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System Demo 2022 Q1 Q&A

Date: 15 March 2022

Location: Online, 09:00 – 11:00 Amsterdam time (CEST)

Link: System demo Q1: digital application dataset integration (DADI) and Product Management Service (PMS) | European Medicines Agency (europa.eu)

Disclaimer

Below is a direct record of all questions asked through Slido.com during the System Demo and answers provided in writing. Questions not asked through Slido.com are not captured. Questions that have no written answers below where either responded to verbally or did not receive a response during the System Demo event. In principle this document will not be updated. Generally the order of questions answered follows the order in which they were prioritised by the audience using the "thumbs up" feature of Slido.com The responses represent the expert view of the development teams at the time of the Demo and are not official statements by the European Medicines Agencies or it partners.

Variations for Human Electronic Application web-form (eAF) aka "DADI" & Product Management Services (PMS) – Product Lifecycle management Value Stream

Question	Reply
According to the DADI Q&A, EMA will organise training for industry prior to DADI go-live. Has this been planned already and if yes, could you please confirm the dates?	That's correct there will be communication and training. This has not been scheduled yet.
After approval the data are fed back to PMS. Who will do that "upload" NCA/EMA Industry?	At DADI go-live applicants still need to comply with Art 57 legal requirements and reflect the approved product data in XEVMPD.
Any additional help/ assistance will be provided by EMA post DADI go live? to address operational related issues.	The support and maintenance will be put into place prior to go-live. It is expected that a new version to address any issues found during initial use has been planned to be released approx. 3 months after the initial go-live.

Apologies for broadening the theme of the demo. Is there a plan in place for Substances terms (as part of XEVMDP), for terms such as "Empty gelatine capsule", meaning, are they going to be allowed to be part of the XEVMPD database?	There is an initiative ongoing to cleanse substance data. While we cannot at the moment nullify/delete those substances from products in XEVMPD we expect to flag them in PMS so they can be corrected in due course
Are the recordings from Jan online now?	https://www.ema.europa.eu/en/events/introducing-dadi-webinar-digital-application-dataset-integration-dadi-network-project-replace
Are the recordings from Jan online now?	https://www.ema.europa.eu/en/events/digital-application-dataset-integration-dadi-webinar-common-factors-fast-healthcare-interoperability
At the end of the procedure approved data will be uploaded to PMS - if different data are approved than those that had been submitted via DADI where do these data come from?	This is not in scope of this demo. We plan to have dedicated webinar on process.
Because DADI intends to exploit the full potential of PMS, does this mean that the implementation of DADI-form is dependent on the delivery and implementation of PMS?	Indeed, there is a dependency between DADI and PMS and the development plans are carefully aligned to ensure that all PMS parts that are required by DADI are addressed. It is important to bear in mind that we are building the data-centric target operating model and will continue to add pieces the coming years.
Can you clarify where (in Andrei's xml demo) these Identifiers for Pharmaceutical product and Ingredients are coming from?	PMS has in scope multiple FHIR resources. In order to read the full data for a product a FHIR Bundle will contain all related resources as shown in the demo. Each resource has a technical ID used as reference from other resources for consistency. Therefore the AdministrableProductDefinition references Ingredients by ID. The Ingredients are also included in the Bundle with their respective ID.
Can you use the DADI form and revert to the “old” pdf eAF later on, or is it the case that once you use DADI all future variations must also use the DADI form?	During the transitional period it is possible to use both, the pdf and the DADI form, but not for the same procedure. If you have more than one parallel variations ongoing, one can use pdf and another can use DADI.
Could you confirm whether DADI will go live in October with a PMS data load or as a pure eAF replacement?	Thank you for your question. This demo looks at development progress over the past increment (3 months) - the planning for the upcoming increment will take place in the coming weeks. This will (re)confirm the scope of the first release of the variations web-form. We recommend keeping an eye on the eSubmissions site for the latest news.
DADI will require detailed data entry through the tool's UI. This data entry represents duplicate data mgt activity for industry (RIM system, DADI). When will an API be available to remove the duplication between RIM and DADI?	This is not the scope of this demo. API/machine-to machine integration will be covered in future Increments
Data that do not come into the PMS via Dadi and not via migration: how do	This is not the scope of this demo. The capability to complete/correct product data will be covered in a future

they get into the PMS? User Interface or own software	increment. At DADI go-live users can still edit product data in present section.
EMA will migrate only "valid" XEVMPD data? There are often changes made by EMA which are not agreed by the MAH (unresolved 3rd ACK). Are MAH supposed to make variations based on data they consider wrong?	Data taken from PMS will appear in Present and proposed sections of variations form. At DADI go-live Applicants can overwrite the data from PMS in present section to indicate data that requires correction/completion.
EMA will migrate only "valid" XEVMPD data? There are often changes made by EMA which are not agreed by the MAH (unresolved 3rd ACK). Are MAH supposed to make variations based on data they consider wrong?	Clarification: EMA will not migrate "valid" data. We will take non-nullified records and migrate the last version of the data whether it has been validated or not. A product would have been validated in v8, but the migrated version would be the last one
Having no SIAMED like sources available for the non-CAPs, how is the data enrichment process taking place?	This is not the scope of this demo. The capability to complete/correct product demo will be covered in a future increment.
How can we apply for the betaUAT?	The UAT process is currently being discussed internally and information on how take part will be published on the eSubmission website.
How can we get involved with user testing ?	The DADI UAT process is currently being discussed internally and information on how take part will be published on the eSubmission website.
How often will data be migrated into PMS? There are regular updates to xevmpd that may not be valid during initial load.	We are implementing an near real time data sync from XEVMPD to PMS. Once an ACK is generated by XEVMPD the data will be propagated to PMS for transformation to FHIR.
How to clean the data alteady in the database in order to have the correct data to fill in the dadi form?	This will not be covered in this demo. Correction and enrichment functionality is on the backlog to be defined and developed.
How to update the name info for NAPs since these products are not in SIAMED - how to update in PMS, per data steward ticket?	If you are submitting a variation that affects the Product name you can complete the name parts in proposed section.
If an AMP is validated in xEVMPD, but the most current version is not. Is this newest version migrated to PMS, or only after validation?	The newest version will be loaded to PMS. The validated data is used for the initial bulk data load to determine what XEVMPD products belong to the same PMS product. The latest version of data is used to do the actual data load. The part of the demo related to valid XEVPMD products was not entirely accurate.
If I understand correctly, you will map the xEVMPD data to RMS when you syncronice the data to PMS. Will you also map the substances to SMS?	Yes, the data load into PMS maps Terms, Organisations/Locations and Substances to RMS, OMS and SMS identifiers.
If IDMP data are not complete, where can we send the missing data to complete IDMP?	At DADI go-live you can complete the data needed for the particular variation in the proposed section. In due course there will be capability to correct/complete all missing data.
If multiple people can work at the same time on one DADI webform, how is data consistency ensured?	There is a user story to address concurrent editing in a future sprint.

If the data in the PMS is incorrect, does this matter and will it affect the processing of a variation application?	At DADI go live users can still complete/correct data coming form PMS in present section.
if the data is being merged .e.g. in case of CP data coming from SIAMED and xEVMPD - what would be the primary source (if for the same field data is available in both of the sources)?	This has been covered in previous DADI-PMS webinars and will be further elaborated in EU IG chapter 7. Generally speaking the product record is composed of fields coming from SIAMED and fields coming from XEVMPD, we strived that the 2 sources don't overwrite each other.
In light of Art.57 data (xEVMPD) for an investigational product being consumed by CTIS, what is the plan? Do EMA plans to move to PMS anytime soon? Do PMS only include information pertaining to authorised products?	This is not in scope of this demo nor current PMS scope. PMS is addressing "Authorised Medicinal Products from ISO not Investigational Medicinal products.
In the EMA Management Portal a new user description "eAF user" has appeared. Will this role be necessary for using DADI?	Yes, all users of the new eAFs via the DADI UI will need to register. The registration will be opened closer to the go-live. For now, the registration is used by SMEs who are participating in the sprint testing.
Incorrect not to migration non-validated XEVMPD records: these are still valid registrations, that need to be used from DADI - otherwise how can it work?	EMA has a validation process of XEVMPD data and eventually all records/versions will be validated and made available to DADI. To facilitate this applicants are encouraged to act on any follow-up questions raised during such validation.
Incorrect not to migration non-validated XEVMPD records: these are still valid registrations, that need to be used from DADI - otherwise how can it work?	The statements in the demo were not completely accurate. We are loading non-validated XEVMPD records to PMS as well. We use validated data, if available, and non-validated data to determine the XEVMPD products which belong to a single PMS Product based on the defining data elements as per EU IG. The chance is that a non-validated product will not have the same data as validated products for those elements, therefore it will not belong to the same PMS Product as validated products. The non-validated product showed by Marcos was actually loaded as a separate PMS Product.
Is my understanding right, that with the migration from xEVMPD to PMS, multiple Packaged Medicinal Products (PMP) are only migrated for countries with MA numbers on package level. For others, there will be only one PMP migrated?	The number of Packaged Medicinal Products is related to the granularity of the data in XEVMPD. 1 Product in XEVMPD is 1 Package in PMS. There are case though where the 1 Product in XEVMPD has a description which accounts for multiple physical packages. That will be loaded as 1 Package in PMS. MA numbers define the granularity of Marketing Authorisation information in PMS. If all Packages share the same MA number and MA related information (status, date) there will be only 1 Marketing Authorisation on Medicinal Product level in PMS.
Is there a free FHIR viewer available?	There are proprietary FHIR viewers available.
only IDs are given for the substances in the PMS. In order to check which substance is meant, you has to look up each ID. This makes checking very time-consuming	This is so in the demo. User will see the data via DADI and there the substance name will be displayed for the relevant Substance ID.

Regarding the technical question from Niklas: Others seem to struggle too, look at the email in your inbox withsubject "Registration approved for Webex webinar: System Demo DADI & PMS", the Registration ID is in there	Thank you Dominik - you can also navigate to the event page and view the broadcast there if you get stuck.
Taking the ingredients from SIAMED, but this list has never been reviewed by MAH. In contrast the excipient list in xEVMPD has. So what if both do not match? What is the leading source for migration?	We consider the SIAMED Ingredient data as related to the Manufactured Item only, while the XEVMPD Ingredient data is related to the Pharmaceutical Product. Therefore we store the Ingredient information from both sources without overwriting.
Technical question: I cannot join directly via Webex because I am required to enter a Registration ID. How can I redeem that?	Hi Niklas - I recommend going to the event page https://www.ema.europa.eu/en/events/system-demo-digital-application-dataset-integration-dadi-product-management-service-pms
The connection between DADI and PMS at least for the selection of medicinal products requires to update the creation & submission process - where is that documented?	DADI uses PMS API to retrieve product data which has been migrated into PMS from EMA DB and XEVMPD. Users will enter "proposed" product data as per business rules defined in Ch 2 of PMS EU IG
To select the correct products from DADI, is it foreseen for Industry to visualize and review (and correct) data in PMS before using it from DADI?	Users can see the product data for the variations/applications they are preparing. At DADO go-live there is no strict dependency to correct/complete data as users can edit "present section".
Under the "two-day data integration", will the data provided in DADI (in FHIR) be uploaded to PMS?	This is not in scope of this demo. "Two-way" integration is used with regards to integration of EMA DB and XEVMP data. Integrations with DADI are under Support to end-to-end-Process and the capability to Import approved data into PMS is referred to as "DADI ingestor"
What will be the mechanism for MAH to check these migrated data?	At DADI go-live applicants will be able to see/review the product data relevant for the application they are preparing. In due course there will be capability to see/correct complete any product data on its own.
what about non-valid records (pending records) in XEVMPD. Are they not migrated? Do you get an info?	This will be answered in the Q&A. A pending product has been validated. Not all the version of the products are validated. As long as the product is not nullified, it will be migrated.
What about the availability of API Tool for the Industry users? Can the API tool be used for accessing the SPOR data?	This is not the scope of this demo. A PMS API is available to support DADI implementation but it is still under discussion how/when and in what conditions access to it will be granted.
What can the industry do now in preparation for the use of the DADI variation form?	The MAHs can ensure their Art. 57 entries are up to date. Additionally please follow the DADI news so that you are aware of the latest news, such as when the UAT will start and when there is training and materials available.
What data are taken from SIAMED for PMS?	This has been shared in DADI-PMS webinars and will be published in EU IG chapter 7.
What is thé différence btw soamed and art 57	SIAMED is the name of the EMA database of Centrally Authorized Products. Ar57/XEVMPD contains all products approved in EU.

What means H CAP & NAP data?	Human Centrally Authorised Product and Non-Centrally Authorised Products (MRP, DCP, NP)
What means XEVMPD?	eXtended EudraVigilance Medicinal Product Dictionary - the dictionary populated by applicants in compliance with Art 57 to support Pharmacovigilance activities.
What plans are in place for migration and enrichment of non-CAP product data into PMS so that DADI can support non-CAP procedures?	At DADI Go-live all Product data from EMA DB & XEVMPD will have been migrated and kept in sync. There is no need to correct/complete this data ahead of variations as users can correct/complete present section. Users only need to complete/correct data in scope of the variation ie if the variation is in indications users do not need to change manufacturers.
What should the MAH do at DADI go-live, when their list of manufacturers is not correct? This information cannot be corrected via xEVMPD, and industry cannot access SIAMED.	At DADI go live applicants can still correct/complete the product data in present section. The capability to correct/complete data in PMS will be covered in a future increment.
What will be the requirements for application forms signed with qualified e-signatures? Do we have to include the pdf rendition from DADI and an electronically signed document separately in the eCTD as it is done with the current eAF?	It will be possible to sign the pdf rendition using a digital signature. The signature requirements will depend on the receiving regulator. More details will be available prior go-live.
When is EMA expecting PMS UAT to take place? Will this still be open to any company from industry that is interested?	This is not the scope of this demo. The PMS UAT is still being discussed with relevant stakeholders and information will be available in due course. We recommend users to monitor the PMS and e-SUbmissions webpage
When is EU Implementation Guide v2.2 expected?	This will not be covered in this demo. New versions of EU IG will be triggered in the case of major updates. They are not bound to a schedule.
When is first migration to PMS planned?	We are currently working on the data migration and continuous sync of data with EMA DB and XEVMPD. The work is considered done/complete upon a successful UAT.
When is the API to PMS scheduled to be available ?	This is not the scope of this demo. A PMS API is required to support DADI go-live however we don't envisage immediate access to it. This capability has been identified and will be covered in a future increment.
When will an API be provided for integration of regulatory information management platforms with NCA/EMA systems?	This is not the scope of this demo. API/machine-to machine integration will be covered in future Increments
When will the DADI PDF extract be replaced with a data connection into PMS?	The DADI PDF already contains the FHIR xml needed to do PMS imports. The work to be done is to establish the easiest way to import that data into consuming systems such as PMS (or national IT systems), which is ongoing.
Where will the current manufacturer data for nonCAPs be sourced from into Variation form?	At DADI/PMS Go-live this data will not be available

Why you are only integrating the data from one 'national' databse called Siamed, - what is about all the other NCA databases?	This is not in scope of this demo. For the moment we have integrated data from XEVMPD and from EMA Database. We dont exclude the possibility to integrate data from National DBs but that has not been agreed and is subject to future Increments.
Will DADI go live only when all data will be cleansed in PMS?	No, DADI go-live is not dependant upon cleansed data in PMS. At DADI go-live users can still edit present product data.
Will data populated in the new eAF be used to populate the PMS or not?	This is not the scope of this demo. At go-live this will not be possible however this capability has been identified and will be covered in a future increment.
Will EU-SMS go live together with DADI and PMS?	This is not in scope of this demo. We hope to integrate all data cleaning effort into SMS , make it available to users and make the cleansing results clear in products but details are still being determined. This will be covered in future increments.
Will it be possible to collaborate on completion of forms with colleagues and/or professional service providers?	This will be possible and convered in detail in the next PI Demo (in 3 months)
Will it be possible to give access to a consultant limited to one product only?	More detailed information and presentation on the different roles will be provided at the next system demo (in approx. 3 months time) as explained by Noel.
Will the implementation of DADI influence the requirements for the submission of originally signed application forms (e.g. BG, PL)?	Unfortunately we are not able to influence the national requirements about signing the form. Those will stay as they are unless changed via a different forum.
Will the PMS data also feed into ePI product information? If so, when is this foreseen to come into life?	This is not in scope of this demo. This is a pilot demo on DADI and PMS alone. ePI will be covered in future increments/demos.
Will the PMS viewer that Marcos is showing right now be made available to industry?	This tool is used to support the demo. If this feature is considered it will be covered in future increments
Will the PMS viewer that Marcos is showing right now be made available to NCA's?	This tool is used to support the demo. If this feature is considered it will be covered in future increments
Will there be a chance to correct/enrich PMS data after Oct 2022, or can we only cleanse PMS data through xEVMPD?	This is not a feature in scope of this demo. At DADI go-live XEVMPD submission continues as-is and there will be a capability to cleanse/correct data in due course.
Will there be a DADI implementation guide? And when will it be published?	There will be user guide and guidance documents from both, regulatory and technical points of view. These will be published prior to or at the time of go-live.