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System Demo 2022 Q2 Q&A

Date: 28 June 2022

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

Link: Quarterly system demo – Q2 2022 | 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
And what if we have already an IRIS user in the company: is the eAF industry user admin a new role and the first one of its kind?	If you have already an IRIS user, you must also have an IRIS admin. That admin will be granted the eAF admin and can create more admins if need be
As the product definition differs between xEVMPD and PMS can you show how you migrate updates from xEVMPD into PMS for e.g. HU, PT or FR. The PMS ID includes in this case multiple PRD codes. If only 1 is updated, how do you proceed in PMS?	For countries where the MA number is granted at pack level these records are migrated together as individual packages of the same product. Therefore, updates will be done at pack level. If all packs contain the same information, this will be reflected at product level as well.
can all regulators see all products (caps and non-caps) without restrictions?	Yes, the use case is that all regulators will be able to Read data on all products in PMS, all CAPs and non-CAPs and all data fields are visible on those products.

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Can one person have two roles, especially IRIS/eAF Industry Admin and eAF Applicant Coordinator?	Yes, You can have an admin role and one of the application roles.
Can we combine roles for a given MAH organization, so as to be Manager for some Application Forms, and Contributor for some others, still for the same MAH?	The roles are related to an individual users, not the MAH as an organisation so it is possible that different users from the same MAH have different levels of access.
Can we combine roles for a given MAH organization, so as to be Manager for some Application Forms, and Contributor for some others, still for the same MAH?	For the same user in a single organisation you can only have 1 application role. It would not make sense to have access to products with one role and not access to products with the other role
can we expect the JSON viewer to become available as soon as the PMS (read) API will be made available?	This is not in the plan for the moment. This is an internal tool we are using to see how the products will look like. PMS API availability is just access to the API. How the products are then displayed will depend on each user. In the future, PMS User Interface would be use to see the product and its information
Can we have link for submitting DADI variation form which is a testing environment?	The details on the DADI external user acceptance testing will be published soon.
Could you please share the link for EMA IAM? Thanks!	https://register.ema.europa.eu/identityiq/home.html
Does every process need to have a co-author, or is it possible for one user to work on an application on his own?	It is not mandatory at all to have a co-author, it is possible for one user only to work on an application on their own.
Does that mean that an MAH will have to grant access in IAM (with Contributor role) to a number of users from other companies to ensure proper working of worksharing Application Forms in DADI?	That is correct, the contributor role has to be provided that enables just sharing of the application. We will publish more slides with examples of how that could look like.
How could we remove a user affiliated to several MAHs including MAHs belonging to our organisation and external MAHs?	If you have set up an admin for multiple organisations that admin can also remove affiliation of users for multiple organisations
How much frequent will sync process works if any change in xEVMPD data occurs? Time from receiving positive 2 ack and getting reflected into DADI forms?	The connection is live, meaning it will take a "short" moment. The exact number of seconds will be tested once we have migrated all 550000 products in the environment.
How shall we enter French homeopathic registrations into XEVMPD for making them available in PMS/DADI? These cover a range of pharm. forms and potency ranges (i.e. many products) which do not fit into the product centric approach of XEVMPD.	Homeopathic products can be submitted to xEVMPD following Chapter 3.II: XEVPRM User Guidance. Not all fields are mandatory and homepathics have already been submitted for several years.
If a user from Industry has IRIS admin access. With this IRIS admin rights will the user have either eAF contributor or Manager role access? or he doesn't have such privilege except granting access to requestors?	The Iris admin can provide the manager role but does not have it implicitly. I could though provide it to himself

If I am a CRO all my role with different locations will be displayed. If I do not want to see for everybody, whom I am working for as soon as they invite me. That might be confidential data. How can I block that?	This is something that was highlighted to us by the DADI subject matter experts and we are currently discussing/planning on changing this by hiding the other organisations that the user is associated with. It is not something that an invidual user can at the moment block or toggle on or off.
IF we want to switch from one software to another when moving from xEVMPD to PMS, could we use this EVPRM message transfer to FHIR message for data migration?	No. There will be different tools to send data to PMS once Art. 57 submissions are decommissioned. For the moment, XEVPRMs are the way to updates products in xEVMPD and therefore in PMS. No FHIR can be submitted directly to PMS by the users.
Is it possible to send 2 or more DADI applications per varatiation procedure, eg 1 application form per MS with different MAHs involved in the same procedure, or is only one DADI application per procedure is allowed?	The regulatory process remains unchanged. the DADI project just provides a new way of creating an application form PDF
It is still quite small and hard to see	Thank you for letting us know - we'll look at what we can doing for the other presenters.
It seems that it will be easier to grant all company users Co-ordinator access and avoid the burden of managing the other access levels - what are the negatives of this approach?	This is a proper way of working. The "downside" is that each user sees the applications other users create. In a trusted environment this is an upside though
Just a hint to the audience: If you change the quality to HD the slides are readible	Thank you for your kind suggestion.
Just to clarify - it is not possible to see which other organisations user is co-authoring, i.e. consultants don't "show" which other clients they are working for?	That is exactly the case at the moment. You CAN see what other companies a consultant is coauthoring. This was brought to our attention as a possible problem and we are looking into taking this feature out again
maybe my question depends more OMS generally. How is it possible to see for me as Industry Super User a list with user's and it's roles for my company? Due to DADI the number of users with it's roles will increase greatly.	This is indeed a question that is more on the IAM side. We will discuss this request with the IAM team. Additionally, if you wish, you can raise a change request using the EMA service desk which will allow you to track the status of your request.
Security model is very granular and inefficient to administer. Will EMA considered modelling Security at the Company level and associating one Company to multiple MAH organizations, reducing the burden of user account management?	You can set up a more generalistic security model by associating an admin to all of your companies. That way you can manage access centrally.
Slide 13, scenario 2: Does that mean you cannot add a consultant, or vice versa, the client cannot add the client via this route?	Adding a consultant you can chose 3 options of access level. Only what he is shared with / product access / or access to all applications
So unlike IRIS currently, moving forward an individual with IRIS admin rights cannot also complete application forms?	No, an admin can provide sombody (or himself) with one of the 3 application roles. He can then create applications
the broadcast frame removes more than half of the screen real estate. Can Kristiina zoom in a bit more please?	Thank you for letting us know - we'll look at what we can doing for the other presenters.

When will the API be available for Industry?	API Access is not intended to be release at least during this quarter.
When will the API become available to MAH? What role do we need in IAM?	Dear Josef, PMS Product Owners will announce when the API will be available and ready for use. Please note that this is not needed for the DADI release in October. Relating to your question on the PMS user roles, please refer to the documentation "On-boarding of users to Substance, Product, Organisation and Referentials (SPOR) data services" available at the following link: https://www.ema.europa.eu/en/documents/other/boarding-users-substance-product-organisation-referentials-spor-data-services_en.pdf.
When will the new roles be available in EMA IAM portal? The external org admin is for users that have no IRIS admin, right? We only have a SPOR admin. Who approves the external org admin?	The external org admin is for small companies who don't want separate admins and is an optional role. It is approved by EMA. The new roles will be available in production after the UAT ends, to not confuse them with the UAT roles that are being set up now
Why isn't it possible for us to grant the access level to users from other organisations?	This could unfortunately lead to access to some applications that you are not associated to or allowed to see due to data confidentiality.
will be these different DADI user roles administered in EMA IAM portal and must be confirmed by company's OMS Industry super user?	Yes, this is correct. The access is administered in the EMA IAM. Invitations to a certain application can be done in the portal but access is limited depending on the role and association to the organisation in IAM.
Will change that EMA (data steward) makes on XEVMPD (3rd acknowledgement) be also instantly visible in PMS?	Yes. Any change done in xEVMPD will be forwarded to PMS not matters who perform the change (QC team or Applicant).
Will the FHIR specification be shared soon, in order for vendors to implement final version?	For PMS the FHIR specification follows the current version of the Implementation Guide for ISO IDMP found at https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/spor-master-data/substance-product-data-management-services Chapter 2 is the one detailing which FHIR version is currently used and the specific FHIR paths relevant to the various data elements in PMS. Note that the chapter mentions the target state will use a stable version of FHIR. The plan for a transition in the future to the target state will be communicated when finalized.
Will the industry admin have the oversight of all Contributors/Managers/Coordinators to perform periodic reviews of access?	Yes, the industry admin has the oversight to see all contributors/managers and coordinators to review who has access.
Will the IRIS Industry Admins automatically get the eAF Industry Admin role for DADI too?	Yes, these roles have been merged now

Will the user platform eventually also show data in xml format, or will it be translated in a more user friendly format?	Dear Irene, the intention is to display PMS product data in a user friendly format.
Will users have to apply for all roles, or is the coordinator the top role with which you can do everything you need to do?	The coordinator role provides the widest possible access. All roles need to be applied for in IAM.
Will you be planning more granularity of PMS industry roles similar to DADI?	We are discussing this point to try to have a simple registration process. More information will be shared as soon as the final roles are defined.
With all this contributor access permission setupsI need to remember whom to "delete" again and hopefully I did not mix up "contributer" with "coordinator". Is there an easy clean-up possiblity on access users?	That would be good, but if a contributor role is forgotten there is no harm done as it does not provide any other level of access to your company. If you feel you need additional features in IAM to organise access management EMA is happy to receive those request via ticket line.
xEVMPD-PMS integration: It was shown that any update in xEVMPD is immediately also visible in PMS. Will the updated value be indicated as "preliminary/pending" in PMS until it was validated and confirmed by xEVMPD QA check?	No. Updates to xEVMPD are not immediately validated and it might take time to perform this validation. Therefore, we can't wait to have the validation to show this update as approved in PMS.
You mentioned that corrections should be made in XEVMPD before transfer to PMS, but what if data requirements differ?	I explained, that if needed, changes can be done in xEVMPD. But not before transfer to PMS. In fact, products will be in PMS and you will be able to see them through the DADI variation form. If any change to xEVMPD data should be done, you can use xEVMPD to do so. But products will be already in PMS.

Emergency Taskforce – R&D Value Stream

Question	Reply
If I have filled in the information and erroneously click "no" afterwards, are all the entries lost, or can they be retrieved?	When completing the form, for example administrative info, there are two options at the bottom of the form "save and return" and "return". Choosing "return" only will not save the entries. You can always edit the unsubmitted draft by going to "My draft submissions"

European Shortages Monitoring Platform (ESMP) / Shortages Management for Medicinal Products – Monitoring Value Stream

Question text	Reply

Has the i-SPOC to be registered to an OMS organisation ID or location ID ?	
When have we start to request roles ispoc iris?	