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DADI eAF Project Q&A

Digital Application Dataset Integration (DADI) Network Project Questions and Answers

Version 3

Disclaimer

This Question and Answer (Q&A) document is for information only and is based on insights available at the time of its release. The aim is to regularly update and rerelease this document. Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the DADI project team.

For convenience many technical terms are explained in the answers. In addition, there is a table of abbreviations at the back of this document.

For general inquiries, please contact the DADI project team via esubprogofficer@ema.europa.eu. For questions or comments around the content of this Q&A document, please raise a ticket via the EMA Service Desk.

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1. What will the DADI project deliver?

- The Digital Application Dataset Integration (DADI) Network Project will replace current PDF-based electronic applications forms (eAFs) with new web-forms in a new eAF portal. During 2022 and 2023 the eAFs for variations and initial marketing authorisation will be replaced for human and veterinary medicinal products. Furthermore, the renewals eAF (for human medicinal products only) will be replaced. Additional procedures will be considered.
- The web-forms will:
    - Support both centrally authorised product (CAP) applications and nationally authorised product (NAP) applications for mutual recognition procedure (MRP), decentralised procedure (DCP), national procedures (NP) and, for veterinary, also subsequent recognition procedure (SRP). Additional procedures will be considered.
    - Standardise input for eAFs in order to effectively provide standard product master data for human and veterinary medicinal products.
    - Enable both the familiar human-readable (PDF) output and a new machine-readable output for digital processing based on the Fast Healthcare Interoperability Resources (FHIR) data exchange standard for medicinal products. The PDF rendition will be generated from the web User Interface and it will contain both the PDF document and an attached FHIR XML (ref. How will the project impact Competent Authorities?).
    - Use available product master data from Product Management Services (PMS) for human and the Union Product Database (UPD) for veterinary medicinal products to prepopulate form fields where relevant.
- The DADI project will *not* change:
    - The process to apply for or submit marketing authorisation applications.
    - The format of the current PDF output.
    - The content of the output form included in the application, changes to which are not governed by the project team.

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2. Why is the DADI project running now?

- Work on replacing the electronic application forms with forms that would support efficiency and better interoperability was first undertaken as part of the Common European Single Submission Portal (CESSP) Phase 1 project started in 2016 and stopped in 2020.
- The need to replace the forms and align IT industry-facing applications has only increased since then, as the current Adobe PDF eAFs are aging, and risk no longer being fit for purpose.
- Momentum, relevant expertise and know-how built up during the CESSP Phase 1 project is there to be capitalised on by DADI. That is also the case with expertise on the technology chosen for the new web-forms which is the same as the IRIS Portal.
- Improvement of EMA's core processes is dependent on delivery of new forms facilitating standardised data entry for CAP applications. The data captured in forms is 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.
- The "Up-scaling the global univocal identification of medicines" (UNICOM) Horizon2020 project received funding to foster the implementation of ISO IDMP and the usage of SPOR (Substances, Products, Organisations and Referentials) in the European Regulatory Network by 2023.
- In the context of the application form seven NCAs members of the European Medicines Regulatory Network are working together with EMA experts in the DADI project: AGES (Austria), BfArM (Germany), AEMPS (Spain), HPRA (Ireland), MEB-CBG (the Netherlands), NOMA (Norway) and SE MPA (Sweden).

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3. What are the main benefits that the web-forms will bring?

- The web-based forms will replace aging technology considered no longer fit for purpose, thus enabling progressive usability improvements for users over the current PDF forms through integration with PMS/UPD data. For example, upon release, the new forms will help applicants' form filling by using available PMS/UPD data to prepopulate form fields where relevant (product selection and structured product data where available).
- User-friendliness will improve over time as all the standardised 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.
- The new forms are a means to enable more efficient application processing, reducing administrative burden. For example, the forms will support validation of applications by competent authorities, reducing errors and discrepancies.

- The forms will facilitate standardised, structured data being fed into databases making interoperability of systems and sharing of data between competent authorities much easier.

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4. What are the next steps for DADI deliverables?

- The variation form for human medicinal products will be the first form to be released. The expected release order of forms after human variations will be confirmed at a later stage.
- The variation form for human medicinal products is undergoing closed User Acceptance Testing (UAT) with members of the DADI Subject Matter Expert Group, which will be followed by testing of the PMS data (through a PMS UAT) that the forms will use.
- Finally, there will be integrated User Acceptance Testing with a larger, but still limited, group of testers representing various stakeholders.
- The go-live 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.
- At the end of the transition period, both the use of the web-form and the use of structured PMS data will be required.
- Further details on User Acceptance Testing and subsequent development on other forms will be shared on a regular basis during the coming months.

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5. What are the next steps for DADI deliverables?

- Communications around timeline are published on the DADI project page of the eSubmission website.

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6. How is DADI taking stakeholder perspectives into account?

- DADI is a Network project as it addresses both Centrally Authorised Product Applications and Nationally Authorised Product Applications.
- The DADI project has established a Subject Matter Expert Group (formerly: Requirements Group) which represents Subject Matter Experts from EMA, NCAs and Industry. Participation to the group is limited.
- The SME Group meets on a weekly basis and provides expert insight into the use of forms, as well as provides input for EMA requirements for CAPs and NCA requirements for NAPs.
- The SME Group is also involved in testing of the forms.
- The project planning and implementation are following Safe Agile principles. Product ownership of the web-forms is shared between EMA and NCA representation, which means requirements gathering and design is done collaboratively between EMA and the Network.

- Product ownership for NCAs is an in-kind contribution of the UNICOM consortium.

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7. How is UNICOM contributing to DADI?

- UNICOM is a European Commission (EC) Horizon2020 funded consortium separate from the European Medicinal Network's IT governance structure.
- Two of its objectives relate to ensuring the availability of Pan-European IDMP Compliant forms (Work Package 3) and IDMP implementation at National Agencies (Work Package 4). UNICOM has an inbound dependency on the DADI project for Work Package 3.
- UNICOM provides in-kind contributions to DADI project work and the web-forms for among others: a product owner, communication and training to NCAs and applicants, supporting NCAs to automatically import form data, liaison with the Notice to Applicants Expert Group, contributing to UAT and IT development for FHIR messages and PDF representations for NCAs.
- EMA has no contractual obligations towards the UNICOM Consortium and the European Commission.

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8. How will the project impact Competent Authorities?

- The web-based application forms will be common for both NAPs as well as CAPs which are processed by NCAs 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.
- The web-based forms create opportunities to automate manual processes related to processing forms and facilitate the collection of standardised data.
- Competent authorities that are not currently using the PDF forms' Extensible Markup Language (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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9. How will the project impact industry stakeholders?

- The current PDF format variation eAF will be replaced by a web-based user input form for CAPs and NAPs applications.
- Any new web-based application form will be prepopulated with available PMS/UPD data. Industry will have visibility of data available on the regulator's side.

- The forms will support the collection and use of standardised PMS/UPD product master data.
- DADI is currently developing the human variation form. Once this moves to external testing and, later, release and implementation, a more detailed breakdown of possible impacts for industry will be made available.

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10. Will there be User Acceptance Testing for the DADI deliverables?

- User Acceptance Testing (UAT) is the testing of the form by users to verify the requirements have been met.
- The UAT approach for the variation web-form for human has three steps:
  - Internal testing;
  - Data testing;
  - External testing.
- Internal testing is performed during the development sprints (according to the SAFe Agile methodology) and tests the functionality of the form with test data. Testing started in November 2021 and is performed by EMA staff and a selection of volunteers from the DADI SME Group. The SME Group comprises Subject Matter Experts from EMA, NCAs and industry and represent those respective stakeholder groups.
- Data testing will test the successful migration of the product data to PMS. The data testing is not in scope of the DADI project; however, it is a critical dependency.
- External testing will test the form's functionality and PMS data together. The aim is to facilitate testing by a wider group of stakeholders.
- A call for interest for the DADI UAT will be sent in advance. Note that the UAT aims to test the forms and data together. The aim will be to cover the most likely scenarios for different stakeholders. This means participation will be limited, however, there will be other opportunities, including the transition period itself, to allow all users to familiarise themselves with the new tool.
- In addition to testing, the project team will demonstrate the new forms in one or more public webinars closer to their release dates.

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11. 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).
- As part of the roll-out of the new forms, a learning offering will be made available, with the exact format to be determined.
- In addition, applicants and stakeholders can expect several webinars to support roll-out and answer questions.

- User guides will be updated to fully support the web-based forms.
- There will be help online and on-screen tooltips within the system.

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12. Will the future forms still be called eAFs?

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

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13. Who will maintain the new web-based forms?

- The system facilitating the forms will be technically maintained and supported by EMA.
- The EMA Service Desk will be available to address issues and there will continue to be opportunities for applicants and other stakeholders to propose features.
- Until further notice the existing eAF Maintenance Group, which plays a key role in maintaining the current 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 a subject matter expert body, such as the current eAF Maintenance Group, will continue to exist with EU Regulatory Network and industry representation.

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14. Are the forms still owned by the NtA group?

- Yes, for human medicinal products the European Commission Notice to Applicants (NtA) expert group will remain responsible for the content requirements of the 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 data management services.

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15. Will the content requirements for the application form change?

- The web-based forms are the input forms to create the application, these will change to accommodate PMS/UPD data requirements.
- The output PDF rendition of the forms will look like the current PDF eAF and will have the same information as the current forms.

- 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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16. Is registration required to fill in an eAF?

- Every person involved in drafting an eAF needs an EMA account and can have different roles depending on access privileges. This enables saving forms online and co-authoring with other users. In case of co-authoring it is suggested to coordinate well with contributors, as there is the possibility of overwriting data if multiple people work on the same section simultaneously.
- Sign up will be possible before go-live to prepare access to the system.
- Each MAH has to make sure that consultants working on their behalf get an EMA role to see their products and are allowed to make changes. The IAM (Identity and Access Management) system will allow for two different types of consultant access: access to all products from that MAH or access to specific applications containing products.
- With regards to registration to user acceptance testing and production use, please consult the DADI webpage on the eSubmission website where information will be provided.

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17. What is the difference between DADI and IRIS?

- IRIS is EMA's online platform to support product-related scientific and regulatory procedures with EMA.
- The future DADI portal will host application forms for all EU procedures (CP, MRP, DCP, NP, SRP). After filling in the web-based form, the applicant will generate a PDF which is submitted through existing eSubmission channels as part of eCTD package.
- IRIS and DADI portals serve different purposes and will be governed differently. 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.
- IRIS is implemented using several technologies that will be also used to deliver the DADI project, i.e. Microsoft PowerApps. Experience gained by EMA in building IRIS is helping to implement DADI.

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18. What is ISO IDMP?

- The International Organisation for Standardisation (ISO) standard for identification of medicinal products (IDMP).
- ISO IDMP specifies 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 EU Member States, Marketing Authorisation Holders (MAHs) 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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19. Will the data requested in forms for human medicinal products be ISO IDMP-compliant?

- The intention is to facilitate exchange of standardised master data, therefore, the forms will use PMS data which comply with ISO IDMP standards for human medicinal products.
- The scope of ISO IDMP and SPOR is 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 covers human medicinal products only.
- See this presentation for further details on the relation between SPOR, ISO IDMP and FHIR.

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

- Veterinary forms are in scope for DADI. This means that when DADI web-based forms for veterinary medicinal products are released, they must comply with the 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 format electronic variation application form has been updated to support regulatory requirements for the 28 January deadline.

- The main benefit of this approach is that there will be 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.
- Development work on the veterinary web-form will start at a yet to be determined time.
- In the meantime, veterinary representatives participating in the DADI SME Group have been invited to stay on as observers to ensure a smooth uptake of veterinary requirements once development starts.

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21. What is FHIR?

- Fast Healthcare Interoperability Resources (FHIR) is a standard for exchanging healthcare information electronically.
- The DADI project team will create a FHIR specification as backbone for each of the new web-based forms.
- FHIR is the machine-readable language chosen to support the easy exchange of data between DADI's forms, systems and product databases such as PMS and UPD.
- 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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22. Is an HTML FHIR viewer publicly available?

- Proprietary tools to transform FHIR XMLs to HTML are publicly available.

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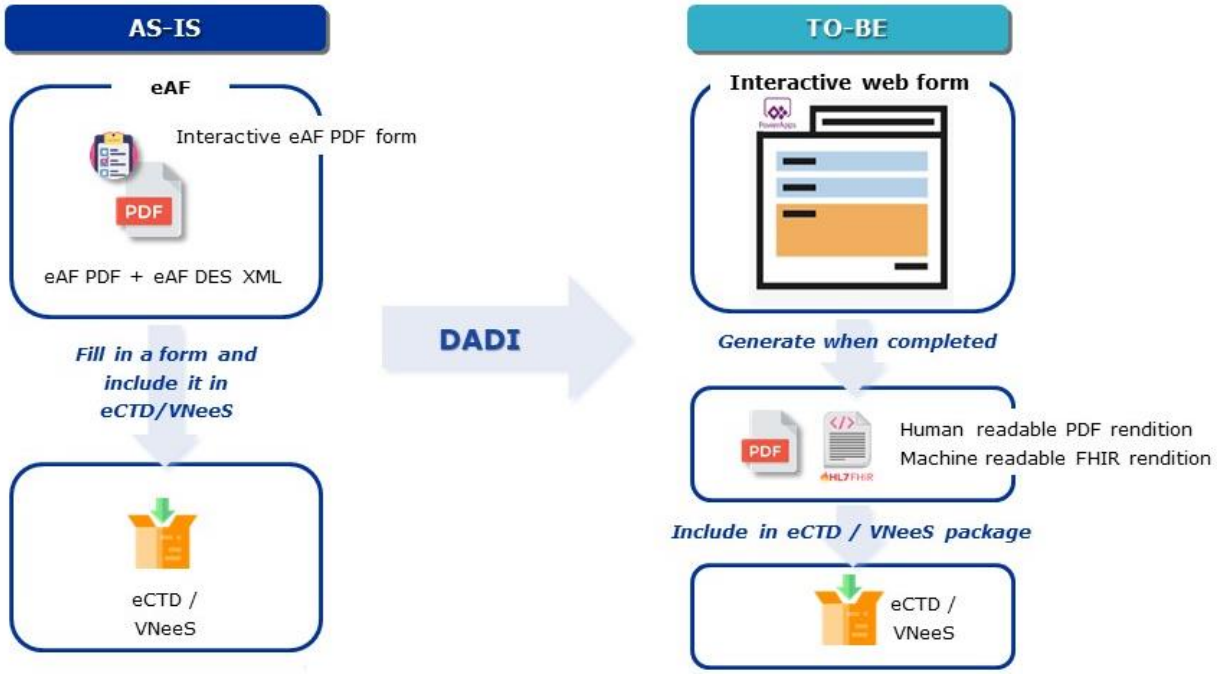
23. What will change technically in the forms?

- Applicants will fill out a 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 the familiar human readable PDF document and an attached FHIR message which can be read and processed by IT systems.
- Submission of DADI variations forms will not differ from submission of the current eAFs.

- See Diagram 1 below for a visual description of technical changes:

Diagram 1 – Current situation vs future situation for eAFs



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24. Which will be the options available to create the eAF PDF in the new interface?

- Three options were considered by the DADI project team:
  - Using the web-based form to create applications and export to PDF with an attached FHIR message;
  - Creating the entire application FHIR message in an applicant's own system to submit to an Application Programming Interface (API) for validation and transformation into a PDF with attached FHIR message;
  - Importing a partial FHIR message into the web-based form to complete the application in the web User Interface.
- Of these three options, the first is what will be available upon initial release. This is the core feature of the web-based forms which enables a move away from the current PDF-based data input while also enabling the FHIR output attached to the PDF output to facilitate handling of applications.
- The second option is undergoing further analysis and design work to ensure validation of data provided through such a mechanism can be ensured. The third option is pending a technical feasibility analysis.

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25. Will all products (CAPs and NAPs) be searchable within the eAF from the first DADI release?

- All products (CAPs and NAPs) will be searchable according to access management rules.

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26. Will the use of web-forms be mandatory for CAPs and NAPs at the same time?

- At this point in time there is no plan to differentiate between CAPs and NAPs.

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27. What is the connection between PMS and the web-based forms?

- PMS is the Product Management Service for product master data for human medicinal products. It is one of the four data management services for human and veterinary medicinal products known as SPOR (substance, products, organisations and referentials). For Veterinary medicinal products, UPD is the service through which product master data is provided.
- The goals of SPOR services are:
    - increased data quality and simplification of data management practices, since data will be reviewed, assessed and approved as part of the new data operating model;
    - more efficient regulatory action and decision-making, thanks to improved data integrity and reliability;
    - regulatory requirements can be met more effectively, by reducing data silos and improving interoperability across EU systems;
    - operational savings and efficiencies can be achieved, as pharmaceutical companies need to supply regulatory data only once, which will be re-used across different procedures and regulators.
- In line with these goals the new web-forms will standardise input for eAFs in order to effectively provide standard PMS data.
- The web-forms will also use available PMS data to prepopulate form fields where relevant.
- FHIR was selected as the application programming interface for the PMS/UPD services and the web-based forms are an example of FHIR being used to read data from the application programming interface and display it in the web forms.

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28. What is the connection between the web-based forms and UPD for veterinary medicinal product data?

- The UPD refers to the requirement for a new Union Product Database for all authorised veterinary medicinal products as per the veterinary medicinal products regulation, EU Regulation 2019/6. The UPD is accessible to the general public and will be a searchable database.
- UPD uses the same data repository for product master data as PMS, and it is commonly referred to as UPD to distinguish it from product master data for human medicinal products.
- The new web-forms will standardise input for eAFs in order to effectively provide standard UPD data.
- The web-forms will also use available UPD data to prepopulate form fields where relevant.
- FHIR was selected as the application programming interface for the common PMS and UPD data repository and the web-based forms are an example of FHIR being used to read data from the application programming interface and display it in the web forms.

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29. Will the FHIR message that is embedded in the DADI PDF export be used to update PMS from the initial go-live of DADI?

- This will not happen at the go-live of DADI, and submissions to Art. 57 are still needed. In the future, the idea is to use the data provided in the DADI variation form in order to update the data in PMS.

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30. Will the mapping of the FHIR resources used by DADI with IDMP be published?

- The medicinal product resources used by PMS and DADI have the same name, so users can look for them in PMS EU IG Chapter 2. The FHIR resources have the mapping to IDMP present in FHIR already (e.g. http://hl7.org/fhir/2021May/medicinalproductdefinition-mappings.html).

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31. How will the eAF FHIR message relate to the PMS/UPD messages?

- The eAF FHIR message comprises two major parts: (1) the procedure part, known as the task resource, and (2) the medicinal products part. The procedure part is eAF specific, while the medicinal products will be represented through FHIR resources which match those of PMS and UPD.

- A resource is the basic building block in the FHIR standard. 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.
- There may be some additional resources and elements in the product part for the eAF that are needed only for a given regulatory procedure i.e. not to be reused. These will not be entered into PMS or UPD.

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32. Will it be possible to download/export products data from the web User Interface?

- The users will be able to see the relevant product data via the web UI and download the forms which contain such data. However, there will be no dedicated capability neither to export only product data nor to perform bulk exports in the web UI.

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33. Does the form need to be signed?

- It will be possible to sign the PDF rendition using own digital signature tools of the applicants. Details on the signature requirements will be available before go-live.
- The web-form contains the fields for the name of the signatories.

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34. How is the web-form submitted?

- The form is filled in using the new web UI. However, the user will need to finalise the form by generating a PDF rendition which must be included in the eCTD submission. It is not possible to submit the form directly from the web UI.

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35. How will stakeholders be notified of future changes to the forms?

- 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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36. My question is not answered here, what do I do?

- The DADI project is still ongoing therefore not all questions have definitive answers. As topics are clarified the project team will share details and supporting documentation, including updates to this Q&A document.
- Applicants wondering about specific features and interests can consider contacting an industry association representative on the SME group or contacting EMA directly.
- For general inquiries, please contact the DADI project team via esubprogofficer@ema.europa.eu. For questions or comments around the content of this 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.
- If you have a technical question about the current eSubmissions systems or the DADI project, please raise a ticket (by selecting "Ask a question" and including in the subject "DADI") via the EMA Service Desk.

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Table of abbreviations

Abbreviation	Explanation
AEMPS	Agencia Española de Medicamentos y Productos Sanitarios
AGES	Austrian Agency for Health and Food Safety
AMP	Authorised Medicinal Product
API	Application Programming Interface
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
CAP	Centrally Authorised Product
CESSP	Common European Single Submission Portal
CP	Centralised Procedure
DADI	Digital Application Dataset Integration
DB	Database
DCP	Decentralised Procedure
eAF	Electronic Application Form
eCTD	electronic Common Technical Document
EV Code	Eudra Vigilance Code
EEA	European Economic Areas
EC	European Commission
EU	European Union
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
xEVMPD	Extended EudraVigilance medicinal product dictionary
FHIR	Fast Healthcare Interoperability Resources

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H	Human
HL7	Health Level 7
HPRA	Health Products Regulatory Authority
IAM	Identity and Access Management
IDMP	Identification of Medicinal Products
IG	Implementation Guide
IT	Information Technology
ISO	International Organization for Standardization
MEB	Medicines Evaluation Board
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
NAP	Nationally Authorised Product (generally used in this document to describe products authorised via MRP/DCP/NP)
NCA	National Competent Authority
NOMA	Norwegian Medicines Agency
NP	National Procedure
NtA	Notice to Applicants
PMS	Product Management Services
PSMFL	Pharmacovigilance System Master File
QPPV	Qualified Person for PharmacoVigilance
RIMS	Regulatory Information Management System
SME Group	Subject Matter Experts Group
SE MPA	Swedish Medical Products Agency
SPOR	Management Services for Substances, Products, Organisations and Referentials
SRP	Subsequent Recognition Procedure
Q&A	Questions & Answers
UAT	User Acceptance Testing
UI	User Interface
UNICOM	Up-scaling the global univocal identification of medicines project
UPD	Union Product Database
VA	Variation Application

Vet	Veterinary
VMP	Veterinary Medicinal Products
VNees	Veterinary non-eCTD electronic submission.
xEVMPD	Extended EudraVigilance Medicinal Product Dictionary
XML	Extensible Markup Language