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Q&A Q1 2025 System Demo

Date: 26 March 2025

Location: Online, 09:00 - 11:30 Amsterdam time (CET)

Link: https://www.ema.europa.eu/en/events/quarterly-system-demo-q1-2025

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.

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

Data Analytics Platform (DAP) – Trial Map

Question	Reply
Are the data related to the products used in the clinical trials tracked the Data Analytics Platform (DAP), or is the DAP consuming data from PMS or any other system ?	Data for the map is copied on a weekly basis from the CTIS public portal. CTIS consumes product details from XEVMPD – the Extended EudraVigilance medicinal product dictionary is a database managed by the Agency.
What if a user does not know that 'high blood pressure' is hypertension? He/she will not see his/her search term in the results.	Thank you for raising this point. You are correct that a user not explicitly seeing their search term in the results can lead to an unintuitive experience. The team is aware of the issue and is working on making explicit why results are returned in those cases where they are not an explicit match.
How in future this will be integrated with different database	Currently, the map copies data from the CTIS public portal on a weekly basis, therefore as all its data comes from one source, that is the CTIS public portal, no further need to integrate data from other databases has been detected.
Is it possible to select one particular clinical trial in EU and check if a similar trial is being conducted in other regions of world (e.g., US)?	Thank you for the interesting suggestion. This is not currently possible and we would be interested in understanding in more detail your use case. A gentle reminder that we have a feedback form here where we would appreciate getting your feedback on desired functionalities: https://ec.europa.eu/eusurvey/runner/ACT_EU_Trial_Map_feedback

Product Lifecycle Management Value Stream

You can subscribe to the quarterly PLM Highlights Newsletter at
https://ec.europa.eu/newsroom/ema/user-subscriptions/3638/create

Product Management Services (PMS) and Product User Interface (PUI)

Question	Reply
Many of our members have issues with data quality in PMS, issues both present and absent as 'known issue' in the available documentation. Is EMA considering to work on data quality and fix all the issues? Tickets are not being answered.	The data fixes have been ongoing since October 2024 and will continue throughout 2025. We recommend regularly monitoring the PMS Q&A document, which is updated frequently. It provides information on upcoming data fixes and addresses any other related issues.
For the Enrichment of non-CAP critical medicines in 2025, will this deadline be reviewed if the PMS API write capabilities are not in production until Q4 or close to end of 2025? This is to allow MAHs to use the API with enough time.	This point is under discussion with the ESMP team. For the moment the announced timelines remain the same announced. In case of further update this will be duly notified via the official channels.
We have a number of valid products which are missing from PMS - but available in XEVMPD - and we know that some of these are on the list of critical medicines. When will issues be resolved concerning these missing products?	If you notice that products are missing please notify it via SNOW ticket (incident) so the team can properly investigate.
We saw the bulk update for MRP/DCP: what should it be like for NP?	The bulk update in PUI will be released for MAHs of NON-CAPs.
We identified Duplicate PMS IDs in PMS for the same Product Registration, there are several mismatches to xEVMPD submission done when PMS data will be cleaned as per xEVMPD submission done	If you notice duplicates PMS ID please notify it via SNOW ticket as incident type so the team can investigate.
when the bulk update possibility is going to be introduced?	The release of this functionality is planned by the end of Q3 2025
we have multiple products above 300 (withdrawn) are missing from PUI excluding LI,IS,NO. How to deal with it with EMA? creating multiple tickets or one ticket for all 300 products? can we do dummy update on withdrawl products?	This type of case require the proper investigation. You are therefore recommended to submit the SNOW ticket as Incident so the team can check the root cause.

Question	Reply
Why the confidential indicator is automatic for “public” While it should be manually changed from “public” to “confidential”? This could cause disclosure of confidential information. The opposite would be safer	The confidential indicator can be set as public or confidential. To mitigate any human error we are implementing a feature to mark by default as public only the manufacturing activity related to the "Manufacturer responsible for batch certification" only. The rest of the manufacturing business operation the user can select the most appropriate value. This is because depending on certain elements ie. origin of the substance a manufacturer operation can be confidential or public (the operation Manufacturing of active substance, where the substance is biologic can be public).
Will the Bulk Update functionality only available for MBOs or also for update of pack sizes? If not, is there a timeline until when it will be available for pack size as well.	The bulk update functionality in PUI will be available to cover the submission of structured pack size and manufacturer data. This will be released at the end of Q3 2025.
For the PMS UI Bulk update feature, can you give the estimated timeline for its release into production? Thank you.	End of Q3 2025.
we already performed a data check (XEVMPD vs PMS). Due to known issues, you are updating migration rules. Should we recheck all data from time to time? It is an effort and it would be good to know if data (already good) will not go bad.	PMS data are updated in accordance with changes submitted in XEVMPD. It’s considered best practice to ensure the data is consistent across the system. If discrepancies are found, investigate the issue by reviewing the PMS Q&A document. If the root cause remains unclear, please submit a SNOW ticket to EMA for further assistance.
We don't see the Strength Presentation field under ingredients>>Excipients(Active Ingredients it is present).Though these data are not migrated from xEVMPD or SIAMED, we should have the field available atleast with placeholder to have added	Please check the migration rules in EU IG chapter 7. The strength may come from SIAMED II for Manufactured Item Ingredients and for CAP only. While it may come from XEVMPD for Pharmaceutic Product Ingredients for both CAP and non-CAPs. If the information is not loaded as explained in the chapter above mentioned, please check if it is a known issue in the PMS Q&A document. If no answer can be found you can raised a SNOW ticket as incident so the team can investigate.
which MBO level should be used in PMS shows higher level , in eAF shows granular level. which one should be used?	Any level can be used as long as is in line with your eAF requirements. Ref. to EU IG chapter 3 pag. 13 : In order to support ESMP, but also, taking into account that in the near future, structured changes will be submitted through the web-based variation form, the same information as provided via eAF, should be provided to PMS. Additional manufacturers or MBOs reported in the dossier but not in the eAF are not required for the moment
What is the limit for the number of products that can be edited in Bulk?	There is no limit as such. Nevertheless, the performance at the beginning will be reduced. Therefore, the suggestion is to start with small amount of product (around 10) until the performance is improved.

Question	Reply
In Chapter 2 it says to have the strength of the Pharmaceutical Product undergone transformation i.e., concentration of reconstituted. In M3 if the excipients are not expressed in concentration how do we present them in PMS.	As stated in Chapter 2, if the strength of the excipient is not reported it can be left blank. Ref. In specific cases where the quantitative composition of the strength of the excipient(s) and/or adjuvant(s) of the medicinal product is not reported in the relevant product information (i.e., SmPC), the substance strength is to be left empty, and the substance reference strength is to be completed. For further information on this exceptional case (i.e., vaccines) refer to Chapter 8 – Practical example. If no quantitative information is available neither in the SmPC nor in Module 3.2.P.1, the substance can be reported without any quantitative information. Note that the quantitative information of the active substance must be provided in all cases.
The way xEVMPD data is QC-ed is still causing issues in PMS e.g., special characters are added to the MP Full name because they are present in SmPC, etc. This causes multiple PMS MPID generations incorrectly. Will this be looked at?	If they are present in the SmPC, they should be provided to XEVMPD, so please, include them. Otherwise, the validation team will perform the updates when validating the product.
What is EMA's plan for managing investigational products using Product UI, given that your timeline slide mentions the decommissioning of XEVMPD submissions starting in 2026?	Decommission of XEVMPD is not starting in 2026. The slides shows activities to be done FROM 2026. When XEVMPD is decomissioned (not in 2026), investigational products will be moved most likely to PMS as well.
How to handle Regulatory Agency until it is improved to the Optional field, will there be a dummy value made available to still continue updating in case no Reference number is mentioned?	There is no dummy value you can enter. Our recommendation is to submit one and as soon as the functionality is implemented (conformance changed to conditional based on the availability of the reference number) you can update it by removing the value. This is foreseen within Q2 2025.
Medicines Regulatory Agency field is set as mandatory, but pulling the data of Location from Certificate is difficult, how EMA is mitigating this. Will this be made as non mandatory?	Yes, this will be changed to conditional as explained during the demo.
During pack splitting, due to evaluation by EvWeb for inserts and updates submissions, we see changes in grouping elements as authorised dose form, leading to PMS ID duplicates. Is EMA considering this? This is a lot of extra reviewing work	Yes, we are aware of this and we want to improve the validation process.

Question	Reply
On the Q&A it mentions that the issue concerning "duplicate" information in PMS (e.g. Route of administration) were fixed in February, however, today we see that there are multiple instances of duplicate data showing. Are you aware of this?	Yes, we are aware, mainly for CAPs. We will be also working on this issue.
In the 'Medicines Regulatory Agency' field, should we select the Regulatory Agency of the Marketing Authorisation Holder (MAH) or the Regulatory Agency of the manufacturer?	The one for the manufacturer. Please, check Chapter 2 for additional information.
A recently authorized medicinal product is seen in xEVMPD, but is missing in PMS - how EMA is mitigating such issues?	Please, check the known issues document. If none of these issues apply, please, raise a ticket.
It was mentioned in the past that Investigational Products (managed using XEVMPD) may be managed in a different system than PMS. Have you made a decision on this?	We are still discussing this option but most likely it will be PMS.
Can you demo how to retrieve the products present in the critical product list of EMA in PMS UI?	Please, check the SMEs webinar: https://www.ema.europa.eu/en/events/webinar-pms-project-made-easy-summary-activities-practical-tips-smes
We have received a lot of 3rd Acks for pack size submissions, these are related to excipients, not related to package description. All these changes are not done by EMA previously - please comment on.	You need to check which changes are performed and if they are correct or not. If you don't agree with the changes, you can raise a ticket for XEVMPD and they will evaluate the decision.
About bulk update for NP. Is it be possible to add a filter for Procedure type in PUI ? In this way the search can be improved	We can discuss this, but for the moment it is not possible.
Is there any limit for doing the bulk update e.g. only x number of medicinal products can be selected for bulk update of manufacturers?	We are working on the performance. We recommend to start with a small amount of products (around 10) and we will be improving it.
As far as I know, for national products, the pack sizes are still not visible in PMS. When will these data be made available?	Pack sizes are visible in PMS for all products.
Can MAH select only Organization name in 2.8. (Manufacturing business operation) Medicines Regulatory Agency Organisation if location is not known?	No. Location is mandatory.

Question	Reply
Can MAH select only Organization name in 2.8. (Manufacturing business operation) Medicines Regulatory Agency Organisation if location is not known?. As per the chapter 2 guidance location is not mandatory. How to manage in this situation?	At the moment it is not possible to select only the ORG ID without the LOC ID. This is because any ORG ID is associated to one or more LOC ID(s).For the moment you can leave it blank. In Q2 we are also implementing the change of conformance. When this will be released, you can leave it blank if you don t know the loc id or if you do not have the reference number.
can we use MBO at granular level right in both PMS and eAF? but in PMS shows higher level should be correct as per granular level in PMS or not ?	Any level can be used as long as is in line with your eAF requirements. Ref. to EU IG chapter 3 pag. 13 : In order to support ESMP, but also, taking into account that in the near future, structured changes will be submitted through the web-based variation form, the same information as provided via eAF, should be provided to PMS. Additional manufacturers or MBOs reported in the dossier but not in the eAF are not required for the moment.
If the MIA number is not available in the EudraGmpd certificate, could we use the certificate number for organisation in EEA, and could we validate the change request without MIA Number?	Yes, the reference number is not mandatory.
In PMS, Presentation unit strength of active substance under pharmaceutical pdt section is missing in most of the PMSIDs even though correct xEVMPD submission is performed. Is it a known issue or should we raise the ticket?	This is a bug that we have identified, and we will be working on it in Q2.
In what extent does PMS follow point 6.2.1 c) and 6.2.2.3 of the ISO 11615 standard part of IDMP? Medicinal Product code segment (Unique Medicinal Product Identifier)	The ISO 11615 contain the section 6.2. a - MPID/b - PCID /c-BAID1 /d-BAID2 referring to authorised medicinal products. The PMS data model is designed to implement point a and b.
is withdrwn products are also need to enrich or Only valid authorisation products ?	Only valid products.
Substances names can be different between SmPC and module 3.2.P.1 - EMA is performing several changes on excipients and sending 3rd Acks, but these are correct when we check against 3.2.P.1 - what would EMA suggest in such cases?	In this case, you need to send in XEVMPD the 3.2.P.1 section of M3. Otherwise, EMA is not able to perform the validation. This is explained in the SMEs webinar for PMS and Chapter 3.II of XEVMPD.
We are currently unable to raise a ticket for inactive organizations in OMS for which products have been withdrawn in xEVMPD. Could you please clarify how it is possible to view these products in PMS?	You will need to request the role for this organisation in IAM.

Question	Reply
What should a NCA do when it notices that a product is valid in PMS, but radiated in the national database?	We are discussing the process with the NCAs. They will either notify the MAH or the Pharmacovigilance working group will get in contact with them. The process is not yet established.
Will there be a "read-only" access for PUI established?	Yes, this will be released in Q2.

Electronic Product Information (ePI)

Question	Reply
Where can I find the overall timeline for the EPI project	As timelines become available, they will be published via the usual channels. In the ePI pilot report, there is a clear outline of the remaining work before implementation.
What about OTC medicines for which it is not mandatory to carry FMD 2D datamatrix? What code should be used for these products?	As long as the code contains the same data carrier identifier as the ePI, any kind of code could be used. For more information, please consult the reflection paper that will be published next week.
When will ePI go live?	As timelines become available, they will be published via the usual channels. In the ePI pilot report, there is a clear outline of the remaining work before implementation.
Could you please specify the roadmap of linking EPI to IDMP SPOR + envisaged timelines to link?	Linking ePI to products in PMS is already implemented, and was demoed in December.
Why is the link between data matrix code and ePI and/or PMS established via the data carrier identifier? In the future the product PMS ID shall be incorporated in the data matrix code (instead of EV code). Why not using this ID?	ePI can be linked to the product(s) in PMS and once linked, the ePI will contain the PMS ID. ePI will also contain the data carrier identifiers if they are present in PMS. The DataMatrix on the medicine package contains the following data: – the data carrier identifier – the serial number – the expiry date – the lot number/batch number – Optional: a national reimbursement number or other national number identifying the medicinal product For this reason, the data carrier identifier can be used to link the box to ePI.
When ePI become mandatroy to be present at PLM Portal?	We do not yet have a timeline for mandatory ePI submission.
We will align our Product data (composition) in PMS to align with Module 3 rather than the SmPC to enhance the quality and consistency of our data. Do you think it would cause any problems with ePI in the long run once we update our data?	We would not anticipate any issue.

Question	Reply
The ePI FHIR API is connected to PMS or PLM Portal?	The API is available here: https://epi.developer.ema.europa.eu/api-details#api=ema-epi-consuming&operation=get-api-retrieval-listbytitle
ePI requirement in Turkey as of Jan 1, 2026. Does EMA cooperate with turkey? will have turkey same format for ePI as EMA?	Please consult the Turkish authorities for questions on their activities.
Using the API documented at https://epi.developer.ema.europa.eu/api-details, I could get the documents (see https://epil.euvabeco.eu/list-plm). But I could not find how to get alternative languages although they are available.	Thank you for the question. We do have a BundleBySearchParameter language code endpoint and will make this available in the production API shortly.
Through the non-documented interface at https://plm-portal.ema.europa.eu/get-epipubliclang/?epiid=e56e360c-78f2-ee11-a73d-000d3a29e2b1, we can see that alternative languages are available.	We do have a BundleBySearchParameter language code endpoint and will make this available in the production API shortly.
Is the submission of the ePI not directly tied to the MA submissions and assessment process i.e. we would not need to add procedure number if it is integrated into the existing process?	Having the information in the ePI regarding which procedures resulted in changes incorporated in that ePI is a very useful and requested feature. Published (current) and Archived ePIs will be available for every product, and the procedure numbers will be useful to distinguish between the ePIs and will provide a history of the PI changes. Although ePIs are not part of the assessment, they do have to be submitted and published at defined timepoints.
Is there or will there be a list of manufacturers that offer software to import content from Word into the ePI-Creation tool?	We are not planning such a list. However, as demoed today, we provide a guidance for validating ePI locally, therefore if you are investigating ePI from any provider, you may wish to run this validation.
Will there be a test version of the ePI-Creation tool in which ePIs can be created for test purposes?	In the PLM portal, it is possible to create ePIs and keep them in Draft status, in case the user wants to test ePI creation before submitting. Before the portal is live, the team will run user acceptance testing, when participants will have the opportunity to work in the test environment.
Is it possible to work on the linguistic text for all EU countries simultaneously?	Linguistic review process will be outside the portal. Translations can be created or uploaded and edited at the 'Manage ePI' page of the ePI. At the moment, translations are imported language by language, but simultaneous upload may be possible in future.
long term roadmap how to link ePI to SPOR that according to you is already avilable, but referencing only high level short term linking via 2 codes. Could the location to the long term vision to link to big SPOR data sets be shared?	Currently, the principal focus of the ePI team is to provide the PI in electronic format, in addition to the current pdf. As the product matures, more integration with other related data is envisaged.

Question	Reply
Please could you explain how you will support the business to keep EPI in sync with the related SPOR data?	Currently, the principal focus of the ePI team is to provide the PI in electronic format, in addition to the current pdf. As the product matures, more integration with other related data is envisaged.
What are the pre-requisites to create ePI from Medicinal Product details point of view?	Currently ePI is created at the PLM portal (authored in the editor or imported) and then the user can search for and add the products in PMS to the ePI.
When exactly will this paper be published? Thanks, looking forward to reading it	The paper will be published on 31st March. We welcome your comments. Details of how to provide comments will be provided.
Will ePI have the ability to auto-populate procedure numbers from IRIS in future? And does it already allow the new format of procedure numbers that are generated by IRIS?	The current functionality does allow the new format of procedure numbers generated by IRIS. In future, ePI will have the ability to take procedure numbers from IRIS, but this is not in the near-term plan.

Electronic Application Form (eAF)

Question	Reply
We have to implement different MAHs in MRP/DCP procedures in the eAF. Did you already publish a description how to proceed with different MAHs and user roles?	The ability to add products from different organisations/MAHs is linked to the user roles and affiliation to these different MAHs. There are different ways of doing this depending on the company structure/rights to see products from different MAHs. Details are available in the eAF Registration Guide and also additionally some details are provided in the eAF navigation guide here: https://plm-portal.ema.europa.eu/Guidance/article/KA-01012/en-us
Is work underway to prepare the web-based eAF to support the upcoming implementation of the revised variations classification guideline for human products?	Yes, the changes stemming from the amended variation regulation will be implemented also in the web based form. We are currently looking at the different technical options on how to ensure smooth transition and ability to continue editing forms for procedures that follow the current regulation vs the updated regulation.
How will you implement updated versions of the web eAF? Will there be a version to use/continue to use for ongoing applications, while the new version is already available for preparing new applications? (same principle as interactive pdf)	The eAF team is looking at most suitable way to implement this requirement.
Will renewal forms be moved to the eAF system in the near future	The renewal application form is included in the scope of the eAF product roadmap, however detailed timelines for the analysis and development of the renewal form are not yet available.

Question	Reply
Will there be coming an import functionality, to import fhir message with data to fill/create eaf?	An API or an import functionality was included in the scope of the eAF product roadmap, however detailed timelines for the analysis and development of this functionality are not yet available.
can we use MBO at granular level right in both PMS and eAF? but in PMS shows higher level should be correct as per granular level in PMS or not ? (edited)	In PMS the granularity of the MBOs should be the same as in eAF for non-CAPs and for CAPs, as the data is coming from SIAMED, the granularity is not the same but there is no need to correct it All the information related to this can be found in Ch 3 of the EU IG: https://www.ema.europa.eu/en/documents/other/process-electronic-submission-medicinal-product-information-chapter-3_en.pdf
For the moment it is not possible to include me as consultant responsible for communication with Drug Agency without having SPOR registration. However, the SPOR registration for RA consultants is not possible now. Will this be changed?	For consultant users, you should register yourself as an PLM Portal eAF user in IAM, and you organisation there would be the consultancy company. You will then need to ask the Pharmaceutical company you are working for as a consultant to affiliate you to their organisation and then you will be able to use the web based eAF.
Any plans for veterinary products?	Replacement of the interactive pdf eAFs with the PLM Portal web based form is indeed included in the scope of the eAF product roadmap, however detailed timelines for the analysis and development of the veterinary forms are not yet available.
Is it ok to submit one variation with interactive PDF eAF and the next variation with the web-based form?	Yes, this is indeed possible and acceptable. We recommend that you do not change the format of the form during an ongoing variation, unless requested by the regulator e.g. the following should be avoided unless specific request by the agency has been made: initial submission of a new type II variation is done using an interactive pdf eAF and validation response is submitted using the web based form. However, we support the approach where you may have various different parallel variations and some may use the interactive pdf and some may use the web based form, this is absolutely fine. Or you might have a simple Type IB variation and you wish to use the new web based form, however, for an upcoming very complex variation where you need to fill in section 4 for orphan/paediatric and medical device you would need to use the interactive form due to current limitations in the web based form.
from which date the 'updated' view of eAF will be available in Production?	The updated 'Product selection' design is planned for production deployment on Monday 31st March. This means that the new look will be available late in the evening of 31st or at the latest early hours of the morning on the 1st of April (CET).

Question	Reply
Could you specify what are the types of signature allowed ? Can eletronic signature been used?	Following the implementation of the integrity stamp feature in the eAFs, only certified digital signatures can be included in the finalised, exported forms. The eAF team has tested compatibility with number of digital signature tools, however, some users have reported compatibility issues with some tool implementations. It is important to note that for example the 'simple' non certified Adobe sign functionality does not work with the integrity stamp.

Union Product Database (UPD)

Question	Reply
Concerning ‘Notification’, where could we find the definition of the different items of the Action” drop down list such as “Bulk upload docs succeeded”, “Bulk upload docs failed”, “Transfer”, “Upload document”, “Delete document” ? Thank you	Question answered verbally during the demo.
How do you define API use? Is this the use incorporated in existing systems and workflows? Is ad hoc use of API not considered API use?	Question answered verbally during the demo.