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SCIENCE MEDICINES HEALTH

DADI NEWSLETTER

News, views and interviews for the informed stakeholder
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Editorial

IN THIS ISSUE

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Welcome to the first DADI Newsletter.

The **Digital Application Dataset Integration (DADI)** Network project will replace the technology for electronic applications forms, a key part of integrating and optimising regulatory procedure management. The interactive PDF forms will be replaced by web-based forms in a dedicated portal integrating **product management services (PMS) structured product data**. This will help make available standardised data that can be easily exchanged and used across systems. In addition, it will also help make regulatory procedures more efficient and data available for other value adding use cases.

The forms will be gradually replaced over the next few years, starting with the variations form for Human medicinal products in October 2022. Several webinars and other communications on DADI have been released, including User Acceptance Testing (UAT) and training announcements, and many more will follow in the coming months.

Also, several materials on DADI have been produced to help both internal staff and external users to retrieve information and answers to potential questions.

This newsletter aims to provide a recap on what has been shared so far and what you can expect in the coming period.

> *DADI and PMS are key enablers for the implementation of more digital and improved core regulatory procedure management as part of EMA and the Network's digital transformation.*
>
> **Karl Hamilton**

About DADI

Overview

The **Digital Application Dataset Integration (DADI)** Network project will replace the current interactive PDF format electronic application forms (eAFs) with new, web-based forms in a new dedicated portal.

The new forms will be released, one form at a time, starting in 2022. DADI will also apply a **measure of standardisation of data entry** based on SPOR (Substances, Products, Organisations and Referentials) to enable easy exchange of data between forms and systems according to globally recognised standards.

The web-based application forms will be available for Variations, Initial Marketing Authorisations and Renewals (human only). The web-based forms for other procedures are still under consideration.

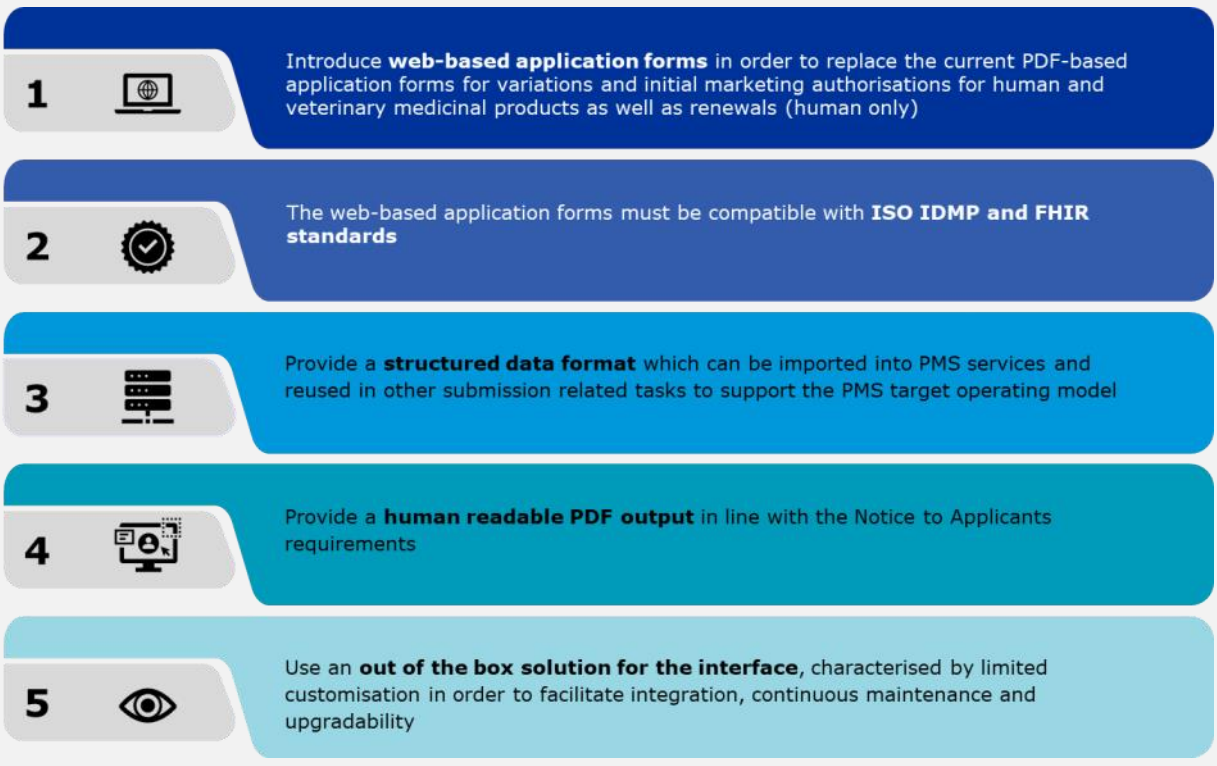
The new web-forms will standardise input for eAFs in order to effectively provide standard Product Management Service (PMS) data. The web-forms will also use available PMS data to prepopulate form fields where relevant. See the section below for more information about PMS.

The first release of the web-based variation form for Human medicinal products will be limited to **Centrally Authorised Products (CAPs)** and the related data will come from EMA's internal database. The **second release,** foreseen in **March 2023**, will **support all types of EU variations procedures, both Centrally Authorised Products (CAPs) and Nationally Authorised Products (NAPs),** including National Procedures (NP), Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP) as well as mixed CAP/NAP worksharing procedures which are processed by National Competent Authorities (NCAs) and EMA respectively.

Find more

For more information about the DADI Network Project, check out the eSubmission website.

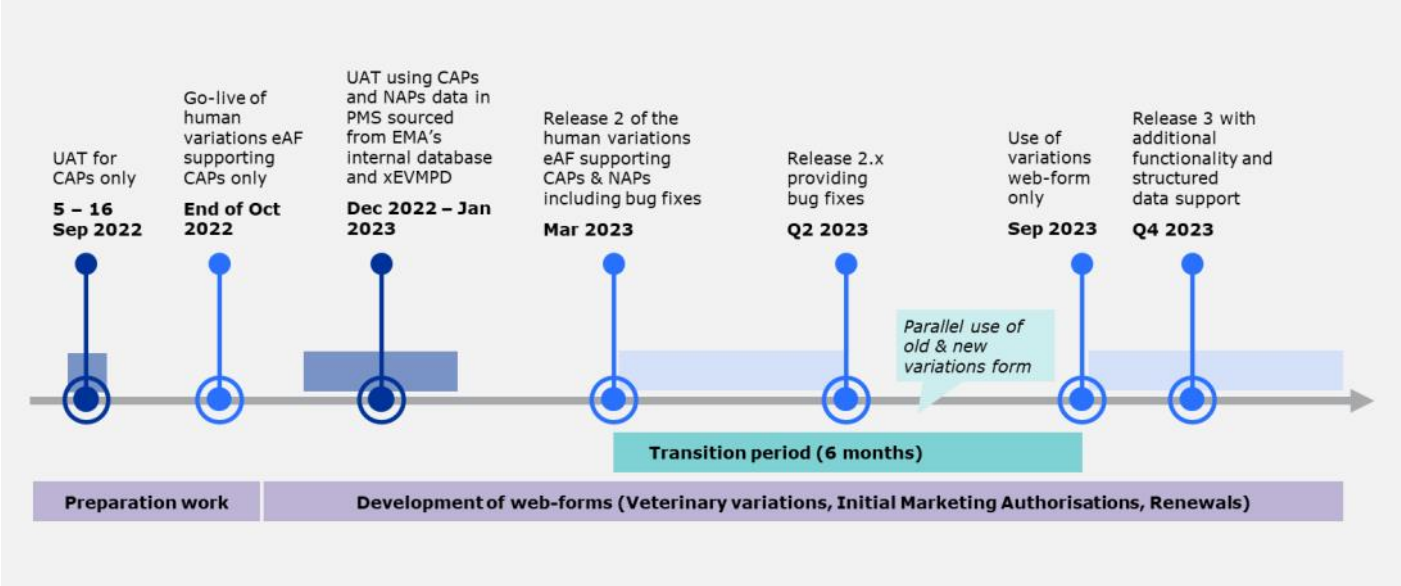
DADI Objectives



DADI Roadmap

Following an earlier announcement published in May 2022, the scope of the October 2022 Go-live of DADI has been revised and an **updated timeline for the releases of DADI web-based variations forms for Human medicinal products**, was published in July 2022.

- The **scope of the October 2022 Go-live** will be limited to **CAPs**. EMA made this decision due to the complexity in synchronisation of the data between xEVMPD and PMS. At this initial release of the form the available data for CAPs is coming from EMA internal database and it is the same dataset currently used in IRIS to support Inspections. This version of the form cannot yet be used for applications containing NAPs, including National Procedures, Mutual Recognition Procedure and Decentralised Procedure as well as mixed CAP/NAP worksharing procedures.
- A **second release of the form in March 2023** will support all types of EU variation procedures (both CAPs and NAPs). The release will be followed by a **6 -month transition period** during which both the PDF eAF and the web-based form can be used in parallel.
- Currently, the variations form for Human medicinal products is undergoing **closed User Acceptance Testing (UAT)** with members of the DADI Subject Matter Expert Group, which is expected to conclude in August 2022.
- Subsequently, there will be **external User Acceptance Testing** in September 2022 with a larger, but still limited, group of testers: **participation** will be **mainly for Industry.** At this time, NCAs cannot test the portal, but might only be requested to look at the PDFs generated by the Industry testers. The UAT will serve to test the system's functions. It is, however, not set up to facilitate early access to the web user interface for a large group of users.
- An **additional UAT** using both CAPs and NAPs data in PMS sourced from EMA's internal database and xEVMPD is foreseen between December 2022 – January 2023.
- **Subsequent releases** planned in Q2 and Q4 2023 will follow the EMA Agile development approach.



About PMS

Overview

The Product Management Services (PMS) is a Network project led by the EMA in cooperation with the European medicines regulatory network and industry and is part of the SPOR Programme.

The first iteration of the PMS will cover a **subset of the authorised medicinal product part of the International Organisation for Standardisation (ISO) Identification of Medicinal Products (IDMP) standards**. As part of this iteration, the new ISO IDMP compatible data submission format (HL7 Fast Healthcare Interoperability Resources - FHIR) replaces the current data submission format, the extended EudraVigilance Product Report Message (XEVPRM).

In the near future, EMA expects to progress the following activities:

- Make **ISO IDMP-compatible product data available** on all authorised medicinal products in the EU, including both centrally authorised products and non-centrally authorised products. This will result from a data migration and continuous updates from the EMA database (SIAMED) and the xEVMPD (Article 57) database to the PMS following the ISO IDMP standards;
- **Enable pharmaceutical companies** to correct and complete PMS product data;
- **Enable data approved** within a regulatory application to be **stored in the PMS**;
- Ensure **adequate data quality** in the PMS so that it can be confidently reused across procedures.

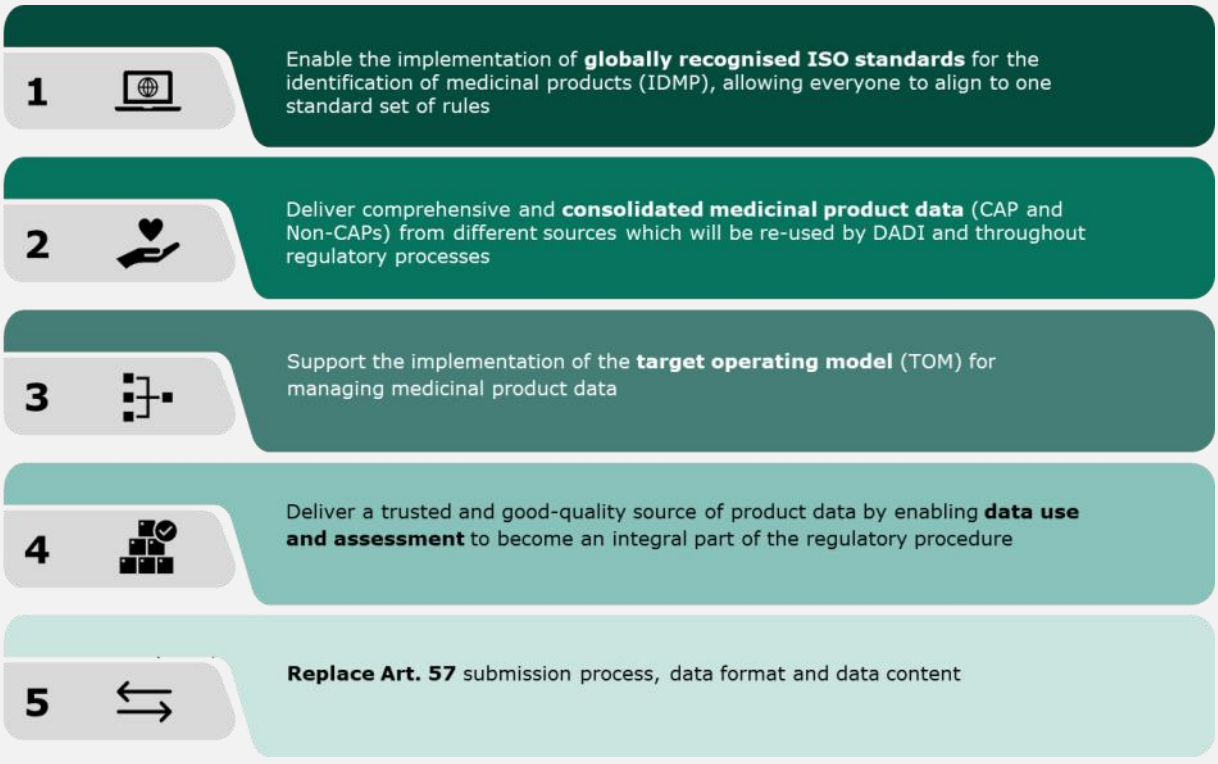
To support the Go-live of the DADI Variations form, the PMS team will release **v2.1.1 of the EU IG**. This version aims to have a complete view of data elements used by DADI at the moment of go-live.

The PMS team has performed an **external UAT of the migration of data into PMS** with the support of Industry and NCAs representatives. The outcome of this UAT will be used to in the new versions of the EU IG to provide general information on the business rules used for the migration of authorised product data from Art. 57 and SIAMED into PMS.

Find more

For more information about the PMS Network Project and the EU IDMP Implementation Guide, check out the SPMS webpage.

PMS Objectives



What's next for DADI?

User Acceptance Testing for Human Variations Form

The Variations form for Human medicinal products will undergo integrated **User Acceptance Testing (UAT)** with a selected group of testers, representing various stakeholders. The DADI UAT is planned to be conducted between 5 September and 16 September 2022. A Call for interest to become an Industry tester was closed on 15 July.

The UAT participants are expected to perform testing activities, by filling in electronic Application Forms as close as possible to real-life scenarios. Namely, this implies filling in an eAF for one or multiple CAPs, single scope or grouping of scopes from different variation procedure types (e.g., type IA or type IB), and to export the PDF output to be included in a submission.

Participation to the UAT is limited. However, there will be other opportunities, including the transition period itself, to allow all users to familiarise themselves with the new tool.

Prior to the DADI UAT, training/troubleshooting material and sessions will be provided to prepare the UAT participants to the maximum extent possible, thereby avoiding potential unnecessary problems that may occur during the UAT phase.

The following two access management troubleshooting sessions have been scheduled:

- **First access management troubleshooting session:** *Thursday, 21 July 2022*
- **Second access management troubleshooting session:** *Tuesday, 23 August 2022*

In addition, two public training and Q&A webinars have been scheduled:

- **First training and Q&A webinar:** *Tuesday, 26 July 2022* - Registration link
- **Second training and Q&A webinar:** *Friday, 2 September 2022* - Registration link

Upcoming changes on EMA Account Management

Collaboration with stakeholders is at the core of EMA's activities. This interaction is facilitated by the systems and applications maintained by EMA, such as IRIS, and the first interface with EMA's systems and applications is the **EMA Account Management platform.**

Given the importance of this gateway to EMA's applications, the Agency will embark on a **new project aimed at ensuring that the registration and access management process delivers a simple, secure, consistent and user-friendly way.**

The **new access request form** will provide users with a guided process and an enhanced Organisation Search, making it easier for users to find their affiliated organisation based on **different criteria.**

Moreover, EMA will introduce the possibility to **select multiple organisations within the same request,** making the process more efficient and saving time for users associated with more than one entity. A clearer overview and description of potential roles based on the selected organisation will be added, providing users with clarity dependent on their user needs.

Once a role has been selected, users will be prompted to attach the **required documentation only if necessary**, ensuring our users have a clear overview of documentation requirements for approval.

The overall aim of the new access request workflow is to **better guide our users** through the entire process, minimise the number of rejections and to ensure that users can access EMA's applications and systems in a swift and efficient manner.

The new access request workflow will become **available in July,** while the current access request workflow will remain available until end of September. During the transition period users will be able to use both the new and the old functionality.

Additional information on **further upcoming changes to EMA Account Management** will be provided in future IRIS newsletters. If you would like further details on the EMA Account Management project, please contact InformationSecurity@ema.europa.eu, if you need further assistance on using the platform please open a ticket in the EMA Service Desk.

Useful material

FHIR Draft Specifications for Human Variations Form

An updated Excel sheet listing all fields in the Variations form and the Medicinal Product has been released in May 2022 on the eSubmission website and Network website.

The FHIR messages relating to the latest mapping will be published on the EU Network website and once all confidential data has been redacted, they will also be published on the eSubmission website.

DADI Q&A Document

An updated version of Q&A document has been published on the eSubmission website in February 2022.

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 "DADI Q&A") via the EMA Service Desk.

DADI-PMS webinars

Digital application dataset integration (DADI) Q&A webinar - variations form for human medicinal products, 12 July 2022
Dedicated Q&A webinar for business and technical audiences from industry and national competent authorities to address questions about the revised scope of the DADI October Go-live

Variations Form for Human Medicinal Products - What will happen at Go-Live, 16 May 2022
This joint DADI-PMS webinar targeted business and technical audiences from industry and national competent authorities wishing to learn more about what will happen when DADI web-based Variations form for human medicinal products will go live.

Common factors in the Fast Healthcare Interoperability Resources (FHIR) data standard for Article 57(2) and electronic application forms (eAF), 25 January 2022
Introducing the Variation FHIR Message and provided an explanation on the PMS data model and how it links to the eAF.

Introducing DADI – The Digital Application Dataset Integration Network Project to replace electronic application forms, 18 January 2022
General introduction to the DADI Network project, providing an overview of its objectives, key changes, and main benefits.

Event materials and/or recording are available on EMA website and eSubmission website.

Need more information?

General Inquiries

If 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 DADI project team via esubprogofficer@ema.europa.eu and/or PMS project 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 "DADI Q&A") via the EMA Service Desk.

Technical Questions

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

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