 2 months in advance. This is subject to a successful outcome of the UAT;
Q2 2024	Start of 6-months transition to mandatory use of web-based eAF for Human Variations. This is subject to a successful outcome of the UAT. Note that the transition period may start earlier, if feasible, respecting the 2-month advance notice period.

Human Variations eAF Updated Timeline



The **updated PLM Portal web-based eAF for Human medicinal products release timeline** is also available on the eSubmissions website.

The site also contains an **annotated version of this updated timeline** (2nd page of the document) which details the impacts to eAF users in the different periods, as supplementary information.

Please note:

- EMA's eAF development team is incrementally releasing functionalities required for mandatory use: all required functionalities will already be publicly available on the PLM Portal before the start of the UAT.
- The use of the web-based eAF will follow the current process for updating data. EAM will implement the use of structured data at a later point.
- The eAF development team is developing the capability to view migrated PMS product data in the Product User Interface on the PLM Portal in parallel – and EMA will announce delivery timelines at a later date.
- The eAF development team will share in due course the details on the organisation and structure of the UAT.

Learn about National IDMP implementation strategies and FHIR through UNICOM

UNICOM continues its exploration of National IDMP implementation strategies and wants to further reinforces the knowledge of FHIR® related to Medicinal Products within all European agencies. You are most welcome to attend UNICOM's next webinars:

- May 24 12.00 PM CEST: **Norway** in focus: REGISTER
- June 2 10.00 AM CEST- Advanced **FHIR training**: how to track changes on a medicinal product?: REGISTER
- June 26 14.00 PM CEST: **Spain** in focus: REGISTER

You may still have access to the previous country knowledge transfer (Ireland, Estonia, Sweden, Croatia, Belgium) and the previous FHIR trainings webinars (the Medicinal Product part of FHIR , FHIR on Variations, Top 10 most wanted IDMP fields) on the UNICOM YouTube channel.

Book the date! On **November 28th,** UNICOM invites all European NCAs in **Ghent (Belgium)**. During this face-to-face event, UNICOM intends to bring to all the European NCAs (and eHealth) Communities the experience, resources and extended knowledge developed by the project and its individual members. The objective is to help each European country to take the appropriate and timely decisions in its now imminent IDMP implementation journey. The IDMP journey requires a lot of (new) competencies, and we believe that a representation of both IT and Business from each agency would be very much beneficial.

During its last year of activity, UNICOM will put the resources developed by the project to the test, establishing a much needed but still often missing concrete link between the regulatory and the clinical domains. The **UNICOM FHIR implementation guide** is available to all and contains a lot of trustable and directly usable information, such as example data with a unique visualiser.

The UNICOM Medicinal Products Pilots List which is an IDMP compliant database constituted with inputs from several national agencies is educational in identifying national gaps and will help to demonstrate further the added value of IDMP in multiple contexts.

UNICOM

PMS News

PMS Network Product Owner nomination

Following the call launched in September 2022 for expressions of interest to join the PMS product team in the **role of Network Product Owner (NPO)**, nominations received have been reviewed against the scope, requirements and expertise as defined in the call for interest and the Portfolio Board, in dialogue with the HMA representatives in NPAG, have determined the suitability of the candidates.

As a result, PMS team is pleased to welcome the **National Competent Authority (NCA) representative Dino Soumpasis** to the product team in the role of Network Product Owner.

With this appointment, the current roster of product owners, Network SMEs and Industry SMEs for PMS is complete.

PMS Priorities for Q2 2023

- PMS Team is working on the release of the **PMS technical FAQs** in which several PMS data-related questions received by external stakeholders and future PMS users will be addressed. The document will be released on the PMS webpage in June 2023.
- EMA PMS Development Team will release further **updates to Chapter 7 of the EU IDMP Implementation Guide** based on the results of latest UAT and minor corrections. This additional update will be published in June 2023 upon completion of the activities related to the release of CAP and NAP data in PMS to support the eAF (DADI) product.
- The PMS development team will organise a series of **public events** (list available in the eAF-PMS events section— page 5) to update the audience on PMS progress and answer questions from the audience.
- **PMS data** coming from xEVMPD ready for release to **production in PLM Portal** at the end of Q2 2023 to support Human Variations eAF.
- Completion, analysis and bug fixing of potential issues identified as result from eternal UAT on xEVMPD Delta. This activity will support the update of Chapter 7 on data migration.

Relevant PMS material

The updated Chapter 7 of the **EU IDMP Implementation Guide (EU IG)** was released on the EMA website on 18 January 2023.

This version provides information on the approach followed by the EMA to enable the transformation, migration and availability of authorised product data to the PMS.

Specifically, Chapter 7 now describes the following aspects:

- migration rules of CAP data into PMS;
- migration rules of NAP data into PMS;
- match and merging rules of data from SIAMED II and XEVMPD;
- the Art.57-SIAMED II-PMS data mapping, including the transformation rules that will be applied to the data during the migration into PMS.

The publication of Chapter 7 replaces the previously released Annex I to Chapter 7.

eAF– PMS events

Latest events

- **Human variations eAF public training** (2 February 2023)
  - Recording
  - Presentation

This event was a training webinar for industry and national competent authorities' stakeholders wishing to learn more about the use of the new PLM portal and web forms features after the go-live.

- **Product Management Service (PMS) Webinar on Data Migration** (23 February 2023)
  - Recording
  - Presentation

This webinar was intended for business and technical audiences working for industry and national competent authorities that are interested in learning more about data migration activities from SIAMED and XEVMPD databases to PMS.

- **Public System Demo** (22 March 2023)
  - Recording
  - Q&A Document

Future events

- **PLM Portal Access Management Training for Marketing Authorisation Holders (MAHs) with NAPs** (25 May 2023, 11:00 – 12:30 (CEST))

This webinar is intended for Marketing Authorisation Holders (MAHs) with Nationally Authorised Products wishing to receive training on PLM Portal Access Management.

Please find here the registration link.

- **Webinar Product Management Service (PMS) Progress** (30 May 2023, 10:00 – 11:30 (CEST))

This webinar is intended for business, developers and technical audiences working for industry and national competent authorities that are interested in learning more about the Product Management Service (PMS) development progress and related activities.

The webinar will be an occasion for the audience to meet the PMS Product Owners ask questions and learn more about the deliverables achieved to support web-based electronic Application Forms (eAFs) as well as the planned PMS activities driving the implementation of PMS ISO IDMP.

Please find here the registration link.

- **eAF-PMS Joint Webinar on PMS Data Go-live on PLM Portal** (8 June 2023, 10:00 – 11:30 (CEST))

This webinar is intended for business and technical audiences working for industry and national competent authorities that are interested in learning more about the Product Management Service (PMS) data release on the PLM Portal between the end of Q2 2023 and beginning of Q3 2023.

Please find here the registration link.

- **Public System Demo** (22 June 2023 – Live Broadcast on EMA YouTube Channel)

A system demo is a ceremony held at the end of a three-month period of work to demonstrate the developments achieved in that period and collect stakeholder feedback.

Participants have the opportunity to review what has been delivered, comment and ask questions on future product increments (planned chunks of work on the final system). EMA will demonstrate developments with several products including eAF and PMS.

eAF Useful material

Training material

User guidance

The updated versions of **eAF User guidance** documents are now available from the Product Lifecycle Management Portal:

- **eAF guide to registration**
- **eAF guide to navigation**

The **guide to registration** provides support to users of the PLM Portal in completing the registration steps needed to access the platform. Most of these steps are independent from the PLM Portal eAF and correspond to those needed to register to use other European Medicines Agency (EMA) systems.

The **guide to navigation** shows users how to access the PLM Portal eAF, as well as prepare application forms. It describes some current known issues in the form functionality and aims to provide workaround solutions. Please share any feedback you may have as this guide is updated regularly.

Training videos:

Training	
eAF public training session 2 September 2022	Access here
Human variations eAF Form (DADI) training session 8 November 2022	Access here
How to monitor Application Forms Status on the PLM Portal	Access here
How to select the scope of the variation application on the PLM Portal	Access here
How to fill in the "Procedural Information" section of the eAF on the PLM Portal	Access here
How to fill in the "Additional Information" section of the eAF on the PLM Portal	Access here
How to fill in the "Finalisation" section of the eAF on the PLM Portal	Access here

Release Notes:

The **PLM eAF Release notes** list and briefly describe the new features and fixed issues included in each release of the PLM Portal. The most recent release appears first.

The known issues are categorised per component or business process of the system so that users can easily identify which issues are relevant for them.

Q&A Documents:

- **Joint eAF (DADI)-PMS general Q&A document**

A joint eAF (**DADI) and PMS Q&A Document** is available from the eSubmission website and the PMS web page. Given their interdependencies, this updated version of the Q&A document includes questions related to both eAF (DADI) and PMS.

For questions or comments around the content of the Q&A document, please raise a ticket (by selecting "Ask a question" and including in the subject "eAF Q&A") via the **EMA Service Desk**.

- **Human Variations eAF-PMS Frequently Asked Questions (FAQs) document**

This eAF-PMS Frequently Asked Questions (FAQs) document is based on questions frequently asked during the Human Variations eAF Q&A Clinics (15 November 2022, 22 November 2022, 29 November 2022, 14 December 2022, 19 December 2022) and Trainings (8 November 2022, 15 December 2022).

Please note that this document is for information only and it will be updated regularly.

- **eAF trainings Q&A document**

This event is a training webinar for industry and national competent authorities' stakeholders wishing to learn more about access management aspects related to the new dedicated portal and the procedure to fill in a web-based eAF at go-live.

Support

eAF Forum

The **eAF Forum** is a public platform where users can stay up to date on the latest eAF news (e.g., new eAF features, release information, known issues), ask each other questions, provide suggestions, and discuss best practices. While posts are visible to everyone, users need to be logged in to the portal to create a new thread or reply to an existing one.

EMA staff may intervene in the forums, but replies to individual questions cannot be guaranteed, as the forum does not replace the established EMA communication channels

EMA Channel	Questions/issues:
EMA Service Desk	*Use of the portal and for reporting faults*
EMA Account Management	*Access and registration requests*
Ask EMA	*General questions not related to a specific submission/procedure*
Direct replies to eAF emails	*Issues relating to a specific procedure*

Please note any text contained in the threads of the forum is **publicly available**, therefore please do not post any type of confidential information.

eAF Chatbot

One new feature launched on the PLM portal is a **chatbot** based on guidance documents and available for all Users. Through the Chatbot you can ask questions and find information on the **forms**, portal **Access Management** and get quick answers to the most frequent queries.

The chatbot compliments rather than replaces any of the communications channels mentioned above.

How to report an issue

For **technical support** with EMA's IT systems, please use the EMA Service Desk portal. This includes issues related to creation of new accounts, access to existing accounts, uploading data and performance of databases.

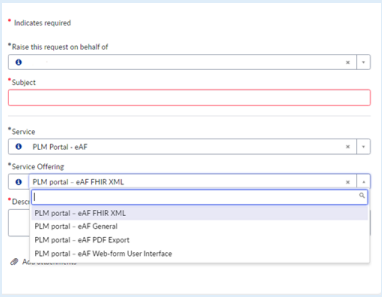
The Service Desk portal is optimised for use with Chrome, Edge, Firefox or Safari web browsers. If you encounter problems, please use one of these browsers instead.

To raise an issue using the EMA Service Desk tool; please select the option Report an issue and select the service PLM Portal – eAF. For questions, please select the option Ask a question

Depending on the issue or question, you can select from different options:

- PLM portal – eAF FHIR XML, for issues and questions on the FHIR xml
- PLM portal – eAF General, for topics covering multiple aspects and/or general nature
- PLM portal – eAF PDF export, for issues/ discrepancies/errors in the generated pdf
- PLM portal – eAF Web-form User Interface for issues/questions/improvements relating to the web UI

Please provide a clear description of the issue and provide screenshots or the generated PDF as attachment as these can help to solve your query faster.



Need more information?

General Inquiries

Should you have any questions about the topics in this update or would like to suggest items you think would be of interest to share in this newsletter, please contact the eAF (DADI) product team via esubprogofficer@ema.europa.eu and/or PMS product team via the EMA Service Desk. For questions or comments around the content of the Q&A document, please raise a ticket (by selecting "Ask a question" and including in the subject "eAF (DADI) Q&A") via the EMA Service Desk.

Technical Questions

If you have a technical question about the current eSubmissions systems, the eAF (DADI) product or PMS product please raise a ticket (by selecting "Ask a question" and including in the subject "eAF (DADI)" or "PMS") via the EMA Service Desk.

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