Information Management

July 2022

Digital Application Dataset Integration (DADI) and Product Management Service (PMS) Webinar – "Variations form for human medicinal products - What will happen at go-live"

Questions and Answers

Disclaimer

This Question and Answer (Q&A) document is for information only and is based on insights available **at the time of the DADI-PMS webinar** "Variations form for human medicinal products - What will happen at go-live" held on 16 May 2022. Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the DADI and PMS project teams.

Please note that this Q&A has **not** been updated to reflect the revised scope (Go-live with CAPs only in October 2022, 2nd Release in March 2023 including CAPs and NAPs).

For convenience, many technical terms are explained in the table of abbreviations at the back of this document.

For general inquiries, please contact the DADI project team via esubprogofficer@ema.europa.eu or the PMS project team via the EMA Service Desk. 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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DADI

DADI SCOPE

1. Will DADI support the needs for the new EMA mandate regarding Shortages Management?

The DADI project will replace the current eAF for Initial Marketing Authorisations, Variations and renewals, while there is another project covering the needs to Shortages. The underlying data used by both projects will be provided by PMS and, eventually, it is expected that data collected via DADI could be re-used for Shortages and vice versa.

2. If DADI is not available for national procedures in April 23, how should the application form be prepared for work sharing with NAP & CAP?

The web-based form to be released in October will be available for all procedure types, including National procedures including worksharing procedures. There should be no reason to revert back to the use of PDF. After April 2023 it is foreseen that the current interactive PDFs will be decommissioned and can no longer be used for new procedures.

eAF WEB-FORMS

3. In case of DADI downtime/issues, would it be possible to use the PDF form after April 2023 (especially in case of urgent variations)?

At go-live you will still be allowed to use the PDF for a transition period of 6 months. More details on the DADI Human Variations timeline and transition period can be found in the webinar presentation *"Variations within the Variations Form for Human Medicinal Products What will happen at Go-Live?"* (slides 12 and 13).

4. Will 2x DADI forms apply for a submission of a grouped variation with a line extension, as it currently works (one for the variation, one for the LE)? What about submissions of

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such grouping between the go-live of the variation and initial submission in DADI?

As line extensions are still part of the MAA form, during 2023 it will be necessary to submit one web-form and one PDF. Easier line extensions will be considered once the MAA form is being implemented.

5. In case applicants have a tight deadline for submission and incur in unexpected technical issues that prevent the submission, how can they handle it?

At go-live applicants will still have the possibility to use the PDF variation form.

6. Will EMA correct submitted DADI data as it works for xEVMPD?

DADI variation form is just like the variation form but based on a web. There is no change to the process at go-live, so no changes to data in eAFs is done by EMA or NCAs.

7. Considering that the current eCTD specification will not recognise a PDF from DADI in comparison to the current form, how will the mandatory use of DADI be enforced after April 2023? Have all the Agencies been informed and onboarded?

Depending on the level of preparedness of the regulatory agency, this process may be manual or automated. We will also need to decide until when ongoing variations that have started using the interactive PDF can continue using the old format.

8. Can DADI web-forms be filled in only manually?

Yes, at the time of go-live that will be the case. We intend to consider machine-to-machine integration, but that will not be possible initially.

9. Which variations will use the web-forms and which not (e.g., a few CP, a few Non-CPs) at go-live?

There is a transition period during which either the web form or the current PDF forms can be used. Users can choose which to use during such transition period. After the transition period only the web-form should be used.

10. If there are no free text fields, how will complex information on the scope and background be included in the variation form?

Free text is allowed, especially regarding scope and background changes.

11. Will all the fields of the new DADI form be drop-down menus?

No, only those that can be filled using structured data (i.e.: SPOR data). Moreover, at go-live, only some fields will be using structured data in the DADI variation form. More details on these aspects can be found in the webinar presentation *"Variations within the Variations Form for Human Medicinal Products What will happen at Go-Live?"* (slide 26).

12. Which web browsers are compliant with the new web-form?

The main browsers (e.g., Google, Microsoft Edge) are compliant with the new web-form. EMA will publish a list of official supported browsers.

13. Will multiple users be able to work on the same form?

EMA is implementing various features to allow multiple users (from the same or different organisation) with different levels of access to work on the same form.

14. During the transition period, will it be necessary to submit both the PDF-based eAF and the DADI web-based form or only one of them?

Only one of the forms.

15. Will the XML code or the PDF rendition be considered the primary source in case of any differences between them?

The new PDF is created by transforming the FHIR message. Technically there can be no differences.

16. Does the DADI form time out if it is not used/edited after some time? If so, what would be the time limit? Does it have a "save" option?

The form will time out after a while of not using it. There is a save option, and many steps will save automatically. Navigating away will also prompt a save.

17. Will it be possible to create copies of an "eAF" that is prepared on a global level, to enable the generation of country specific "eAFs"?

The "copy" feature is in the pipeline but will most likely only make it into the next version.

18. A grouped variation might require hundreds or thousands of MAs to be selected. Is it possible to upload a list of "my products"?

Yes, it is possible to apply filters and select multiple products.

19. Does the new DADI form accept digital signatures?

It will be possible to digitally sign the PDF after downloading it using your own infrastructure.

eCTD

20. Is the FHIR xml format message and PDF output one document, or will be adding two documents to our eCTD submissions?

There will be a single output from the portal. The PDF rendition will contain the FHIR xml. A pdf eAF should be added into the eCTD package.

21. How the validation of the eCTD will work with the FHIR xml format message and new PDF format output?

The pdf rendition output form will contain the FHIR xml message and hence, the eAF which is added into the eCTD package is still in PDF format and therefore the eCTD validation will not be impacted.

FHIR

22. What is FHIR?

FHIR stands for Fast Healthcare Interoperability Resources and it is a standard for health care data exchange, published by HL7. Both projects, PMS and DADI are supported by these standards to exchange messages.

23. Will applicants have to adapt their IT systems to accommodate the new FHIR xml format?

At Go-live in October only manual entry is foreseen. Although in the future we foresee that machine to machine will be possible we envisage that a manual possibility will always be available i.e., it will not be mandatory to change your systems.

DADI & OMS

24. Does DADI interact with the OMS database to exchange/import organisations' information?

Yes, DADI uses OMS for organisations (similarly as the current interactive PDF forms do), but with the difference that the use of OMS will be mandatory.

Article 57

25. Will applicants need to update Art. 57 with regard to applications affecting Northern Ireland, but no other EU member state? Will MHRA have access to the new forms?

Yes, Art. 57 rules and process do not change. New form still has a PDF rendition that can be used by all NCAs.

DADI - OTHER

26. Does anyone in the EMA lifecycle team have direct experience in the evaluation or assessment of human medicinal products within the centralised procedure?

The expert group around creating the requirements of the project has 3 representatives from EMA business on the different central human variation areas.

PMS

PMS DATA

27. What Applicants should do to submit a variation in case the product is not included in PMS?

The steps to follow in case a product cannot be selected or found are outlined in the webinar presentation "Variations within the Variations Form for Human Medicinal Products What will happen at Go-Live?" (slide 25).

28. Will EMA databases be automatically updated based on data that is manually inserted in the DADI form?

At DADI variations form for human medicinal products go-live in October this will not be possible, this is planned for a later stage.

29. Has the network fully agreed that PMS will be a trusted/good quality source of product data, or is that only EMA's view at the moment?

There is agreement on the goal of SPOR or PMS as trusted and good quality data. However, there is ongoing assessment on how and when to achieve that.

30. Which data will be stored in PMS after the go-live i.e., (xEVMPD or DADI)?

At go-live Data in PMS will continue to come from xEVMPD and SIAMED/EMA database.

31. Who is ultimately responsible for the data in PMS? Currently, there are changes made by EMA to xEVMPD data without notifying the applicant. Will this change with PMS and DADI? How will applicants be informed of changes to their data?

Currently, changes to xEVMPD are communicated to the applicant by sending a third acknowledgment and are reflected in PMS and DADI.

32. How will industry or NCAs cleanse and align PMS data before their mandatory use in DADI?

This is not required at DADI go-live, further details about enrichments/corrections will be provided in due course.

33. How would MAHs proceed if the granularity of Medicinal Products in PMS does not fit? (e.g., caused by migration errors as identified in the PMS UAT)

PDF forms can still be used during the transition period. More details on the DADI Human Variations timeline and transition period can be found in the webinar presentation *"Variations within the Variations Form for Human Medicinal Products What will happen at Go-Live?"* (slide 12 and 13).

PMS & SIAMED Data

34. In case of data discrepancies within SIAMED data, how industry will be able to raise that or amend the data before it can be included within the eCTD package?

At the time of DADI go-live SIAMED/CAP data is being used for product selection and that data is already available in public EMA sources (Annex A) so we do not expect corrections to be required.

35. How often will PMS data be synchronised with SIAMED (e.g., daily, immediately)?

Synchronisation is foreseen to happen near in real time.

36. When will EMA publish the migration rules between SIAMED to PMS data base?

As shown in the webinar presentation *"Variations within the Variations Form for Human Medicinal Products What will happen at Go-Live?"* (slides 21-26), there is no change on the process. Just a different form is used. Therefore, updates to Ch. 3 are not expected for the moment.

xEVMPD

37. We are working into identifying gaps in xEVMPD to be prepared for the migration. Is it a good approach to ask for an update now in order to amend/fill these gaps?

At DADI go-live only xEVMPD data is required, there is no need to complete/provide additional data.

38. Will the migration from xEVMPD to PMS occur before the launch of the web-form eAF (i.e., before October 2022)?

Indeed, to be able to retrieve authorised product data in DADI variation form, the data must be routinely migrated (in production) from xEVMPD to PMS. This is performed via using deltas from xEVMPD to PMS that synchronises data almost in live time.

39. When will xEVMPD submissions be no longer needed?

At Go-live of DADI and PMS (scope of this webinar), xEVMPD submissions still apply. In future, when there is more information on when xEVMPD submissions are no longer needed, we will communicate it.

40. Is it necessary to enrich the XEVMDP database in order to fill in the eAF?

If you have submitted all your Authorised Medicinal products to XEVMPD you will not need to do anything else.

41. Will DADI be used for peculiar national products (e.g. homeopathic, or traditional herbal medicines in the future)? Currently, these are not covered by the Var. Reg. and are not mandatory in the art. 57 database (in Germany).

All products required for DADI should be registered in PMS (and in xEVMPD) so these products should also be registered in xEVMPD.

42. What data will industry need to submit from April 2023? Will it be still necessary to submit xEVMPD?

Yes, xEVMPD submissions are still applicable. More details on xEVMPD submissions can be found in the webinar presentation *"Variations within the Variations Form for Human Medicinal Products What will happen at Go-Live?"*.

43. When will the xEVMPD elements, updated by an XEVPRM, be reflected in the PMS system/ DADI Portal (e.g., after an overnight refresh or in real time after the xEVMPD update success acknowledgement is received)?

Almost real time.

44. Which data from xEVMPD will be transferred to PMS?

All data from XEVMPD will be migrated into PMS.

45. How much time does it take to update the PMS database once information is updated in xEVMPD database?

The data synchronisation between xEVMPD and PMS occurs almost in live time. Depending on the volume of data and products to load it may take 15 minutes to visualise the data in PMS.

46. Will Applicants have to check/enrich data at the go-live to ensure the correctness of current values, especially in case of a migration from xEVMPD to PMS?

No, it is not correct. Enrichments and corrections will happen later on time.

GENERAL

DADI & PMS ROADMAP

47. When will the PMS UAT where a bigger audience can participate be? And when DADI UAT? When will the findings of the first PMS UAT be fixed?

More information on DADI and PMS UAT will be shared in due time. The technical team is already working to fix the finding of the first PMS UAT.

48. When will EMA publish the updated chapter 3 guidelines to capture the impact of the new web-based forms in the IDMP data submission process?

As mentioned at the webinar, at the time of the launch of the new web-based form there is no change on the process. Therefore, updates to EU IG Chapter 3 are not expected by the time of the launch.

49. When will structured data in the full PMS EU IG v2 scope be provided (e.g., in Q4 2023, Q2 2024)?

As mentioned at the event this is not required at DADI go-live, further details about enrichments/corrections will be provided in due course.

50. When will EMA communicate about the new timelines? Are the previous timelines obsolete? Is it expected to be full implementation for CAPs and NAPs at the same time?

The timeline for the development and implementation of DADI Human Variations can be found in the webinar presentation "Variations within the Variations Form for Human Medicinal Products What will happen at Go-Live?" (Slides 12 and 13).

51. Will the Q4 2023 release for structured data fields be optional first? If yes, how long will the transition phase to mandatory use be?

There will be a limited set of fields for which users need to perform structured changes. The transition period - to stop using the current PDF - is 6 months. More details on the DADI Human Variations timeline and transition period can be found in the webinar presentation *"Variations within the Variations Form for Human Medicinal Products What will happen at Go-Live?"* (slides 12 and 13).

52. When can Industry expect a clear timeline on the next steps (e.g., when will we be able to have PMS access, xEVMPD be switched off, PMS on, etc), in order to start contacting IT tools' vendors for implementing IDMP and enabling systems exchange?

This is not required at DADI go-live, further details about enrichments/corrections will be provided in due course.

53. When is it planned that DADI writes data back to PMS?

This will not be possible at the time of DADI-go-live. We will provide further details and more concrete plan in due course.

VARIATIONS PROCESS

54. Considering that the process will not change, will EMA and NCAs use DADI to upload data in their internal product databases? In other words, will it be necessary update the DADI form if data changes during a variation?

The process will not change at the time of the variations form launch. Eventually EMA will start using IRIS to manage applications. NCAs may have different solutions.

55. If only products that are part of the PMS can be selected for a variation, how to submit a variation after 30 days (i.e., following the finalisation of DCP) in case the MAs are not granted yet?

The process at go-live of DADI Variations Form including the drafting of a variation is explained in the webinar presentation "Variations within the Variations Form for Human Medicinal Products What will happen at Go-Live?" (slides 21-26).

56. If the variation concerns, for instance, a change of MAH, will OMS need to be updated before submitting the eAF in the new web- form? In other words, will industry need to update OMS/xEVMPD before the submission? What about products that are not yet in the xEVMPD database, but for which a

variation has to be submitted (e.g., a product in an MRP / DCP for which the national approval is not received yet, but a variation has to be submitted)?

There is no change in the process with respect to how it works today.

TRAINING

57. When will training material be available for industry considering that the go-live is foreseen in October?

The team is aiming to have draft training materials ready for the UAT in September.

58. Will there be any EMA training program regarding the different web-apps?

Indeed, training will be provided to get confident in using the different webapps. More information will follow in due course.

REGISTRATION, ACCESS & ACCOUNT MANAGEMENT

59. Is there already a role available in the EMA Account management to use DADI? Which role is it?

Currently, there are only a few UAT roles that are reserved for a restricted number of testers. Later, EMA will communicate when it will be possible request an account to use DADI.

60. Regarding user access: what does MAH mean? Is it the "global MAH" containing all subsidiaries? Or is each MAH handled separately?

A MAH corresponds to a single organisation that is situated in a country. If a global organisation is located in two countries, it will have two specific organisations' entries that will require different authorisations for their products. Information on how to set up users' accounts and manage the access for the organisations will be provided in the next system's demo on 28 and 29 June 2022.

61. After the initial registration to the new eAF portal, will consultants have the possibility to change registration data on an ongoing basis to reflect possible changes in the range of MAHs for which they work?

The roles associated to different MAHs/applicants/companies can and should be updated where relevant (this will be possible on an ongoing basis).

62. Will there be a limit to the number of users per company that can be created in the new eAF portal?

The forms will be using the EMA IAM system to manage accounts. This system is used for all EMA activities and there is no limit for accounts.

63. Can you provide the link to the EMA registration portal?

Registration is not yet possible, but we will publish some news once the registration to the portal opens.

Table of abbreviations

Abbreviation	Explanation
CAP	Centrally Authorised Product
CESP	Common European Submission Portal
CP	Centralised Procedure
DADI	Digital Application Dataset Integration
DCP	Decentralised Procedure
eAF	Electronic Application Form
eCTD	electronic Common Technical Document
ePI	Electronic Product Information
EV Code	Eudra Vigilance Code
EEA	European Economic Areas
EC	European Commission
EMA	European Medicines Agency
EU	European Union
EUDAMED	IT system established by Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices and developed by the European Commission.
EudraGMDP	The EudraGMDP database is the Community database on manufacturing, import and wholesale-distribution authorisations, and good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates
xEVMPD	Extended EudraVigilance medicinal product dictionary
FHIR	Fast Healthcare Interoperability Resources
GB	Great Britain
GMP	Good Manufacturing Practice
H	Human
HL7	Health Level 7
IAM	Identity and Access Management
IDMP	Identification of Medicinal Products
IG	Implementation Guide
IRIS	EMA's Regulatory & Scientific Information Management Platform
IT	Information Technology
ISO	International Organization for Standardization

MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure (MRP)
NAP	Nationally Authorised Product (generally used in this document to describe products authorised via MRP/DCP/NP)
NCA	National Competent Authority
NP	National Procedure
OMS	Organisation Management Service
PLGB	Great Britain Product Licence
PL	Product Licence
PMS	Product Management Services
RIMS	Regulatory Information Management System
RMS	Referentials Management Service
SIAMED	EMA database for Centrally Approved Products
SPOR	Management Services for Substances, Products, Organisations and Referentials
Q&A	Questions & Answers
UAT	User Acceptance Testing
UPD	Union Product Database
VA	Variation Application
VMP	Veterinary Medicinal Products
xEVMPD	Extended EudraVigilance Medicinal Product Dictionary
XML	Extensible Markup Language