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Q&A Q2 2023 System Demo

Date: 22/06/2023

Location: Online, 09:00 - 13:00 Amsterdam time (CET)

Link: Quarterly system demo – Q2 2023 | European Medicines Agency (europa.eu)

Disclaimer

This document contains a direct record of all questions asked through Slido.com during the System Demo and their written answers.

Questions not asked through Slido.com were not captured. Questions that did not receive written answers below where either responded to verbally or did not receive a response during the System Demo event. Questions asked in the "Plenary" room were generally taken as not addressing specific IT products and are not included below. Where it was clear that a question asked in the "Plenary" room referred to a specific IT product it was moved to the appropriate product room. Wherever this happened, if anywhere, this is indicated in the question text below.

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 System Demo and are not official statements by the European Medicines Agency nor its partners.

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Research & Development Value Stream

Priority Medicines (PRIME)

Question	Reply
Are PRIME pre-submission meetings still to be requested via email? Or via IRIS?	Until the launch of the new process for PRIME meeting request that is foreseen in Q3 pre-submission meetings are still to be requested according to current practice
Does the Scientific Advice or Protocol Assistance applicant for PRIME designated products need to be the same applicant that holds the PRIME Regulatory Entitlement?	Yes, and more importantly so for SME/academic applicants as the PRIME regulatory entitlement also gives access to an incentive. Incentives will only be applicable for the PRIME designation holder.
For the PRIME Kick-off meeting with EMA once PRIME granted, is it planned to develop a new process too on IRIS? under which timelines?	The PRIME meeting request process type that we will be developing in Q3 2023 will allow for request of PRIME Kick-off Meeting, Introductory meeting, Ad-hoc meeting, Submission readiness meeting and Pre-submission meeting.
when is this launched ?	The go-live date is set for July 10, 2023
Is the PRIME request submission form still required?	No, the submission form has been replaced by the application form in IRIS.
[this question was moved from Plenary room]In the PRIME application, is the MedDRA coding a drop-down menu?	It is a lookup menu.

Real World Metadata Catalogues (RWMC)

Question	Reply
Would Institution end up to be stored and maintained in OMS?	The catalogues are integrated with other SPOR components (e.g.: RMS) but not with OMS. The Institution part of the catalogues contains a small number of specific entities, migrated from ENCePP, aiming to specifically support the data sources and studies catalogues. The integration with OMS might be considered for future releases of the catalogues if found appropriate.

Product Lifecycle Management Value Stream

Electronic Application Form (eAF)[1] / PLM Portal

Question	Reply
Will the issue with the synchronisation in PMS cause a delay in the published timeline for eAF PLM? Especially with the planned UAT in Q4 2023?	Unfortunately, due to the issues we found in the split of CAPs in UAT, we do have a delay in loading the non-CAPs in to lower environments of the eAF. Due to this we do anticipate a delay with a launch of the Nationally Authorised Products in the PLM Portal eAF in production. Next week we will have the Planning Increment meeting and following that meeting we will be able to provide a confirmed timeline for the NAPs go-live and also we will then know if the UAT timelines will be impacted.
What is the dependency of PLM with PMS Go Live? PMS records migrated at the right granularity (PMS ID, PCID)? The minimal 15 fields to allow product selection? All the PMS fields for structured changes?	The requirement is to have the minimum set of fields required for product selection and the correct granularity of medicinal products available for both CAPs and NAPs for the current release of the eAF.
Would the Pending Package (just added in the form) be registered in PMS, and down to XEVMPD, or should the new Package be submitted to XEVMPD upon approval, and then synced with PMS?	Pending packages will be imported through the eAF into the EMA procedure management system (SIAMED and then IRIS) and synchronised to PMS from there. The synchronisation from PMS back to xEVMPD is not ready yet and will most likely require a separate submission
Who will validate the synchronised data for NAPs in PMS?	There is currently no validation planned for the NAPs that are migrated from the Art 57 database. They will be selectable in a variation and go to the regulator as they have been created by the applicant in xEVMPD. If there are additional validation requirements, please forward this to the SPOR PMS team.
The helpdesk cannot solve my problem since months. I cannot use the eAF portal since January. What can I do?	We will contact you directly outside the system demo to ensure that you have access.
it is not clear why some submissions feature are developed in IRIS while others in PLM portal. What's the rational behind ?	Even though IRIS and PLM share the same database, the Portals are being developed separatly with the logic that: IRIS is mainly a case management system with workflows including EMA, NCAs and applicants, whereas PLM is a system to create applications / messages

[1] This IT product was formerly managed as part of the Digital Application Dataset Integration (DADI) project

Question	Reply
it is not clear why some submissions feature are developed in IRIS while others in PLM portal. What's the rational behind ?	To continue from the previous response, different portal to IRIS was created for the 'products' for the use by the whole EU network, such as the eAF which is for all EU applications for CAPs and NAPs, the ePI and the PMS. All of these products contain also non-CAPs. So the main logic was; IRIS ->EMA led procedures, PLM Portal -> procedures/activities related to the wider EU network
Are electronic signatures on the application form after exporting mandatory , required or optional?	The signature in the eAF exported from the PLM Portal is optional. It is possible to include a digital signature or an image of a signature, however, unsigned forms are also accepted.
If you accidently use the UAT environment are applicants then ask to fill in the forms again on production environment?	We want to encourage users not to use the UAT environment as it is offline once a week for deployments and not all features are garanteed to be working. The product information is kept updated, so applications will most likely look the same as if done in production. A regulator will not be able to say from which environemt the eAF was exported unless something went wrong. Unfortunately, we have had to reject some applications that have been created using the UAT environment as the forms have not contained all the required data due to lack of the non-live synchronisation with SPOR and due to issues with certain features leading to data being missing from the exported forms. It is very important to use the correct environment for production submissions.
it is not clear why some submissions feature are developed in IRIS while others in PLM portal. What's the rational behind ?	Even though IRIS and PLM share the same database, the Portals are being developed separatly with the logic that: IRIS is mainly a case management system with workflows including EMA, NCAs and applicants, whereas PLM is a system to create applications / messages. Different portal to IRIS was created for the 'products' for the use by the whole EU network, such as the eAF which is for all EU applications for CAPs and NAPs, the ePI and the PMS. All of these products contain also non-CAPs. So the main logic was; IRIS ->EMA led procedures, PLM Portal -> procedures/activities related to the wider EU network
That's for the direct input of the data via the web interface. What about the API allowing the industry to push the data from their own systems ?	We are working on several parts that are necessary in order to enable applicant API submissions. 1. NCAs are being trained in receiving the message first and assited in importing this automatically into their system 2. We are working on FHIR validation profiles in order to validate API submissions and give applicants documentation to create these messages. 3. After the profiles are created which are necessary for RIM developers and NCAs are ready to receive automatic messages we will enable the API for applicants.

Question	Reply
Kristiina showed a slide with feature numbers, and another one with fixed bug numbers. Are these lists somewhere publicly available? I am particularly interested in the bugs as I am tracking my tickets which depend on a bug fix.	You will find a list of all the bugs and user stories we have implemented from the latest version of the Release notes: https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20-%20Release%20Notes.pdf I have added a section where I'm also describing the 'coming soon/under development' stories to give indication on things that we are working on at the moment.
Could it be cloned the package from an investigational product with a complete clinical trial (Phase II) performed by a different sponsor?	We currently do not receive data on investigational products from PMS. I believe this is planned for a future phase in the SPOR programme and once they are there we could create a feature to include this requirement

Product Management Services (PMS)

Question	Reply
Data will be migrated from XEVMPD to PMS during Summer 2023. The migration will not cover all IDMP data fields. By when enrichment is expected to start, to complete, and how (Product UI, APIs)?	As anticipated at the demo the discussions on the features as enrichment process as well as data correction processes via both UI and API have to be finalised and the relevant process agreed. The Agency will promptly communicate when the process and functionality will be available for users to correct and enrich the data.
The testing of APIs needs systems (and vendors). Will there be a testing environment for vendor to test APIs? Should vendors directly connect with the PMS Team, or only via Industry?	We will take into consideration your proposal to involve vendors to test APIs and discuss with the relevant PMS SMEs when the API is ready to be tested and UAT is about to be launched.
Once data is migrated to PMS, there will be a synchronization with XEVMPD. However, once enrichment starts, and for cases of different granularity between PMS and XEVMPD (split/merge), how the synchronization will work?	EU IG chapter 7 reports the migration rules applied to perform the data load from xevmpd to PMS. The same migration rules applied for the initial data load will be applied for the deltas. Additionally, PMS team foresees to keep xevmpd aligned with PMS product data however the PMS to XEVMPD data synch is not yet in place as rules have to be defined and tested.
Will a list of PMS post-migration activities for industry be released, with proposed data operations (possible data corrections in xEVMPD prior UI/API availability and/or servicenow and/or using the UI/API when possible)?	A publication of the PMS post migration activities is not planned. However we take your proposal on board and recommend industry user to keep their xVEMPD product data as updated and best quality as possible in order to ensure that the data loaded to PMS have the same level of quality.

Question	Reply
For enrichment, there will be data gaps but also corrections. Should industry expect to be obliged to rectify data within a specific time period? Is there an intention to prioritise what is corrected or enriched?	Enrichments and corrections will be different activities. As soon as the Product UI and the read API are release, people will be able to see the data that is already in the system and a process to correct that data will be in place. Take into account that this data is coming from XEVMPD and SIAMED so a process will be stablished. Enrichments will come later in time as we need to deliver other enablers so applicants can submit new data to PMS.
Which are the current timelines for PMS go-live?	PMS is already live and used to support EMA inspections activities and eAF for CAP products. The product will have several go-live dates based on the release of each feature and completion of epics over the time. We are now working to complete the data load for CAP and non-CAP products from xevmpd/SIAMED in order to land in PMS production. However please note that the PMS system will not be available for use until other epics and features have been finalised. The result of PMS data load will be available via eAF. The Agency will release an official communication to inform all stakeholders on this type of release/go-live.
Features are being developed (Product UI, APIs) and about to be available. What are the timelines for roll out to Industry, and by when it is expected from Industry to use these features (optional use, mandatory use)?	The Agency will release an official communication to inform all stakeholders on the availability of the Product UI and API when these are fully functional and available for users.
The following XEVMPD fields are grouped together as a single PMS medicinal product for management purposes. If a product has multiple local trade names linked to different EV codes, is it still treated as a single PMS product ?	Yes. As stated in EU IG Chapter 7 EV codes with the same product data in the xEVMPD fields reported at pag 7 are grouped under the same PMS Medicinal Product. In this case medicinal products such as Belgium (BE), Finland (FI) and Lichtenstein (LI) have more than one official language. Following Chapter 3. II, one record per official name in its official language shall be submitted to xEVMPD. In order to group all the records under the same PMS Medicinal Product, the full product name cannot be used and the Marketing Authorisation Number (corresponding to the same for all the records independently of the language) is used to apply the grouping logic. With this logic a product having multiple local languages will be grouped within the same PMS product entity.
EU IG Chapters 2, 3, 7, 8... are still evolving. What is the forecast for the release of each chapter update, so that Industry can prepare data collection, data migration, data submission process...? How will be informed about updates?	PMS team will release an updated version of the EU IG Chapter 7 at the same time of the completed data load of product data in PMS production environment. This chapter will contain updated migration rules for CAP and non-CAP products. A minor version of the EU IG Chapter 2 and 8 is expected to be released by Q1 24 to support the read functionality of the Product User Interface in PLM portal. While the release of the new version EU IG Chapter 3 defining the data submission process depends on the outcomes of the discussion which have to be completed.

Question	Reply
	External industry stakeholders can stay up-to-date via following System Demo, via communication circulated to the Industry trade association as well as via the eAF-PMS newsletters published or alternatively via the nominated Industry PMS Subject Matter Experts.
Can we see data down to the level of for eg. CMS national data as part of MRP/DCP Procedere? As in UPD	Data will be seen as submitted in XEVMPD. So for MRPs and DCPs there will be one record per country. More information on how products are defined in PMS can be found in Chapter 2 and rules for migration in Chapter 7: https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/spor-master-data/substance-product-data-management-services#eu-substance-registration-system:-ema's-role-section
For the enrichment, correction and variation process, the main steps are likely to be submit > review > update > approve/validate. Who will be in charge to update data? Industry always (as data owner)? NCAs sometimes (as data steward)?	This point is currently under discussion at the Agency and across the stakeholders, considering the EU legislation. More details will be released as soon as the point has been completely addressed and clarified.
in the split example, why product 1 and 2 are not split as well? What's the full example please	Products 1 and 2 are the ones splitted into the new products. Products 1 and 2 are already in the system. We use them as the basis to split the products and then we need to nullify them.
Why there is actually invented PRD ID? Why there is no option to use product number as identifier?	That was just an example to show the mappings between PMS and XEVMPD.
Are IDs stable? Once industry has read access, can we consume PMS ID, MPID and PCID into our own systems?	Only the PMS ID is a stable ID. It will never change. Moreover, MPIDs and PCIDs are not generated for the moment and therefore you should not take them into account. As soon as we are able to generate them, we will notify it and they will be created in the system

Product User Interface (UI)

Question	Reply
Will the product UI allow some bulk update, like change of QPPV for all products under the same MAH, same country?	Yes this is foreseen in Product UI.

Question	Reply
Features are being developed (Product UI, APIs) and about to be available. What are the timelines for roll out to Industry, and by when it is expected from Industry to use these features (optional use, mandatory use)?	The Agency will release an official communication to inform all stakeholders on the availability of the Product UI and API when these are fully functional and available for users.
Will the feature such as 'download' be associated to a specific access role, as part of PMS roles ?	This point is scheduled to be discussed with PMS team and PMS SMEs.
Linked to question IRIS versus PLM. How this is now linked to marketing status reports submitted in IRIS	PMS and IRIS team are in contact in order to clarify the data flow among the shared data elements such as marketing status. Additional information will be released by the Agency when available.
Does industry see all products or only its own organisation ones ?	They will be able to see a list of all the products and the 5 fields shown in the PLM portal, but only the data for the products belonging to their organisation.
How those cmc information will be managed in case of changes ?	Edit pages of the Product UI as well as the process to update information after a variation are under discussion and development. Once this information is available, it will be shared. For the moment, no updates are required through the Product UI.
If the Agency releases an official communication to inform all stakeholders on the availability of the Product UI and API when available, Industry and Vendors cannot prepare. We need timelines upfront, at least 12 months ahead.	The communication plan of the Agency foresees to host System Demos, public webinars, release documentation and guidance, newsletters and keep the Industry stakeholders groups and the regulatory network timely updated also via email, NPO and SMEs on the progresses made in the context of the project. This is to ensure that the stakeholders have enough time to prepare for it. Additionally, dedicated discussions with the relevant SMEs are hosted on a weekly basis to make sure the voice of the external stakeholders is heard and taken into consideration for planning purposes.
Is the MedDRA coding given as drop-down menu?	It will be provided as a drop list with a search option
It will be very helpful if EMA can provide guidance on the integrated operating model and associated timelines , the role of product UI in data enrichment, data updates where no regulatory evaluation is needed, the role of APIs update	Thanks for the feedback. As soon as we have more information on the timelines and processes, it will be shared with the Network.
what about search for historical names?	We are discussing how to search and store different versions of the product.
For the manufacturers, every operation type will be on different line and will be able to add?	Yes, for each manufacturer, every operation type will be a different line and users will be able to add new operations.

Electronic Product Information (ePI)

Question	Reply
Will the ePI consume PMS approved data, and/or allow to generate 'pending for approval PI' using eAF proposed data changes within a variation package?	ePI could indeed enable this use case with the eAF when the product is mature. We will also explore further integration with PMS going forward.
Will the ePI creation tool have an import function to import SmPC, PL and labeling? If not, what should the pharmaceutical manufacturer do? Are there any software vendors to contact?	The current MVP allows for authoring within the portal and has a limited capability for importing in FHIR format. Increasing the FHIR upload capability is one of forthcoming priorities. Software vendors may of course emerge, but we have not partnered with any
Will ePI lead to 're-use' with the availability of the PI documentation being used to support eCTD submissions, IDMP data submissions, etc. without the need to provide these PI documents?	In addition to Elizabeth's answer, Product information that is created in the ePI tool can be exported (to Word) and submitted as part of eCTD
Are there now cooperations with major relevant software providers to integrate ePI functionalities in regulatory software?	No cooperations are in place although software vendors may of course emerge
Are there now cooperations with major relevant software providers to integrate ePI functionalities in regulatory software?	EMA is publishing as much information as possible to support development and may undertake other actions to support developers in the future.
Once the labelling is approved I understand it will be available on the dedicated EMA and MEB. Can it be made available on any other platforms? If so how would this be done?	The authorised ePI will be publicly available via an API.
How the linguistic review process for CAPs will be managed with the ePI?	Work on handling ePI translations, including the linguistic review process, is still ongoing.
After the pilot will there be a voluntary implementation period. If so how long will this be?	It is highly likely that implementation will begin with a voluntary period. The timelines are yet to be determined.
We are still on time to participate on this pilot phase?	Applications to participate are closed. However, interested companies are advised to keep up to date with the published guidance on the PLM portal, which will give a good overview of the pilot process.
Is there a good overview of the planned timelines for mandatory ePIs?	We do not yet have this view. The outcome of the pilot will inform the next steps and the roadmap.
Which products are in scope for ePI?	Human medicine CAPs and NAPs are in scope. In the pilot, we will focus on EMA and the participating NCAs. The EU ePI Common Standard can be extended to vet products in future.

Question	Reply
Will the business process for the NCA pilots bd broadly similar to the EMA pilots?	We plan to publish procedural guidelines for both CAPs and NAPs. The business process will be broadly similar.

Regulatory Procedure Management (RPM)

Question	Reply
Will this case management be available to EMA/NCAs only, or to Industry as well?	We can confirm that relevant procedure information will be available in the Industry Portal (currently under developement). Please refer to the recording available on this link: Quarterly System Demo - Q1 2023 - YouTube: https://www.youtube.com/watch?v=TlW9Qg_yx7M&t=1s For regulatory procedures, we presented a 15 min demo, starting at 1 hour and 18 min of the recording.
Are also NAPs in the scope or only CAPs? Timelines, if any available?	At the moment, NAPs will be managed in IRIS only if they are part of a WS variation including a CAP. We are looking into requirements to include NAP products if they are part of procedures managed by EMA (i.e. PSUSA NAP).
What will be the process for MAH to be registered to use these functionalities?	The prerequisite of working in IRIS is to request access (see below instructions). Nevertheless, since the go live for IRIS product lifecycle regulatory procedures, will follow a phased approach, this year we will only onboard about 120 human and veterinary products. Later next year more products will be onboarded onto IRIS. We will communicate to the concerned marketing authorisation holders the timelines and the requirements in due course. https://iris.ema.europa.eu/access/
For the regulatory procedure management in IRIS, will the impacted products be taken from PMS?	Indeed PMS will be the single product database and will be also used for regulatory procedures case management.
Related to previous answer IRIS versus PLM, eAF are to be done in PLM but variation in IrIS ? Does not make sense	Even though IRIS and PLM share the same database, IRIS is mainly a case management system with workflows including EMA, NCAs and applicants. We are working to streamline the regulatory journey as much as possible and that's why we're also looking at user experience and journeys as an embedded practice.

Improved Regulatory User Journey for EMA Stakeholders

Question	Reply
Will the new system is expected to offer availability of more accounts for the assessors from the national agencies?	The assignment of the assessors accounts will be managed outside of IRIS, namely by the national competent authorities IRIS administrators (NCA internal process).

Monitoring Value Stream

Critical Medical Devices Shortages (CMDS) Reporting System

Question	Reply
How is the economic operator defined? Who exactly?	Answered verbally during the demo. In addition, Article 26.1 of the Regulation (EU) 2022/123 provides further information: In order to facilitate the monitoring referred to in Article 23, the Agency may request manufacturers of medical devices, or their authorised representatives, as applicable, and, if appropriate, importers and distributors, included on the public health emergency critical devices list and, where necessary, relevant notified bodies, to submit the information requested by a deadline set by the Agency.
For EO, is an access given to santé data collection plateform only to the EO-spoc registered?	Answered verbally during the demo. Yes, Access to the webform will only be provided to the EO-SPOCs registered in EMA's IRIS system
How will the information integrate with EUDAMED?	Answered verbally during the demo.
Access and LOGIN, EMA and the Commission has different solutions, will they be merged	Answered verbally during the demo.
In overview of dossiers, why not have a label that includes for instance the category of the device?	Answered verbally during the demo.
Will the SRNs be added to the different EO once Eudamed is fully functional? Also in the EO selection screen for the EO-SPOC?	Answered verbally during the demo.

Veterinary Union Pharmacovigilance (UPhV) Database

Question	Reply
[No questions received for this product.]	