EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DADI Project FAQ

Digital Application Dataset Integration Project Frequently Asked Questions

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What will the DADI project do?

- DADI is the acronym for Digital Application Dataset Integration.
- The project will convert the current PDF format electronic application forms (eAFs) to new, web-based forms. The forms will be released, one form at the time during 2022 and 2023;
- It will also apply a measure of standardization of data entry to enable easy exchange of data between forms and systems according to globally recognized standards;
- To facilitate data exchange DADI will deliver human and machine-readable application datasets to underpin the forms;
- The project will replace forms used for all EU procedures, including the centralised procedure (CP), mutual recognition procedure (MRP), decentralised procedure (DCP), national procedures (NP) and, for veterinary, also subsequent recognition procedure (SRP);
- Through the web-based forms, the project will provide the means to feed data to SPOR data management services, for human and UPD, for veterinary, which in turn makes the data available to core business processes to use;
- As it feeds SPOR, DADI will comply with the ISO IDMP standard for human. Data from application forms will feed Product Maintenance Services (PMS) data. In turn for variations applications, the forms will pull available PMS data to prepopulate application where relevant, enhancing consistency;
- The project will focus first on supporting Marketing Authorisation, Variation, and Renewal applications for human and, later, veterinary, where applicable;
- As DADI is developing, releasing and implementing forms new requirements such as for instance those for Medical Device Regulation (MDR) will be included as they are approved;
- DADI will not change the procedures or requirements for the above submission procedures, however additional data may be requested through the forms to support and streamline procedure handling and management.

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Is DADI project a Telematics project & what does that mean?

- Yes, DADI project is a telematics project, as it aims to deliver the replacement for all PDF format electronic application forms covering both centralised and national procedures.
- This means that the governance of the system is shared between EMA and the National Competent Authorities in the EEA member states. More information about telematics can be found on the EMA Telematics webpage.
- Within this collaboration EMA, together with NCAs, is delivering forms for Centrally Authorised Product applications and Nationally Authorised Product applications.
- EMA will build and maintain the forms and the portal on which they will be accessible.

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What are the main benefits that DADI web-based forms will bring?

- First and foremost, not a benefit: application forms exist to obtain data for medicinal product related applications. That is their primary function.
- DADI web-based forms are a means to ensure data entered is standardized and can therefore be more easily and efficiently, validated, processed, transmitted, accessed and re-used.
- Specifically, the forms will:
    - support easier validation and processing of applications by competent authorities, reducing errors and discrepancies
    - help applicants' form filling by interfacing with PMS and UPD to prepopulate variations and renewal (H) forms based on available data, meaning not every form needs to be filled from an empty sheet
    - facilitate "first-time-right" data is fed into databases making interoperability of systems and sharing of data between competent authorities much easier
- The web-based forms themselves will be more user friendly to use than the current PDF form. User-friendliness will improve over time as all the standardized Product and Substance Management Service databases become available, for example substances drop down lists will take much shorter time to load and will have less duplicate or confusing entries.

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Why is the DADI project being started now?

- There are several factors why now is the right time to review the forms and adapt the PDF forms to web-based forms;
- The current Adobe PDF forms are aging, and risk no longer being fit for purpose;
- Improvement of EMA's core processes is dependent on delivery of new forms facilitating standardised data entry for Centrally Authorised Products applications. The data captured in forms are the entry point for data used throughout EMA's own core processes which are a key area for improvement over the coming months and years
- Seven NCAs, AGES, BfArM, AEMPS, HPRA, MEB-CBG, NOMA and SE MPA, obtained European Commission Horizon2020 funding to implement ISO IDMP compatible application forms. that the goal is to accelerate ISO IDMP implementation in Europe.
- The UNICOM project of which these NCAs are participating in, adopted the commitment to the Commission to implement ISO IDMP at EU and NCA level by 2023. UNICOM is partnering with the DADI team to realise this objective. For more information on UNICOM see: https://unicom-project.eu/;
- Momentum and relevant expertise have been built up through a predecessor project CESSP Phase 1 project which can now be leveraged for the benefit of the web-based forms development;
- Relevant knowledge has been built up in EMA with Microsoft PowerApps, which is the chosen platform to facilitate the new web-based forms. Microsoft PowerApps Portals are a Microsoft tool EMA is leveraging for easy to build and easy to use web portal functionality.

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Which application forms will be adapted by DADI?

- All forms will be adapted, starting with the variations for human medicinal products in 2021, with release expected in 2022, followed by application form for marketing authorisation and extensions in 2022 and renewals in 2023, with other forms to follow.
- The forms for Veterinary Medicinal Products are also in scope with their definitive timeline to be confirmed. The DADI project will not deliver the initial update of the variation form to reflect changes as a result of the Veterinary Medicines Regulation (Regulation (EU) 2019/6, with deadline of January 2022. The existing PDF format eAF will be updated to address the regulatory requirement in time for the deadline, with the web-based form to be developed after the deadline. This will allow a transitional period to move from the PDF technology to the new web-based forms also for veterinary users.

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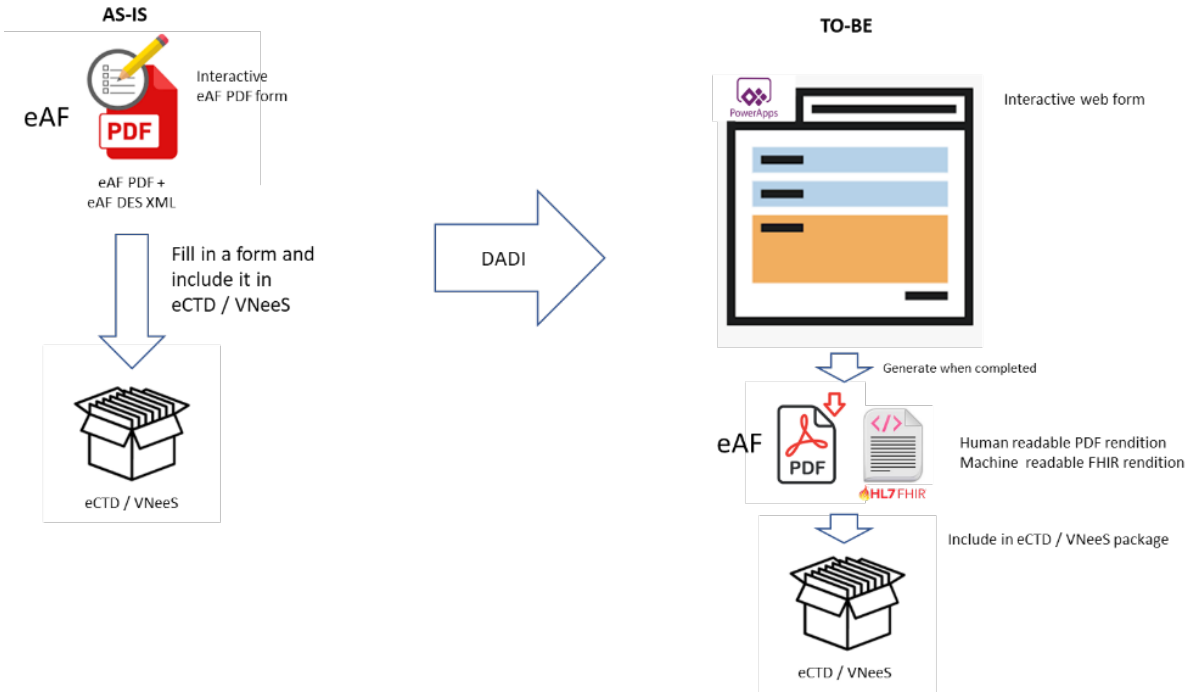
What will change technically in the forms?

- Applicants will fill in an online, web-based form instead of an interactive PDF form.
- The output, which the regulators will receive as part of the submission package, will include both, a human readable PDF document with an attached FHIR message that can be read and processed by IT systems.
- This FAQ will be updated as further details on the technical aspects of the form are decided.
- See the diagram below for a visual description of technical changes:



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How will the project impact Competent Authorities?

- The web-based application forms will be common for both Nationally Authorised Products as well as Centrally Authorised Products which are processed by National Competent Authorities and EMA respectively;
- The forms impacted are used in NCA relevant authorisation procedures:
    - mutual recognition procedure (MRP);
    - decentralised procedure (DCP);
    - national procedure (NP).
    - Subsequent recognition procedure (SRP) for veterinary
- Overall, the web-based forms will facilitate:
    - The possibility to automate manual processes related to processing forms;
    - Overall standardisation of data and data entry;
    - Avoiding business continuity risk by moving away from a PDF only approach that is no longer fit for purpose.
- Competent authorities who are not currently using the PDF forms' XML functionalities will notice little change – the PDF output of the web-based form may look a little different;
- Competent authorities currently using the PDF forms' XML functionalities will need to adjust their systems to accommodate the new FHIR compliant XML.

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What does this mean for industry stakeholders?

- The current PDF form will be replaced by a web-based form for CAPS and NAPS applications.
- Any new web-based application form will be prepopulated with data available in the SPOR databases for human and UPD for veterinary. Industry will have full visibility of data available on the regulator's side.
- The forms will make use of standardised PMS data and are essential to being able to sustainably maintain and reap the benefits of PMS data in the future. PMS data is being built up from the current SIAMED and Article 57 databases requiring significant reconciliation efforts. This may mean that applicants will encounter pre-populated data they do not immediately recognize. Applicants should therefore initially expect additional time and effort to support data reconciliation as they populate their application forms.
- Integration of eAF and Article 57 submissions into a single process – the Product Maintenance Service Target Operating Model – will facilitate greater efficiency, and better data quality overall.
- DADI is currently developing the first form. Once this moves to testing and later, release and implementation a more detailed breakdown of possible impacts for industry will be made available.

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How is DADI taking industry perspectives into account?

- A Requirements Group represents subject matter experts from NCAs and Industry.
- The Requirements Group provides expert insight into the use of forms and provides input for EMA requirements for Centrally Authorised Products and National Competent Authority requirements for Nationally Authorised Products.
- EFPIA, Medicines for Europe, Animalhealth Europe and EGGVP are represented on the DADI Requirements Group.
- The requirements Group will also be involved in testing of the forms.
- The Requirements Group meets on a weekly basis.
- See also: *Is DADI project a Telematics project & what does that mean?*

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Will DADI deliver forms complying with Veterinary Medicines Regulation (Regulation (EU) 2019/6)?

- Veterinary forms are in scope for DADI. This means that when DADI forms become available, they must comply with Veterinary Medicines Regulation (Regulation (EU) 2019/6).
- Due to the regulatory risks and the development risks of the form the Steering Committee of DADI decided to decouple the development of the veterinary variations web-based form from the regulatory deadline of 28 January 2022).
  Instead the current PDF based form will be updated to support regulatory requirements for the 28 January deadline.
- Development work on the veterinary form will start in early 2022 with release later in 2022.
- In the meantime, veterinary representatives participating in the DADI Requirement group have been invited to stay on as observers to ensure a smooth uptake of veterinary requirements once design starts.
- The main benefit of this approach is that there is a reduced risk of new technology disrupting the transition to the new regulatory requirements. In addition, it means that a transition period can be facilitated, which will benefit from lessons learned from rolling out the human variations form.
- The downside is the postponement of the availability of a web-based form for Veterinary variations.
- The decision on whether further future forms, such as initial marketing authorisation will be coupled or decoupled across human and veterinary will be made as development on them starts in 2022.

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How do PMS and DADI's deliverables relate?

- PMS is the Product Maintenance Service, one of the four data sets maintained by substances, products, organisations and referentials (SPOR) data maintenance services for human medicinal products.
- EMA is developing SPOR data management services for the centralised management of master data that comply with the ISO IDMP standards.
- Organisational and Reference Master data services are live with Product and Substance master data services under development.
- There is a two-way exchange of data between application forms and Product Maintenance Services (PMS) Data.
- Data entered by the applicants in the Marketing Authorisation Application (MAA) forms and Variation Application forms created by DADI project will be used to populate and update PMS.
- The FHIR data message automatically created by the web-based form matches the data format for medicinal product data of PMS.
- In the web-based forms created by DADI, product data available in PMS will be also used to prepopulate relevant fields in an applicant's Variation/Renewal applications.

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How do DADI and UPD relate?

- The Union Product Database (UPD) will be the new Union database for all authorised veterinary medicinal products as per the veterinary medicinal products regulation, Regulation 2019/6. The UPD is accessible to the general public and will be a searchable database.
- The UPD comprises a range of functions required for the administration and quality management of information and documents related to authorised veterinary medicinal products and it's the secure electronic transmission of such information.
- There is a two-way exchange of data between forms and UPD Data.
- Data entered by the applicants in the Marketing Authorisation Application (MAA) forms created by DADI project will be used to populate and update UPD.
- The FHIR data message automatically created by the web-based form matches data format for medicinal product data of UPD.
- In the web-based forms created by DADI, product data available in UPD will be used to prepopulate relevant fields in an applicant's Variation applications.
- Generally, UPD captures less data on approved products than PMS does for human medicinal products. Therefore, veterinary medicinal product applicants will likely need to populate more data themselves than their human medicinal product applicant counterparts.

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Will the data requested in forms for human medicinal products be ISO IDMP compliant?

- The intention is to facilitate data exchange of standardised master data; therefore, the forms will use SPOR data which comply with ISO IDMP standards.
- The scope of ISO IDMP and SPOR are different: ISO IDMP covers the entire medicinal product lifecycle, including development while PMS in SPOR covers only the Authorised Medicinal product part of IDMP.
- ISO IDMP applies to human medicinal products, SPOR applies to both human and veterinary products
- See this presentation for further details on the relation between SPOR, ISO IDMP and FHIR

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What is the difference between DADI and IRIS?

- IRIS is EMA's online platform for the internal handling product-related scientific and regulatory procedures with EMA.
- The future DADI portal will facilitate the population of complex forms with standard FHIR based datasets
- IRIS and DADI portals serve different purposes and will be governed differently.
- IRIS is implemented using several technologies that will be also used to deliver DADI project, i.e. Microsoft PowerApps. Experience gained by EMA in building IRIS helps implementing DADI.
- However, the intention is to facilitate and develop ease of use across the two portals wherever feasible.
- For instance, the aim is to have the new portal benefit from the same access control model with user accounts and affiliations managed via the separate EMA Account Management System. This determination is still to be definitively made.

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Who will maintain the new web-based forms?

- The system facilitating the forms will be technically maintained and supported by the EMA.
- Until further notice the existing eAF Maintenance Group, which plays a key role in maintaining the current Notice to Applicants (NtA) owned forms as well as providing expertise on the new, web-based forms will continue.
- As part of DADI, the governance will be reviewed, transparently, with the expectation that an advisory body, such as the current eAF Maintenance Group will continue to exist with EU regulatory Network and industry representation
- The EMA Service Desk will be available to address bugs and there will continue to be opportunities for applicants and other stakeholders to propose features.

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Other non-EEA regulators have projects that seem similar in scope to DADI, how different the DADI will be to that?

- Regulators globally are recognising the importance of standardized data formats and data exchange protocols to facilitate much smoother data exchange and system interoperability;
- ISO IDMP and FHIR standards were created for the express purpose of facilitating such a standard language, structure and exchange protocol;
- There is currently no direct collaboration with any other non-EEA regulator on the topic of submission forms. We cannot say how similar or different DADI's deliverables will be to that of any non-EEA regulator.

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What is ISO IDMP?

- The International Organization for Standardization (ISO) standard for identification of medicinal products (IDMP).
- ISO IDMP standards specify the use of standardised definitions for the identification and description of medicinal products for human use.
- Their purpose is to facilitate the reliable exchange of medicinal product information in a robust and consistent manner.
- They help to ensure wide interoperability across global regulatory and healthcare communities, which is critical in ensuring accurate analysis and unambiguous communication across jurisdictions.
- Commission Implementing Regulation (EU) No 520/2012 (articles 25 and 26) obliges European Union (EU) Member States, marketing authorisation holders and EMA to make use of the ISO IDMP standards. This will impact on many areas of the pharmaceutical regulatory environment, both in the EU and other regions.
- For more information, see this Introduction to ISO IDMP and SPOR.

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What is FHIR?

- Fast Healthcare Interoperability Resources (FHIR) is a standard for exchanging healthcare information electronically.
- FHIR is the machine-readable language chosen to support the easy exchange of data between DADI's forms and, for instance, SPOR databases.
- FHIR aims to simplify implementation without sacrificing information integrity. It leverages existing logical and theoretical models to provide a consistent, easy to implement, and rigorous mechanism for exchanging data between healthcare applications.
- The basic building block in FHIR is a Resource. All exchangeable content is defined as a resource. Resources all share the following set of characteristics:
    - A common way to define and represent them, building them from data types that define common reusable patterns of elements
    - A common set of metadata
    - A human readable part

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Will the future forms still be called eAF?

- The expectation is that the web-based forms will still be called electronic Application forms (eAF). However, this determination is still to be definitively made.
- In DADI communications EMA will frequently refer to web-based application forms to distinguish them from the current PDF electronic applications forms. Technically both are electronic application forms

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Can the data in the application form be re-used in a future application?

- Yes, where the data requested in an application form, especially variations, is the same data provided in previous applications, particularly MAA, this will be pre-populated in the form. This is one of the main mechanisms through which the forms support accuracy and efficiency based on SPOR master data.
- This means data only needs to be provided once, unless the data itself needs to be modified or updated.
- Details on what the pre-population will look like will be made available as part of the roll out of forms, starting with variations.
- The forms will make use of standardised PMS data and are essential to being able to sustainably maintain PMS data in the future. However, at the initial release of the variations form, applicants should expect additional time and effort due to data reconciliation!

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Are the forms still owned by the NtA group?

- Yes, the European Commission Notice to Applicants (NtA) group will still be responsible for the content requirements of the human application forms.
- The web-based forms will meet these content requirements. They will however also ask additional information to support efficient handling of applications and SPOR services.
- As a result of the new Veterinary Medicines Regulation (Regulation (EU) 2019/6), the veterinary forms will no longer be governed by the Veterinary NtA.

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Will there be training?

- EMA and NCAs will team up to provide support, guidance and training for applicants. Details will be shared closer to the roll out of the first form (Variations), expected in 2022.
- As part of the roll out of the new forms training will be made available, with the exact format to be determined.
- In addition, applicants and stakeholders can expect several webinars to support rollout and answer questions.
- User guides will be updated to fully supported the web-based forms.
- There will be help online and on-screen tooltips within the system.

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Will the web-based form have the same information as the current eAF, or will it be different?

- The web-based form, the future eAF, will request and display the information according to the latest requirements specified by Notice to Applicants (NtA).
- In addition, the FHIR XML backbone may contain additional metadata to facilitate regulatory activities.
- Details on all changes in data requested in the web-based form compared to the current eAF will be shared as part of the implementation and roll out.

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How will stakeholders be notified of future version updates and changes to the forms and submission portal?

- The web-based forms support both centrally and nationally authorised products applications – requiring some coordination around updates and changes.
- The change control and maintenance processes are part of DADI's deliverables however they have not been agreed yet at this time.

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My question about the DADI project isn't answered here, what do I do?

- DADI is currently in the development phase of the first form with a few decisions on requirements still pending, therefore not all questions have definitive answers. As the structure of the form is clarified the project team will share details and supporting documentation, including updates to this FAQ.
- Applicants wondering about specific features and interests can consider contacting their industry association representatives on the requirements group
- In case you have any doubt about who to contact regarding your DADI-related question, email eSubprogofficer@ema.europa.eu which is the inbox checked directly by the DADI project team.
- If you have a question about the current eSubmissions systems rather than the DADI project, please contact EMA via the EMA Service Desk

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