17 December 2025
EMA/391744/2025

Q&A Q4 2025 System Demo

Date: 16 December 2025

Location: Online, 09:30 - 12:35 Amsterdam time (CET)

Link: https://www.ema.europa.eu/en/events/quarterly-system-demo-q4-2025

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.

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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Product Lifecycle Management Value Stream

You can subscribe to the quarterly PLM Highlights Newsletter at
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Electronic application form (eAF)

Question	**Reply**
Could you please confirm that the web application form is updated to v1.28.0.0 which enters into force on 15 January 2026?	*Question answered verbally during the demo.*
If I open an eAF now and I will finalize and export it after the 15th of January, which version will be exported? When the web form will be updated to the new version?	*Question answered verbally during the demo.*
I can not find the Q&A on 8th January 2026 in the events website of the EMA, will it be added later or how to find the event site for joining?	*Question answered verbally during the demo.* The details of the event will be published on the EMA event page. The session will be held on 8 January 2026, 10:00 - 11:00 CET
Can a person without access to the PLM Portal (EAF) sign the PDF after export and is this considered a validator of the PDF?	*Question answered verbally during the demo.*
Products with status "Pending national phase" appear in PMS but cannot be found when selecting products in eAF. What can we do? A service ticket was already started, however, without any solution up to now.	In PLM Portal eAF, only the MRP/DCP "Pending national phase" can be selected. If the products you refer to are MRP/DCP, please let me know the ticket number, to follow-up.
When will the iMAA eAF be made available?	The priorities and the timelines for eAF and for other PLM products are under review, and an updated timeline will be published in Q1 2026.
It would be interesting having the number of eAFs submitted (collecting info from the RMSs), rather than the ones prepared , considering that many users are doing tests in the system.	Yes, that is a statistic we can ask for from other systems, as in the EMA systems we can only check the number of received PLM eAFs for CAPs.
It would be useful to view the revision history of a form (i.e the details of the revisions made to the AF by each user collaborating on filling out the form). Is there a plan to implement this feature? What's the timeline?	Thank you for the suggested feature. We do not have this on our current roadmap, but we will add it to the backlog, and should the capacity permit, we can analyse it in the upcoming quarters.
Is XML FHIR format affected by eAF 1.28.0.0 ?	No, the eAF 1.28.0.0 refers to the interactive PDF eAF. The FHIR XML can only be found in the PDFs exported from the PLM Portal, so they do not impact each other.

Electronic Common Technical Document version 4 (eCTD4)

Question	Reply
Will the results and findings of the UAT be published soon?	*Question answered verbally during the demo.*
is there any list or way to know which products will use eCTD v4? As a national competent authority, how can we find out if a centralised product uses this new version?	*Question answered verbally during the demo.*
Is the optional use of eCTD4.0 possible only for very initial submissions of MAA or even if the MAA is ongoing?	*Question answered verbally during the demo.*
A session is planned for January 28th to kickoff the Forward Compatibility pilot, is it going to Happen?	*Question answered verbally during the demo.*
Do yo know how manny MAA that wil be submitted as eCTD v.4.0 i Q1?	*Question answered verbally during the demo.*
Is the new eCTD Module 4 version not applicable for lifecycle management activities?	The eCTD v4.0 for lifecycle management activities is indeed the 'Forward compatibility' scenario for which we will start the pilot in 2026.

Union Product Database (UPD)

Question	Reply
Do I need to create different submissions for C1 and C6 or can I send them in the same submission?	*Question answered verbally during the demo.*
Will there be any improvements in the VoS submission as it always creates errors (although the video guidance is followed). The process is not very user friendly.	*Question answered verbally during the demo.*
Is there any indication of the timeframe for a NCA to create a new VMP in the Union Product Database after the end of the procedure?	*Question answered verbally during the demo.*
When will FHIR for API shift to version 5.0?	*Question answered verbally during the demo.*
For the bulk submission of QPPV and PSMF data for non-CAPs, how is the fee payment managed? Depending on the Member State, the MAH may be required to pay in advance, while in others, payment is made upon receipt of the tax invoice	The UPD team is not in a position to comment on fee related matters. You may wish to redirect your question to CMDv.

Product Management Services (PMS)

Question	Reply
There are 4 pages of 'known issues'. Why are these not prioritized instead of continuing the development? Data quality is blocking most real uses of the PMS. Additional functionality is useless until the data is true	*Question answered verbally during the demo.* Issues are triaged and resolved by a dedicated PMS DQ team, while a separate PMS development team is responsible for building and enhancing PMS functionality. Known issues are prioritised based on their impact, with highest priority given to those affecting the largest volume of products.
Could you please clarify which data will be published via the public API? Is the intended dataset closer to level 2b or to level 1 as described in impl. guide ch 5? If closer to 2b, what is the rationale for publishing much more than today?	*Question answered verbally during the demo.* The information is explained in Annex A of Chapter 5. There you have the fields that will be made public with the public API. This data access was agreed among the SMEs and the EMA.
Some of my tickets were "handed over to the development team". Constantly re-testing or guessing which FAQ item refers to my issue is rather cumbersome. Could we make these issues/tasks traceable?	*Question answered verbally during the demo.*
Can you please also provide option of selecting multiple PMS IDs at once in search option at PMS PUI?	We will track this requirement in our backlog and implement it when capacity permits. Thanks a lot.
Could you please confirm which data will be made available for the PMS API UATs? I mean will the data come from previous UATs sessions ot we will have new fresh data?	No, we will use data from previous UATs as we will use the same environment. We might have some new products included along this time.
For interest to test public API, can consultancy [which is not linked to any MAH] apply for it?	Yes, it is a public API, so there is no link to any MAH needed.
From when we can expect to see the UoP - Pharmaceutical product in PMS UI? Would we be able to see the values as well?	This issue has been fixed already as explained in the FAQ document. It is also explained there that, in case you don't see them, you can submit an update to one of the EV Codes of the product and that will trigger the system to take the value. Also, with the normal lifecycle of the product, updates submitted to XEVMPD, PMS will be updated and capture the correct information.
Is CRO details required for non biological medicinal products too submitted in PMS ?	Yes, if there has been any bioequivalence study conducted for the medicinal product, the CRO should be submitted to PMS.
is CRO main study conducted CRO only required to submit in PMS right ?	Any CRO that is part of the dossier should be provided to PMS. That is to support any referral that might apply to any of the CROs involved in the development of the medicinal product.
In the Call for interest to test Public API, in the Diverse Tester Representation, Industry/MAHs are not mentioned as stakeholder group. Can you confirm this and update the pdf document if Industry/MAHs can participate in the UAT?	MAHs and NCAs can also submit their interest to participate in the UAT.

Question	Reply
It looks like MAHs are not invited to participate in the PMS public API UATs. Could you please confirm how the MAHs can test that only the public information are visible in the public API?	The MAH and NCA are not expected to use the Public PMS API, as they are intended to access the system through the registered API area. For this reason, priority is given to the four stakeholder categories listed in the call. PMS industry SMEs may participate in the UAT. Subject to availability, other industry or NCA organisations may also be included.
Once the public API will be live, does a user need credentials to access? Based on which business scope? Especially considering the current quality/non qualified data in PMS.	The Public PMS API will be publicly accessible via the endpoints. Users will not be required to register in IAM to access it. With reference to the data quality aspect the Agency is committed to gradually improved it raising the level of data quality. This is already occurring and will continue over the time.
PMS Public API: How will EMA ensure that any Confidential Commercial Information (CCI) and Personally Identifiable Information (PII) are made unavailable	With the execution of the UAT
When can industry expect the chapter 4: data quality assurance?	The target date is end of Q1 2026
Will the search parameters in public API also include partial search terms like MA number starting with BE (use of wildcards)?	In some fields it will. For example, in the search by name, it is not exact match but it is for the MA number. We will gather this feedback during the external UAT and then prioritise the improvements.

Product user interface (PUI)

Question	Reply
There are often duplicate PMS IDs created for the same pack size, this is raised with EMA SD - has EMA taken any steps to prevent such issues in the future?	*Question answered verbally during the demo.*
When can we expect the xEVMPD PMS UI sync issues will be resolved? Any timelines planned already?	*Question answered verbally during the demo.*
Can you please indicate by when this will be solved, this is an error message when trying to create a report? All ATC Code report has known issues and the Critical Medicine flag is not calculated correctly.	*Question answered verbally during the demo.*
could you please demo bulk removal in PMS PUI	*Question answered verbally during the demo.* Bulk removal to be demo'ed during the next Q&A session on Thursday 18 December.
How a pending authorisation at national phase could be added in XEVMPD (then pushed into API then PUI) if no SMPC is available yet ?	*Question answered verbally during the demo.*

Question	Reply
How a pending authorisation at national phase could be added in XEVMPD (then pushed into API then PUI) if no SMPC is available yet ?	*Question answered verbally during the demo.*
How often is the Shortages data updated for pulling the reports?	*Question answered verbally during the demo.*
If the known issues does not explain why there are multiple PMS ids for one MP in PMS UI, should we then reach out to service desk or not? Is there no idea to review the data until the EMA fix has been applied?	*Question answered verbally during the demo.*
Is updating BCRO data in PMS required only for generic products, or does it apply to originator products as well?	*Question answered verbally during the demo.*
What will be the license code for Valid pending national phase?	*Question answered verbally during the demo.*
Will it be possible to do bulk update for pack sizes and not only MBOs?	*Question answered verbally during the demo.*
We are experiencing issues completing web-based eAF forms due to incorrect PMS product migration, where products with identical details are merged under one PMS ID despite belonging to diff. procedures and procedure types.	This is a known issue but it has not been prioritised for Q1 as we need feedback from different countries. Nevertheless there is a workaround explained in the FAQ document of PMS where you can include a space in the name in XEVMPD and the product will be split in PMS.
As per the solution provided for question 2.16 in the FAQ document, adding a space in the XEVMPD name is not a sustainable fix, as the name reverts to its original format once the AMP record is validated by the EMA.	Please, take into account that EMA is not validating all the updates submitted by MAHs as explained in the validation process of XEVMPD. Additionally, the validation team is aware that some names might have additional spaces to support this work around. We will be working with the NCAs to understand their requirements per country and include these requirements in the business rules of PMS. In the meantime, you could still use the PDF eAF if your product is not updated correctly. We are working to have all the business rules implemented but this takes time.
Apologies but I missed the reply to this part during the demo: Is there no idea to review the data until the EMA fix has been applied?	Not all products are affected by issues. In fact, most of the products are correct and data can be reviewed. Therefore, for those products not affected by a known issue, please proceed to review them.
For pack size, can batch update be done? how would the pack size data be updated for multiple products? is it based on package descriptions when there are many packages	Yes, you can perform a bulk update for pack sizes. Please refer to the PUI navigation guide.
We see that the Pack PMS ID is unique ID assigned to a Package. If so it should have 1 ID each package. We see for countries with Multiple Language each Language is associated with individual Code which is not correct.	This is explained in chapter 7 and 9 of the EU IG. Each EV Code is considered a packaged medicinal product in PMS. For multilingual countries, the recommendation is to provide the same package description for the packages that will have to be merged. This merge will take place in the future when other blocking bugs are resolved.

Question	Reply
Is updating BCRO data in PMS required only for generic products, or does it apply to originator products as well?	If there has been any bioequivalence study conducted for the medicinal product, the CRO should be submitted to PMS.

Electronic product information (ePI)

Question	Reply
By when will the PLM ePI platform be mandatory for the MAH? The EU General Pharmaceutical Legislation is getting closer to adoption, so some countries might transpose the directive into national law by late 2026.	*Question answered verbally during the demo.*
Will QRD template changes be included/summarized in the FHIR IG? (In addition to the latest profile versions.)	*Question answered verbally during the demo.*
Can we upload our version of ePI? Instead of creating only in Ema portal?	Yes, companies will have 2 options for creating ePI to submit to the regulator: 1. using the editor at the PLM portal 2. creating FHIR ePI themselves and importing into the portal.

Regulatory Procedure Management (RPM) for Product Lifecycle management on IRIS

Question	Reply
Is there a plan to develop functionality for applicants to download a full case communication incl attachments, for MAH archiving and records retention?	*Question answered verbally during the demo.*
For iMAA: What is the first communication that must be sent via IRIS? Is this with the LoI?	*Question answered verbally during the demo.*
For iMAA: When must the pre-submission meeting folder be created ? Please share detailed timelines with process and key info.	*Question answered verbally during the demo.*
For iMAA: What is the transition point from EudraLINK to IRIS?	*Question answered verbally during the demo.*
If the Applicant has had pre-submission interactions before IRIS go live in 2026, will the submission of the iMAA be in scope for IRIS? Or is the go live from pre-submission interactions stage?	*Question answered verbally during the demo.*

Question	Reply
When asked in service now its said that Not marketed is used when the its permanently or temporarily ceased back from market. But there is also a status as temporarily unavailable. may we know when this will be used. Not clear on this	
Will there be the possibility in the future to add more IRIS contact persons that can receive communications on procedures?..this is in case the original contact person is unable to enter into IRIS	

Data Analytics Platform (DAP) – Business Intelligence reports for National Competent Authorities

Question	Reply
[No questions received]	

Research & Development Value Stream

Clinical Trials Information System (CTIS) modernisation – new CTIS safety module

Question	**Reply**
There are situations when ASRs are issued after the end of trial but they cover a period when the trial was ongoing - I understand that status of SG is "inactive, pending" or "inactive" at this time. Are these ASRs still assessed by MSCs?	For the submission and assessment of ASRs after the CTs have been concluded - this is not something that is directly addressed in the IT system (Safety Module) as was demonstrated today. This is a question that should be addressed in another forum, as it concerns the Member State Safety Assessor community and their practises.

Monitoring Value Stream

Antimicrobial Sales and Use (ASU) platform

Question	Reply
[No questions received]	