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EUROPEAN MEDICINES AGENCY
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eAF (DADI) NEWSLETTER

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

eAF Go-live

Human Variations electronic application form

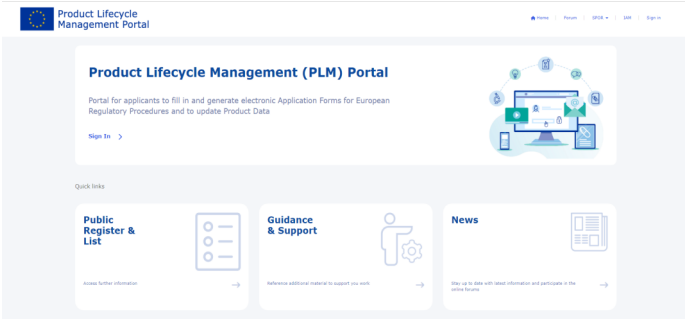
The **web-based Human Variations electronic application form** (eAF) for Centrally Authorised Products (CAPs) - often referred to by its former project name: DADI – has been available for use as of **4 November 2022** on the new **Product Lifecycle Management (PLM) Portal**.

This release represents a big, first, milestone in the ongoing journey to improve the eAF related processes. EMA (European Medicines Agency) is collaborating with the **UNICOM*** consortium to develop this and other new web-forms. The **eAF team** would like to thank all the hard work of **colleagues from across EMA and the Network** to get this form ready for release, showing an example of excellent cross network collaboration. Users of the Human Variations eAF should expect continual work on improvements, fixes and new features through regular releases.

Currently, the **use of the new web-based Human Variations eAF** will remain **optional**. This release has not triggered a transition period towards mandatory use.

The new PLM Portal will in due course host all eAFs. In the future it will also host the data input user interface for product management service (PMS) data and the interface to provide data for electronic Product Information (ePI). The PLM Portal will develop over time to inform and support you in the use of these services.

EMA has hosted several webinars and shared other communications on the Human Variations eAF, as well as hosting User Acceptance Testing (UAT) and trainings. Many more will follow in the coming months. Furthermore, there are several resources such as Guidelines to help users familiarise themselves with the new form and 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.



Access to the new Product Lifecycle Management (PLM) Portal

Please note that DADI name will be phased out and replaced by eAF

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

Update on 2023 UAT and releases

Following the launch of the **web-based Human Variation electronic Application Form (eAF) for Centrally Authorised Products (CAPs)**, many users are already accessing the **Product Lifecyle Management (PLM) Portal** to work on variation applications using the new web-based electronic application forms (eAF). This is a valuable step for applicants and marketing authorisation holders, as users of the platform, to familiarise themselves with the system as well as for the EMA development team to gain more insights on features to develop and improve and issues to fix.

The development team's priority is now to address post-go live issues in the web form and ensure its stability and reliability. Following this, work will continue adding the data and functionalities needed to fully support national, MRP and DCP variations application procedures and submissions.

Recognising the importance to stakeholders of being able to plan resources in advance, EMA has therefore decided that the previously planned industry **external User Acceptance Test (UAT) in January 2023 will be rescheduled** to a date expected to be announced **in the first half of 2023 .** The UAT will be scheduled when the new features and capabilities for the next major release are ready to be tested.

To support your planning for possible participation in the UAT and anticipate eventual transition to the use of the web-forms, please note the following:

- The **target window for introducing Nationally Authorised Medicinal Products** (all NAPs, including MRP/DCP) to the human variation application form is now **Q2 2023**
- In addition, **further capabilities** need to be introduced to make the variations eAF ready to start a **formal transition period**, the **target window for release of these features is Q2-Q3 2023**
- More **precise time windows** will be shared as early as possible during the **first half of 2023** with the aim of providing a minimum of a **2-month lead time before the UAT** or a major release to allow time for stakeholders to plan their participation.

Creating interoperability at the source and distributing it: how is UNICOM involved?

Article Author: UNICOM Consortium

Launched in December 2019 and funded by the EU, the **UNICOM project** unique characteristic lies in the involvement of all the actors of the Medicinal Products value chain and in demonstrating the benefits of a wide IDMP (Identification of Medicinal Products) implementation across all use cases and countries. UNICOM thus aims at the creation of a globally integrated and governed ecosystem related to safe IDMP.

Among the **41 UNICOM partners**, no less than 11 national competent authorities (NCAs) have accepted to implement structural changes and have begun their concrete journey towards the adoption of an IDMP compliant database. Three options were available to NCAs: 1) investing in an entirely new IDMP compatible IT system; 2) adapting the existing system to make it IDMP compatible; or 3) creating a transformation layer which would map the national database to the required format. This has of course consequences on the use cases potentially supported by national databases. Estonia, for example, opted for an entirely new system, while Austria and Croatia (which has recently documented its IDMP journey in this article) decided to adapt their existing systems. But in all cases, all scenarios require a very important mobilisation of the human and financial resources of the agencies. Each country experience is shared with all EU Member States agencies during regular knowledge exchange webinars.

The communication between the **European Medicines Agency (EMA)** and the **National Agencies** also requires investing in the development of new skills related to the understanding and use of the **HL7 FHIR standard**. UNICOM is facilitating the adoption of this standard by all competent authorities, also by means of knowledge exchange webinars covering thus a wide array of situations and issues. The **last session** had Estonia in focus and took place on **25 November 2022**.

UNICOM is also making readily available a number of recently released working papers under the resources section of the project website. Finally, UNICOM YouTube provides access to a large number of video resources including discussions with the community on many specific aspects and challenges of the IDMP implementation.

UNICOM

eAF events & useful material

Upcoming events

EMA Quarterly System Demo

- 21 December 2022 (Live broadcast on YouTube)

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

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**.

- **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.

- **Pre-go live session Q&A document**

This event is a Q&A webinar aiming at addressing questions from industry and national competent authorities' stakeholders concerning the release of the web-based variations eAF for Human CAPs.

- **Human variations eAF Form (DADI) training Q&A document**

This event is 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.

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

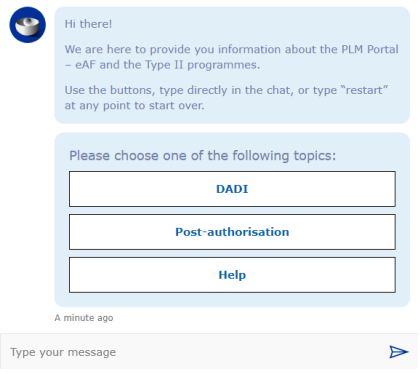
EMA Channel	Questions/issues:
EMA Service Desk	*Use of the portal and for reporting faults*
EMA Account Management	*Access and registration requests*
Ask EMA	*General questions not related to a specific submission/procedure*
Direct replies to eAF emails	*Issues relating to a specific procedure*

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?

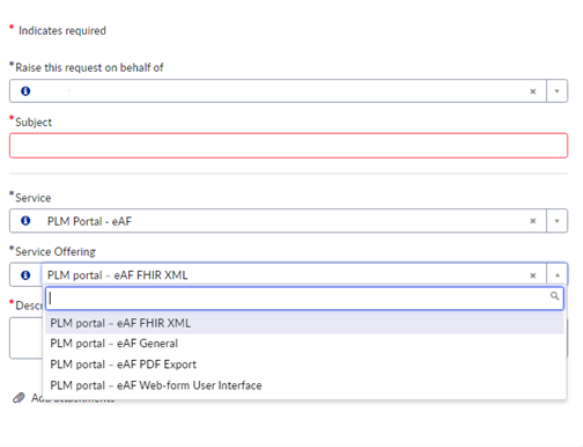
For **technical support** with EMA's IT systems, please use the EMA Service Desk portal. This includes issues related to creation of new accounts, access to existing accounts, uploading data and performance of databases.

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.

PMS News

PMS EU IDMP Implementation Guide: Celebrating Cross EMA-NCA-Industry Collaboration and Agile Mindsets

The **PMS EU Implementation Guide (EU IG) for the submission of data on medicinal products** defines the implementation of regional requirements of the **ISO IDMP standards** and will be the basis for submission and exchange of medicinal product data in the European medicines regulatory network. The first iteration of the PMS will cover a subset of the authorised medicinal product part of the ISO IDMP standards.

The **EU IDMP Implementation Guide (EU IG v2.1.1) is available** on the EMA website

Summary of changes PMS EU IDMP Implementation Guide

This version reflects the latest alignment of the **Product Management Service (PMS) data model** with the web-based application forms developed by the eAF (DADI) product and aims to support the go-live of the web-based Human variations form for Human medicinal products in November 2022.

EU IG v2.1.1 provides further details on the data elements introduced to support the **new web-based forms,** updated business rules and FHIR (Fast Healthcare Interoperability Resources) paths, updated details on the applicable RMS lists being created and/or updated during the year to support PMS and eAF, as well as more practical examples and clarifications included in Chapter 8.

The EU IG 2.1.1. also contains **Annex I of Chapter 7** which is intended to support the **first release of the eAF variation form for Centrally Authorised Products (CAPs).** It provides details on the applied migration rules between SIAMED (internal EMA database) and PMS for CAPs.

Visit the Substance and product data management services page to access the Implementation Guide.

Click on the **guidance update history** to find out more about the changes introduced by this and previous updates.

PMS SMEs nomination

Following the calls which were launched in September 2022 for expressions of interest to join the **Product Management Service (PMS) product team** in the role of **Industry Subject Matter Expert (SME) and Network SME**, nominations received have been reviewed against the requirements as defined in the call for interest and the Portfolio Board, in dialogue with the HMA representatives in NPAG for Network SMEs, have determined the suitability of the candidates.

As a result, PMS team is pleased to welcome to the product team the **newly appointed Subject Matter Experts**: four members are nominated to represent the Network and four to represent the Industry in Europe. Their nomination will ensure the successful transition to the **Safe Agile Methodology Working Model.**

The SMEs were selected on the basis of **their expertise** and represent Industry and Network's voices within PMS product team.

Meet the Cross EMA-NCA-Industry PMS Data Focus Group

The **PMS Data Focus Group** has worked as one trustworthy body of experts in an Agile setting across the PMS and eAF (DADI) projects during the past 12 months resulting in the release of the PMS EU IDMP Implementation Guide (EU IG v2.1.1) publication on 27 July 2022.

Members of the PMS Author Team are the following:

EMA Members:

- Marcos Fernandez Gomez
- Veronica Lipucci Di Paola
- EMA Subject Matter Experts

NCA Members:

- Blanca Pérez Pérez (AEMPS)
- Barbara Yutzy (PEI)
- Peter Bachmann (BfArM)
- Sudheendra Achar (PEI)
- Members of the PMS SubGroup

Industry Members:

- Angela Muller (schwabe-group)
- Anne Bourrelly (Roche)
- Barry Hammond (terminologeze)
- Caroline Mandret (Stallergenes)
- Costas Mistrellides (merckgroup)
- David Wilson (JNJ)
- Elisabeth Godet (Sanofi)
- Josef Pellizzari (Pellizzari Consulting GmbH)
- Liam Nelligan (Teva UK)
- Lisa Passot (GSK)
- Maria Grazia Vaccari (Novartis)
- Martin Jeffrey (lakemedelsverket)
- Vada Perkins (Bayer)
- Members of the PMS SubGroup

Priorities for Q4 2022

1. The **PMS Data Focus Group** is working on the **next version of the EU IG to support the launch of the forthcoming NAPs features for the Human Variations eAF**. The key updates of the next version will address the final Medicinal Product Identifiers, establishing the granularity rules and completing the remaining Referentials Management Service (RMS) lists (Reason (Provenance), Medical Device Type) all supporting the eAF.

2. PMS Data FG Team is also working on the release of the **PMS technical Frequently Asked Questions (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 SPMS webpage.

3. EMA PMS Product Owners will work on releasing **updates to Chapter 7 of the EU IDMP Implementation Guide** to provide the full set of details on the applied migration rules between SIAMED (internal EMA database), xEVMPD and PMS for Centrally and Nationally Authorised Products.

4. In view of PMS transitioning to Agile governance, PMS NCA and Industry members will be supportive on the onboarding of **newly appointed PMS Subject Matter Experts (SMEs)** to ensure a successful transition to the **Safe Agile Methodology Working Model.**

Download the presentation from the PMS webinar held on 9 September and find out more on the PMS transition to Agile here!

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