Information Management

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Human Variations eAF go-live Q&A session (27 October 2022)

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 Human Variations eAF go-live Q&A session held on 27 October 2022. Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the eAF (DADI) and PMS product teams.

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

For general inquiries, please contact the eAF (DADI) team via esubprogofficer@ema.europa.eu or the PMS 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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Acronym key and glossary terms

CAP	Centrally Authorised Product
CP	Centralised Procedure
DADI	Digital Application Dataset Integration
DCP	Decentralised Procedure
eAF	Electronic Application Form
EMA	European Medicines Agency
EU	European Union
ePI	Electronic product Information
FAQs	Frequently Asked Questions
IRIS	EMA's Regulatory & Scientific Information Management Platform
ISO	International Organisation for Standardisation
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare products Regulatory Agency
MRP	Mutually Recognised Procedure
MPID	Medicinal Product Identifier
NAP	Nationally Authorised Product
OMS	Organisation Management Service
PMS	Product Management Services
PCID	Packaged Medicinal Product Identifier
PMSID	Product Management Services Identifier
Q&A	Questions & Answers
RIMS	Regulatory Information Management System
SIAMED	EMA database for Centrally Approved Products
SPOR	Management Services for Substances, Products, Organisations and Referentials
UAT	User Acceptance Testing
xEVMPD	Extended EudraVigilance medicinal product dictionary

1. General information about the PLM Portal – eAF

1.1. Before xEVMPD export in PMS system, how the data regarding products is populated in the portal?

Only SIAMED data (CAPs data) is migrated to PMS for the moment.

1.2. Can you give an approximate date when the data will be fetched from xEVMPD?

As announced, the authorised product data deriving from xEVMPD will be available in March 2023.

1.3. How to manage the data with DADI after go-live? If we would like to start using it for CP after go-live, how can we update the data not part of xEVMPD? Can we send the message to update the PMS?

In case you consider the data incorrect, you should open a ticket via Service Now and it will be assessed. If any changes should be applied, the SIAMED team will be involved in this procedure.

1.4. Is there any plan to include PCIDs in the variation web-form for CPs? Are PMSID/MPIDs displayed in UAT real-time data?

Packaged medicinal product identifier (PCID) with missing values as the information is not available in SIAMED (EMA PCIDs are not available yet as the product data set in PMS is incomplete. As mentioned in the PMS EU IG Annex I to Chapter 7 (section 2.2), there are some elements of the PCID with missing values as the information is not available in SIAMED (EMA system) and xEVMPD, triggering the unavailability of the PCID generation.

The PMS ID is not updated in real-time as it is a stable identifier, while we are testing the Medicinal Product Identifier (MPIDs) updates.

1.5. Is there any data connection between xEVMPD and SIAMED?

No. There is no connection between xEVMPD and SIAMED. For Centrally Authorised Products (CAPs), both systems will be used as source of data for PMS. Business and migration rules will be published in the new version of Chapter 7 of the EU IG.

1.6. Once we update our RIMS, will PMS/xEVMPD also be updated automatically at the same time?

Please note that submissions through RIMS to PMS will not be possible as the machine-to-machine connection is not yet available. While submissions through RIMS to xEVMPD will be processed as normal updates to xEVMPD.

1.7. Will ePI be part of the PMS in the end?

It is very premature to explain the connection between ePI and PMS, as ePI has just started as a project. Additional information will be shared through the Agile ceremonies.

1.8. Will you be providing a guide to structure data and source data for SPOR fields?

Yes. For now, there is already the Annex 1 of Chapter 7 of the EU IG where all the fields coming from SIAMED are explained. The new version of Chapter 7 is planned to be released in December 2022. The new guide will explain where the data is coming from, if from xEVMPD or SIAMED; which are the enduring fields depending on the product; if it is a CAP or not. It will also include information regarding the source data of all the fields.

1.9. When is the migration from xEVMPD system to PMS system planned?

It is planned to happen in March 2023.

1.10. How can bugs be reported once the system goes live?

Recently we have moved from JIRA service to ServiceNow through EMA Service Desk. We put in place the dedicated area for the web-based forms that could be found on PLM portal eAF. There are 4 different options that you can select: if a bug relates to the PDF, to the web-user interface, to the XML, or if it is a general issue.

1.11. When the training materials / guides will be available?

We consider that when we go-live there will be certain number of issues and certain scenarios that will not be covered, and, hence, these guides will also contain quite a lot of information related to work around it and they will be regularly updated. These documents will also update the training materials based on the feedback and questions that we receive from users. We are planning to include a portal navigation guide that contains the user guide for filling in the web-based form and short videos. Some of them will be available by the time of go-live and the rest of them will become available soon after go-live.

The guides will be updated as the new features and functionalities become available on the portal and bugs and issues are fixed. On 8th November 2022, a post-go-live training session is planned. Moreover, on the portal we are going to start piloting the chatbot to answer some basic queries and most Frequently Asked Questions (FAQs).

1.12. At what time will the web-based eAF be available on 4 November?

Ideally, we will have the application available to you in the morning on 4 November.

1.13. Who will validate the data? Will the validation be comparable to the xEVMPD validation?

The data that you include in DADI will be assessed as in the current process for the variation form. There is no validation of the data in DADI variation form.

There will be another process in PMS to verify the data that is submitted to PMS. Currently, there is no process to validate the data in the form, similar to xEVMPD. The xEVMPD submissions are still needed but there is no validation.

If you are referring to the validation of the application form or validation of the procedure, this does not change. If it is a type 1 notification, then within the procedure we validate the form, but it is not an official validation as, for example, type 2 variation. There are different types of validations for different types of data.

1.14. When the application for UAT, for NAPs/MRP and DCP will be opened?

We expect UAT to take place in March 2023. We are working on that topic, probably the UAT training will take place in December. The dates have not yet been confirmed, but you will be kept updated.

1.15. Are there any bugs outstanding?

Yes, there are still some bugs. The list of the existing issues will be published on the go-live day and will be regularly updated. You will be notified every time a bug from this list is fixed.

1.16. How can NCAs get test files? It has not been possible to access the test environment to create files?

We can provide you the test files. If you would like to receive the test files, please contact Kristiina Puusaari (kristiina.puusaari@ema.europa.eu).

1.17. For MRP/DCP products: will it be possible to submit variations through eAF portal for MAs which are still pending, after a recently closed procedure?

Yes. We are currently working with xEVMPD colleagues on developing the feature in xEVMPD that will allow a submitting of the variation through the portal for those non-CAPs for which EMA is still pending.

1.18. Which kind of digital signature is considered applicable?

There are no specific limitations regarding the digital signature. The only requirement is that the signature should be official. Moreover, it is not a mandatory requirement to sign the form.

1.19. Can two people work at the same time on one eAF via the portal?

It is not advised to work simultaneously on the same form as users could inadvertently override each other's changes. This is a scenario we still need to test.

1.20. Can a draft eAF be completely deleted from the portal?

Yes, it can. A feature that deactivates the form is available from the portal.

2. Identity and Access Management in the PLM Portal – eAF

2.1. How many eAF applicant coordinator access credentials is it possible to have per each organisation? Is it possible to have 3/4 people having the same access for the same organisation?

Yes. Regarding the eAF applicant coordinator access, the number is not limited as each organisation has its own working model. Certainly, it is possible to have 3 or 4 or even more people with the same access from the same organisation. It is important to remember that there are 3 different levels of co-author. You can have contributors, coordinators and managers. Indeed, it is possible to have as many people as needed for each role for each organisation.

For those colleagues who already have their credentials, you can access the system at the same time while you are doing the training. The guide for the registration is already available for everyone, so, you can also take all the necessary steps to be prepared for the access management to the portal.

2.2. Could you please confirm that manager sees only applications he creates? All products of the MAH or only the products of applications he creates?

The manager role allows managers to see only their own applications. To see all applications, the coordinator role is required.

2.3. Will the eAF Administrator role always be the IRIS Administrator and vice versa?

No, it does not need to be the same person. It is up to the company's management to assign one or different people to administrate the access to IRIS and to eAF.

2.4. Do I need a smartphone for Multi Factor Authentication to Login into the portal? Or is it also possible via e.g. Yubikey?

For Multi Factor authentication you must use Microsoft Authenticator app or the SMS code. Hence, you will need a mobile phone.

2.5. If I am the applicant for a DCP procedure, can I name my local colleagues to add local info without giving them the possibility to manage the whole form? Considering that they need the Coordinator access for DADI due to their local variation?

This is an issue that we need to test more in the context of DCP and non-centralised procedure applications. If you have been associated with certain access rights to a certain MAH that same access level applies for the whole organisation, not only for the specific application

User can have different roles for different organisations – you can have a coordinator role for local marketing authorisation holder, and, for instance, a manager role for another organisation. Please always check that your user account is assigned to the right role.

3. Navigation through the PLM Portal – eAF

3.1. How long will it take between editing xEVMPD and updating it to the DADI module?

The release of next week contains only SIAMED data, which relates only to CAPs. There will be no xEVMPD data for now. Consequently, if some changes are made in xEVMPD data, they will not impact DADI variation form. Once xEVMPD data will be in place, any change that occurs in xEVMPD is automatically processed in real-time. It will go to PMS and from PMS it will be reflected on DADI variation form. It will take 5 -15 minutes.

3.2. Is it possible to save the data input as a draft application form template before signing it in order to amend it, if necessary, and avoid filling in data again from scratch?

Yes. Once you are logged into the portal, you create a draft form. You can come back to the form and save it multiple times. For instance, if during completion of the form you realise that some information is missing, you make needed changes, make request or raise a ticket through the ServiceNow portal. You can always save and export that draft to review it as often as you wish.

3.3. How can we make an eAF in DADI for another MAH? Should we ask for permittance first from the other MAH via EMA Account Management?

Yes. First, you would need to do a request to be associated with another Marketing Authorisation Holder (MAH) or, for example, if you are a consultancy wishing to work for several MAHs, you will have to make a request in the EMA account management to associate with the organisations you wish to work for. It is possible to hold different roles in different organisations, but not different roles within the same organisation.

3.4. Can external eSignature applications (DocuSign etc.) be used to sign the form?

Yes. You export the PDF rendition from the web user interface, fill it in and then outside of the portal you sign it with DocuSign or any other eSignature system. After signing the document you include it into your eCTD package.

Please note that the form is locked as soon as you export it. It means that you cannot change neither the PDF nor the XML.

3.5. For our company there will be a single function in charge of creating eAF for all the countries. The plan would be then to download the eAF from the portal and share this by e-mail with countries involved. Is it possible to send eAF via e-mail?

Yes. It is possible to share the exported PDF rendition via email but the colleagues, who receive it, will not be able to edit the document. The editing can only take place in the web-user interface. If you want to share eAF and allow your colleagues to edit it, it would be better to assign those colleagues as co-authors of that eAF through the portal.

3.6. Can we use EMA Service now to ask support in the analysis of data for our organisation if they are good and ready for DADI?

No. The data that we are migrating right now is the data that is coming from SIAMED.

The data that you have been using in annex of your product is the data that you see on the DADI variation form. There you can see the name of your product, dosage form, active substances etc. At the moment, we do not have any service to export the data that we have in SIAMED.

3.7. Once the eAF is finalised is there an "automatic signature" or something that proof the validity of the eAF or the applicant must sign the eAF after download?

There is no automatic signature. If you wish to sign the form, you use, for example, DocuSign or any other e-signature tool to sign the PDF rendition before you include it into your package.

3.8. We should not attach any document to this web-form? All the attachments (annex 51, annex 56, 59…) must be included in the eCTD sequence as always?

Yes, this is correct. You should not attach anything using the paperclip function. Please do not include any attachments into the form. If you need to provide any attachments, it could be done in the module 1 of section 1.2 where the form provides the access to it.

3.9. Once you download the eAF, is it editable or locked? If a country would like to change something in it, is it possible?

Yes, it is editable. You can download and export the PDF multiple times. If you click the button called "Finalised", the form just moves to the tab "Completed", and you can still edit that form. If you have co-authors with the correct privileges assigned to that application, they can also go back and edit that form.

3.10. Will MAH of NAP be able to navigate in the eAF Portal during and after UAT?

We plan to keep UAT open. If you have been involved in the alpha UAT or in the beta UAT, we have not deactivated or deleted any roles. We are constantly working on fixing some bugs, and soon there will be a release of the new features available for testing in UAT environment. Moreover, the NAPs will be available soon.

3.11. For a variation, if we receive validation request, do we need to submit an updated eAF? Can we edit and use the one prepared for the first submission in DADI?

Yes. Indeed, that is what we advise you to do as an ideal process. You fill in the form on the portal, export and finalise it. Then it moves to the folder "Completed". After this process, you submit the form as a part of your package. When you receive the validation comments, you should go back to the "Completed" folder and edit that same form based on the validation feedback and then you finalise it again.

3.12. Is signature of the finalised eAF not mandatory?

Yes, it is correct. For now, there is no signature requirement, however, we do recommend including a digital signature in the pdf export included in the eCTD submission. The form should not get rejected if it is not signed. The final recommendation will be posted in the user guide.

3.13. Have you checked the export against publishing tools such as Lorenz?

For now, we cannot say which exporting tool or eCTD tool has been used for the test. If there are any issues, they should be communicated to your vendors or you can also inform us.

3.14. Is it still possible to insert a signature via image in the generated PDF form?

No. If you want to sign the form, you must use a digital signature. It is not possible to include an image of a signature and it should be only in PDF rendition.

3.15. Will there be a warning if a user starts working on a form when someone else is already updating it at the same time?

Not yet, we are currently working on fixing this issue.