Information Management

July 2022

Digital application dataset integration (DADI) Q&A webinar - variations form for human medicinal products

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 Q&A webinar on variations form for human medicinal products held on 12 July 2022. Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the DADI and PMS project teams.

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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Table of abbreviations

Abbreviation	Explanation
CAP	Centrally Authorised Product
CP	Centralised Procedure
CRO	Contract Research Organisation
DADI	Digital Application Dataset Integration
DCP	Decetralised Procedure
eAF	Electronic Application Form
EMA	European Medicines Agency
EU	European Union
xEVMPD	Extended EudraVigilance medicinal product dictionary
FHIR	Fast Healthcare Interoperability Resources
H	Human
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
MAH	Marketing Authorisation Holder
MRP	Mutually Recognised Procedure
NAP	Nationally Authorised Product
NCA	National Competent Authority
NtA	Notice to Applicants
OMS	Organisation Management Service
PMS	Product Management Services
RA	Regulatory Activity
RIMS	Regulatory Information Management System
RMS	Referentials Management Service
SIAMED	EMA database for Centrally Approved Products
SMS	Substance Management Service
SPOR	Management Services for Substances, Products, Organisations and Referentials
Q&A	Questions & Answers
UAT	User Acceptance Testing

1. Are the Industry coordinators supporting also the transition phase or only September and December/January UATs (e.g., to detect common issues across Industry and help prioritising them)?

At the moment, Industry coordinators have been invited to support the UAT. The possibility of further support during the transition phase will be evaluated in due time.

2. Can you please confirm when xEVMPD data enrichment will be required?

As announced in previous events, it is recommended for users to keep their xEVMPD product records up to date in view of the new eAF forms releases.

The data enrichment is a slightly separate process. Indeed, structured changes will be implemented in the form for release 3.

In parallel to DADI variation forms product, PMS tools for data correction and enrichment is under development. More information on the timeline for the delivery of these tools will be provided as development goes on.

3. Currently, full SMS data is not available in SPOR. Can we expect SMS data while filling DADI, does it have any impact?

If meaning that the substance is not yet in SPOR, this can be requested as per SMS procedure. Please note that most substances are available in SMS database. The substance as mentioned in the current section 2 of the interactive pdf, is automatically filled in using the substance(s) contained in the selected products.

4. Could downtime of xEVMPD/PMS database affect DADI tool?

Please note that xEVMPD downtimes are planned and communicated like for any other system and Service Desk processes are in place to respond to any incident. This process can allow the applicant to plan the relevant regulatory activities accordingly.

5. How does EMA intent to fix the data quality gap for the NAPs xEVMPD data migrated to PMS?

The Agency is testing the product data migrated from xEVMPD. This activity will allow the Agency to promptly identify and fix any bug to improve the quality of the product data migrated via both initial load and the routine updates loaded in PMS via the use of the deltas.

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Additionally, with the scope to further enhance the quality of product data available in PMS, the Agency is working to develop and release the tool to allow users to perform data correction / enrichment to PMS directly.

6. Please can you confirm when DADI becomes mandatory for CAPs and NAPs?

The eAF web form for human variations will become mandatory for CAPs and NAPs in September 2023.

7. The 6-month transition period starts in October 2022 or March 2023?

The transition period will start in March 2023, after the release of the forms for all procedure types (CAPs and NAPs).

8. Which actions should a company do to be part of the UAT?

Please visit the eSubmission website for details around how to express your interest.

9. Will it be possible to test NAPs in the DADI UAT in September? Some MAHs do not have CAPs but still would like to test.

The September UAT will focus on the scope of the October go-live, i.e. CAPs only. The NAPs will not be available in the system for testing. The December 22-January 23 UAT will concern both CAPs & NAPs.

10. Will there be a call to the NCAs on the NAP data so that they can prepare a data package just like the UPD to ensure NAP data quality and avoid invalidation on eAF forms based just on xEVMPD/PMS data?

This is not a prerequisite for go-live, but indeed some NCAs have expressed an interest in this possibility at some point in the future. Further discussions on this topic will take place in the context of portfolio prioritisation, particularly with the Network Portfolio Advisory Group (NPAG) which has NCA representation, and any updates will be provided in due course.

11. Will UAT consolidators decide what is the limit on Industry participants since they are the ones providing consolidated feedback to EMA?

Yes. EMA will not limit the number of testers, but it is the UAT coordinators who will decide how many testers they can facilitate. So, EMA will provide the coordinating Industry Associations with a list of applicants who volunteered to participate.

The Associations could decide to limit the number of selected participants if they judge there are too many of them.

12. A big part of DADI for MAHs will be account management. When will a guide be made public on: 1) How to create role for the manager of the accounts for MAHs? 2) How to manage accounts for the employees who need to use the new DADI webform?

The guide on Access Management is now available on the eSubmission website . It will be also available on the portal for testers.

13. Will all national portals or application forms be replaced by DADI at go-live/at the end of the transition period?

The use of eAFs is mandatory, even though some national Member States may have specific national requirements. The implementation of web-based forms in place of interactive PDF forms will not directly impact the use of national portals.

14. Is it possible during the 6-month transition period to choose for each variation application whether to use the DADI form or the current PDF eAF? So, is it possible to step back to the PDF eAF if issues arise using the DADI form?

Yes, it is possible to choose the PDF eAF or web-based eAF for each variation application and move to the PDF form if issues arise while using the web-based form. Before the submission, users can also fill both the PDF form and the web-based form for the same application, and then decide which one to submit.

Of course, users are encouraged to use the new web-based form in order to detect issues and report them to improve their functionalities as much as possible before their use becomes mandatory.

15. Since available data for CAPs are coming from EMA internal database, does this mean that no data will be migrated from xEVMPD for the initial October go-live?

Yes, CAPs that are available in initial go-live and in September UAT will be coming from EMA internal database and will be the same products currently used in IRIS for Inspections. Therefore, no data will be migrated from xEVMPD at the moment, even for CAPs.

16. When will the final requirements (e.g. how the fields must be filled in with information, for example with a picklist from PMS or manual entry) made available?

The final requirements table will be published once the development has been finalised, most probably in late August or at the latest in September 2022.

Concerning the example of fields filling, more pick lists from PMS will be used, starting from product name. This means users will no longer type the product name into the field, but they will select a product from PMS. There will be little possibility for manual entry.

17. Is 'EMA internal database' the same as SIAMED? Moreover, for the October 2022 release, will the data from the EMA internal database be loaded into the DADI form via PMS, or will this be an entirely different database feeding the form?

The EMA internal database is indeed called SIAMED.

From a technical point of view, the authorised product data in PMS will be available for retrieving purposes in the new DADI forms. DADI is not a mean to load product data from PMS but to display in order to automatically complete the eAF. However, from a technical point of view, the product data flow follows the following path: from PMS these are stored in IRIS, from which data are retrieved into the relevant DADI form.

18. Can we already register for DADI access via EMA account?

For the purpose of User Acceptance Testing, you can already register. For production, you cannot register yet. More information on access management will be published in the guidance.

19. How will the digital eAF work for authorisations within MRP/DCP that are not yet nationally approved (i.e. they are not yet in the Art. 57 database) but for which variations have to be submitted? This case often happens.

More information on this will be provided later on.

20. Regarding the Release 3 on structured data: is the scope of that data (roughly) known at the moment?

The scope of structured data covers structured changes, like ingredients or manufacturers. This information is covered by EU IG in IDMP format, so the data will be coming from PMS, where available from xEVMPD. This topic will be addressed later in time because the structured changes are still in development.

21. Being there will be only 2 structured data fields in the first version of the DADI form, how will the rest of the data be included in the FHIR output of DADI? Is there a 'best practice' for industry on how to fill the free-text fields?

There will be limited amount of data fields in first structure of DADI. It is advisable to use OMS if there are changes in any addresses, like it is done in current PDF forms. Concerning other best practices, there will be no change in how the forms are used for present and proposed.

Furthermore, a new version of the EU IG will be released soon. The implementation guidance will focus on the fields that will be used by the DADI team for filling the forms. It is a total of 15 data attributes, still a limited number, but there is also an annex to chapter 7 (chapter dedicated to data migration) explaining how this information will be found. In conjunction with chapter 2, you will see how this data will be available for you and how it should be completed when we will go live.

22. Can you further define what is the limit of UAT capacity?

Industry Associations will consolidate the feedback provided by testers and they will communicate it to the EMA. Each Association may have different capacity to consolidate the feedback.

Therefore, there could be more volunteers to participate to UAT than the number industry associations are able to cater for. Therefore, you could be communicated that associations cannot receive your feedback. We understand the high interest to participate to the UAT, but resources and time are limited, so also participation must be limited.

23. Pharmaceutical companies are sometimes contacted by IT companies offering a solution for DADI. Is it necessary to buy a specific tool? We understood that DADI will be accessible via a login?

It is not necessary to buy specific tools. DADI is a web-based tool where you log into a particular portal linked to EMA access management. Therefore, for the time being, there is definitely no need for any particular tool to use DADI forms.

24. Will DADI use PMS data? If yes, when will the switch to PMS be made?

PMS data will be used by DADI basically for regulatory purposes. The switch to PMS, if meaning the full functionality (e.g., product editing, product notification, product update, product creation), will be made available once all the required planned activities have been completed (i.e. availability of data correction and enrichment functionalities, availability of API and UI, availability of delta between xEVMPD/SIAMED, user accessibility tested and design of PMS to xEVMPD feed-back loop migration rules fully functional).

The PMS to xEVMPD feed-back loop migration rules are necessary to secure the core activity of the Agency which relies on xEVMPD.

25. From go-live to the start of the transition in March 2023, will the EMA check the IDMP structured data as part of the validation of the variation application?

There will be a very limited amount of structured data at the go-live in October. The user will select the product, which will be fed from PMS to the form. The EMA is feeding the internal databases with a tool which is currently used for the interactive PDF form.

We hope to continue feeding our internal database with the procedural data coming from the web-based forms. However, there is no particular check of IDMP structured data as part of the validation.

26. As the call for volunteers for CAPs was made with notice, will an announcement be published more in advance for the planned second UAT involving NAPs? Moreover, since there are so many NAPs, will more participants be involved?

The call for interest for the September UAT on CAPs was not published earlier in order to be sure the EMA would be ready and able to run the UAT for CAPs according to the planned timeline.

For what concerns the 2nd UAT to be held between December 2022 and January 2023, the intention is to publish an announcement with more advance. Of course, there will be more participants to this 2nd UAT, in order to ensure the participation of MAHs representing CAPs and NAPs. In fact, in the European market there are more NAPs than CAPs, so that testing these products requires a larger number of participants.

27. For those who are not accepted for UAT, will it be possible to create 'test' forms using DADI when the system launches in Oct 2023?

Everyone can register to use DADI forms in October 2022. Even if you have no CAPs, you can still register as a user for the DADI forms just to see the portal.

Even though you cannot get very far in the application process without CAPs, you will be able to create test forms.

28. Without xEVMPD for CAPs, how are applicants going to request data changes, where the data from SIAMED is incorrect (as found in the last UAT)?

If SIAMED data is incorrect (e.g., you are not able to select your product because it is incorrectly in SIAMED), the issue should be reported as soon as possible raising a ticket through Service Desk. Thereby, the discrepancy of data can be checked.

Since there are not many structured data fields at the moment, there is little data from the products themselves currently available in the system.

Please note that, from a PMS perspective, the product data loaded from SIAMED have been tested with the scope to ensure that all identified bugs are fixed on time and the best quality possible is achieved in PMS. This activity is even more relevant with the recently announced change of the scope of the 1st DADI release in October.

29. When will MAHs be able to register in IAM system and assign roles to the responsible employees/consultants?

It is already possible to register in IAM, both as an administrator or as a UAT applicant. Please read the User Guide for Registration for more information. If you already have an IRIS and eAF admin role, you can already approve access requests to the eAF portal in UAT.

30. Do we have sign the new eAF? Is signature mandatory?

It is expected that the DADI form can be signed. The current PDF forms use a flattened electronic signature which is used in a purpose of locking the form. We are currently

testing whether it is possible to use a digital signature to sign DADI forms. The discussion from the regulatory and legal point of view on the need of signatures for forms created in the portal is also being reviewed at the moment. This part will be addressed during the UAT in more detail. Of course, more information on how to sign the forms will be provided for everyone before go-live.

31. Are the data elements in DADI forms the same used to fill in PDF eAF forms?

Yes, there are minor changes in terms of data: a few additional data fields, but basically the form stays the same. The form is owned by the Notice to Applicants (NtA), so there is limited capability to even change the fields.

Therefore, the change does not concern much the content, but how the user will fill the form, going form an interactive PDF to a web-based system. Moreover, in the future, the free-text fields for present and proposed will be replaced by structured data fields where relevant.

As currently, there will still be some variation scopes as per the classification where there are no structured changes for now, or potentially ever, and users will still be able to include free text for those type of changes.

32. When the xEVMPD should be replaced by PMS?

The aim is to replace the xEVMPD submission, namely the electronic submission, rather than the xEVMPD database. The XEVMPD submission will be substituted with the provision of authorised product data via the PMS database only. With the integration of the feedback loop migration business rules, the product data submitted in PMS will be fed back to xEVMPD. The need for the feedback loop to xEVMPD database is due to the connection to several other Agency's systems with the scope to maintain the correct execution of the EMA core activities. The above will be achievable once the migration rules have been agreed and successfully tested.

33. When is it planned to write data back from DADI to PMS?

Within the Agile framework, there is an agreement on specific priorities in terms of epics and features. Writing back data from DADI to PMS is a priority because it should be ensured that the FHIR message, which is using basically PMS data, can be reusable into PMS. The PMS team has already started exploring with platform architect and IT colleagues how this could be possible (i.e. the tool, technology, data flow and architecture).

34. Will the testers participating to the 1st UAT be able to test in the 2nd UAT?

The 2nd UAT will be a separate exercise. If a user has participated to the 1st UAT, there is no automatic participation to the second one. It is likely that quite a few new testers will participate to the UAT in December because it will be open to a whole new user base for NAPs. However, as CAPs will also be included in this 2nd UAT, testers from the 1st UAT could take part to both UATs.

35. What happens if data coming from PMS in picklists in the DADI form is wrong or incomplete?

Currently, the picklists from PMS would only refer to the product details. If a product is not available or the details are incorrect, the user should report to EMA the discrepancy and use the interactive PDF. For other picklists, the data is coming from RMS, as it does in the current PDF forms.

36. How can external parties (e.g. consultancies, CROs etc.) be involved in the creation of the forms for their clients in the future? What kind of user role model is going to be in place?

This was described in the system demo in the section dedicated to access management. In the future, it will be possible for consultancies and CROs to create forms for their clients. This means the consultancy/CRO must be registered in IAM, and will need to be affiliated to their MAH. If the consultancies/CROs are working for multiple MAHs, they need an affiliation to each MAH. Different MAHs can provide consultancies and CROs with different levels of access (e.g., contributor for one MAH, coordinator for another MAH). The details on access management and the different roles will be available and published soon.

37. Can DADI be implemented in the internal MAH RIM system?

The current implementation of the web-based forms is through the EMA web user interface, the portal through which the forms are created. The possibility of sending a FHIR message or a message from MAH RIM system into a machine-to-machine communication will not be available in the initial release.

38. Currently, full SMS data is not available in SPOR. Can we expect SMS data while filling DADI, does it have any impact?

In the current variations form, the user selects the substance and manually enters the products the variation relates to. In the DADI form, the products will be selected from PMS. Then, the substance field will be auto-filled based on the substance contained in that product in PMS. If the substance is not available in SMS in SPOR service, there is a procedure to request it, especially if it is a new substance.

However, for the moment users have to type the information about substance. When PMS and DADI will have structured data, users will be able to select SMS IDs. For the moment it is only migration data, and in variation form text will be used for the moment.

39. With the PDF eAF, a separate (additional) present/proposed document for some complex variations is still provided. Will this still be possible with the DADI eAF?

This would still be possible with DADI eAF. In some scenarios, present and proposed information is not meaningful to be included directly in the form because of the nature of the change. The introduction of DADI forms will not change variation procedure for this initial release.

40. Can multiple users work on one DADI submission?

Yes, it is possible. The user starting the form could invite other colleagues to contribute to the form. There can be contributors, coordinators and applicant managers to be invited and work on the form.

It is possible for a person different from the one who started the application to sign and finalise the submission.

41. For the 2nd UAT (for CAPs and NAPs) will there be a call for companies to participate and apply in case of interest or participants will be the same as in the 1st UAT round?

Yes, there will be a call for interest for the 2nd UAT, and it is possible to have different participants from the 1st round.

42. How is PMS synchonised with xEVMPD? Can we make changes/updates either ways (i.e., data updated in either PMS/xEVMPD) reflected or pulled into DADI or only xEVMPD updates will be reflected in DADI?

For the moment, data are under migration from xEVMPD into PMS and the information in xEVMPD is still in sync with PMS. This means any change in xEVMPD will be reflected almost immediately (e.g., change of the name).

These are the only changes to be reflected for now because there is still no user interface for DADI. Therefore, changes in DADI are not reflected for the moment.

43. Can the PDF eAF still be used for other types of forms or will the other web-based forms (i.e. initial marketing) be available by September 2023?

The PDF eAF form for other types of procedures (e.g. Vet and H marketing authorisation application form, renewal form) will continue to be available after September 2023. The EMA will start working on other web-based forms after having finalised the Variations form.

Information on these epics, i.e. new forms, will be available in due time. For example, the H variations form is being used by Member States for procedures such as transfers, which are not variations per se. This practice could continue after September 2023. Discussion with Member States on how to maintain the PDF variations forms available for usage for other types of procedures is ongoing. The future evolution of the transfers procedure is also under discussion.

44. Will there be any technical specifications for DADI to implement in internal RIMS of MAH?

For the October go-live, there are no specific requirements with regards to RIM systems in order to fill the forms.

For the future machine-to-machine filling for the forms, there will be some technical specifications and requirements, but not in the initial releases.

45. When will UAT applicants know if they are selected as participants?

The call will be closed on 15 July, so in the beginning of the following week applicants will be informed about the outcome.

46. How can MAHs ensure data in SIAMED is accurate? As it is populated to DADI as well, will there be any access to SIAMED for MAHs?

No, SIAMED is the EMA internal database, so there is no access for MAHs. If a user notices inaccuracies in the data within the DADI form, the issue can be reported.

In the initial release, the presence of structured data coming from SIAMED or other databases will be limited and will mainly concern product selection.

47. Will the data inconsistencies in OMS data be overcome before DADI go-live for NAPs?

Currently, there are some issues with OMS data. The goal is solving any issues related to OMS before go-live for NAPs, but, for example, historical entries from OMS still cannot be shown in DADI forms in the way they would be required.

Therefore, even though the EMA is working to solve issues with OMS data, it cannot be guaranteed all inconsistencies will be solved before the go-live for NAPs.

48. Is there or will there be a list of structured data that will be available at first go-live?

The structured data fields that will be available in the form at the October go-live are those of ATC code and medical devices. Since there is no structured data for medical devices in SIAMED, the present fields will be empty and users will include the proposed data in the form. For what concerns ATC code, data will come from SIAMED.

49. Can DADI information be shared with partners for revision before submission?

Yes, there is careful access management implemented in the portal and users can share the form with other registered users affiliated to their MAH.

50. Is it possible to fill-out the DADI form for a specific project at different times and not all at once? Will the draft remain available for a certain number of days?

Yes. Users do not have to finish the form in one go. They can log in to the system and come back later. Retention periods are under discussion, but they will be quite lengthy. Indeed, the draft will remain available for a certain number of weeks.

51. How likely is it that the quality of migrated xEVMPD data to PMS will be sufficient to use in DADI? Would it be more reasonable to use DADI only with the 3rd release for structured fields when also PMS can be updated/fixed directly?

It is important to go live with DADI as soon as possible, namely in October 2022. In this first release, product selection from the EMA internal database will be used, so there will be no xEVMPD data in this first release.

In the release in March 2023, users will select products from PMS. These products will have been imported from xEVMPD. At that point, there will be still a limited number of structured data, so there will still be minor concerns about data quality. Hopefully, closer to the time of go-live with structured data enrichment and correction user interfaces for PMS will be released.

52. If the data at the go-live comes from EMA internal database and not from xEVMPD, how can pre-populated data in DADI forms be corrected?

Pre-populated data will mainly concern product selection at this point. If users find inaccuracies, they can use interactive PDF forms while the EMA fixes the data.