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Q&A – Quarterly System Demo Q3 2026

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

Link: <https://www.ema.europa.eu/en/events/quarterly-system-demo-q3-2026>

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 were either responded to verbally or did not receive a response during the System Demo event. Questions asked in the "General feedback" 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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Research & Development Value Stream

Clinical Trials Information System (CTIS) modernisation

Question	Reply
Does CTIS interact with PMS and if yes, how?	<i>Question answered verbally during the demo.</i>
Would it be possible to receive in one of the next sessions an overview about the plans/roadmap to link CTIS to PMS (also considering XEVMPD decommissioning)	<i>Question answered verbally during the demo.</i>
Does EMA plans to release guidance on the drop-down list for the field 'During the reporting period ASR includes' in the Step 3?	<i>Question answered verbally during the demo.</i>
Regarding my question on guidance: i have already raised a service desk ticket as the guidance does not provide clarity on the values. The ticket is unanswered still.	<i>Question answered verbally during the demo.</i>
What will be the exact sponsor-facing channel by which saMS will communicate RFI or final assessment after the transition period ends (for ASR submitted before 28Sep2026)?	<i>Question answered verbally during the demo.</i>
Previously the role for ASR submitter and ASR notification was needed. Is this still necessary or is the ASR submitter role sufficient to both submit ASRs and see all notifications?	<i>Question answered verbally during the demo.</i>
How will authority safety admin role be assigned?	<i>Question answered verbally during the demo.</i>
Will ethics committees that have been assigned to a certain trial during the application process automatically have viewer permissions for ASRs linked to that trial or do they need additional roles? Would be "ASR assessor - specific trial"?	<i>Question answered verbally during the demo.</i>
Can the presenter explain the difference in the functionality of roles on the safety tab? Remain the role functions the same?	<i>Question answered verbally during the demo.</i>
Will authorize ASR assessor roles previously assigned in CTIS be active in the New safety module?	<i>Question answered verbally during the demo.</i>

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 Service (PMS) and product user interface (PUI)

Question	Reply
When will a MAH be required to create a pending product via PUI?	<i>Question answered verbally during the demo.</i>
what is foreseen to submit as document for the type I variation (a pilot is planned)?	<i>Question answered verbally during the demo.</i>
The cloning functionality is currently effective only for manufacturers & not for pack sizes. Could you please share timeline for the planned enhancements to address this limitation as for some pdts we have 30 packagings to update pack size	<i>Question answered verbally during the demo.</i>
Concerning your demo about CAP pending products: Could you please give some context by when this will be needed or which purpose this will serve once it will be required?	Timelines of release are not available. The scope is to support the TOM and XEVMPD /SIAMED decommissioning.
when will the demonstrated functionality be released and when will we get the full edit access for already existing records? Please kindly suggest.	<i>Question answered verbally during the demo.</i>
In the med prod record in PUI, when editing a product, there are new fields that are visible (PV/QPPV data, status of supply, and GMO). Kindly share your input on it.	<i>Question answered verbally during the demo.</i>
What is the meaning of the new button "associate", in the Packaged med prod section for the Medical Device subsection in the Change for data submission?	<i>Question answered verbally during the demo.</i>
CAP query is not in ticket! is happening for several MAHs!	We do apologise but we do not clearly understand this comment. You may prefer to open a question ticket in service now and provide a bit of context.
The newly created EMDN will be used for "medical device type" IDMP field alignment? The list has a hierarchy with different levels of data; kindly share some input for alignment.	<i>Question answered verbally during the demo.</i>

Question	Reply
CAP with combined ph prod are now are merged into one single PMS ID. Initially were split in 2 PMS ID, now the combined record is visible in PMS. why and what action is expected from MAH?	<i>Question answered verbally during the demo.</i>
So, after getting an approval for a product would it be responsibility of MAH to create product in PMS or EMA will perform that and then management would be the responsibility of MAH?	Process is still to be defined. This demo is only to display pages.
Will the creation of pending products also be available on the API?	<i>Question answered verbally during the demo.</i>
So, does this mean that in the future, the MAH will have to populate it directly, rather than it being populated by Siamed?	MAH cannot populate products data in SIAMED. Yes you will be able to use PUI and API.
When will the new pending product creation functionality in the PMS go live ?	The date is not available.
Is there an option to clone Manufacturer authorisation reference No, date and medicines regulatory location. We have to manually enter the same information multiple times instead of clone, duplicate data.	<i>Question answered verbally during the demo.</i>
What is the use case to create a product manually in PLM?	To support TOM.
Why are multilingual PMS records in BE, LU and FI not merging after identical English package descriptions were entered in XEVMPD as advised in the guidance? Only one record shows English in PMS; others remain in national languages.	Kindly open a ticket as we need to investigate.
Why can a product record in XEVMPD remain missing from PMS after a dummy update, and what action is needed for integration? With delayed ticket responses, what escalation or workaround can prevent submission delays?	We need to investigate on the issue. So we need a ticket. You can follow up in the ticket itself.
When the API write access (for whole chapter-2 as presented for CAP) will be enabled to MAH in PMS UAT?	The date is not available.
Will you provide documentation and enable the PMS Validation option in PMS UAT API to MAHs?	If you are referring to the business rules, these are in Ch 2. These are the ones used to validate data in PMS.

Question	Reply
Why are UK/UK-NI products flagged 'Candidates for Enrichment=Yes' in All ATCCodesreport if OOS per Ch.3 & PMS FAQ? If it flags critical products, can field name avoid 'enrichment' wording? RITM██████████ Asked in last Q and A;Veronica,checking	The report is set up based on the list of ATC Code. It does not filter per country. This is why you see your product resulting i the list of yes. However please consider the Ch 3 indication. We will check if it is possible to implement a UK/UK/Ni country filter.
Any impact expected on other systems or process, if MAH is unable to enrich the non-CAPs by end of 2026?	You may pose this question to ESMP team.
Is there a training available to update or enrich data in PMS PUI? The trainings videos on youtube are gone.	Please use this guide https://plm-portal.ema.europa.eu/guidance-and-help/article/?artid=KA-01048 and watch any recording available on PMS events hosted (links and recoding are retrievable by searching in EMA/Event page)
Please allocate more time for the PMS section next time.	Thank you for your interest.
Current concept of full portfolio visibility to all users creates problems when working with 3rd parties. When will the PMS/PLM be enhanced with functionality to limit the visibility of products to groups (as in XEVMPD virtual affiliates)?	This function is not foreseen. As per chapter 5 3rd parties can request the regular PUI industry user role so they cannot see confidential data as agreed with the network.
SMS is now changing the preferred name. Our RIMS have the previous name. What will be the approach in pui in the future? Which terms will be used so that we can standardise in rims	PMS reads from SMS API directly.
Currently, it is not possible to perform enrichment in PLM. Is this a general problem right now?	The function is working. Please open a ticket so the team can investigate on your PUI access.
Will the new NAP requirement include the procedure number as well? Some products share the same reg. number but have different procedure number, so the reg. number alone may not uniquely identify the product.	No, if there are other requirements like this one needs to be raised and discussed so please share it with the PMS SMEs of NPO or submit a ticket to provide us more examples and context.
For Pending products is needed the submission of the submitted SmPC?	MAHs is only required to structure the proposed product data. The provision of the SMPC as attachment will need to be discussed with technical team and eAF team.
Will there be alignment in EV codes listed at Medicinal Product level and list under Package Medicinal Product level?	If you see misalignment please open a ticket for us to investigate and fix it.
We continue to observe MP records (PMS IDs) for BE and LU becoming unavailable in PMS PUI. Despite follow-ups under RITM██████████, the issue remains unresolved and impacts PLM eAF submissions. Could you confirm the root cause and timeline?	Please follow up in the ticket to receive the most appropriate answer.

Question	Reply
We have changed presentation strength to concentration strength in XEVMPD to have all presentation of the product under one PMS ID in July, but the PMS records were not updated. Ticket opened a month ago still not answered. How to proceed?	Please follow up in the ticket to receive the most appropriate answer.
CAP with combined ph prod are now are merged into one single PMS ID. Initially were split in 2 PMS ID, now the combined record is visible in PMS. the issue is not in ticket and is affecting other MAHs	Kindly raise a ticket with a bit more context and please share the pms id. Thanks
There are cases of duplicate PMS IDs where packaging records have been incorrectly migrated across different strengths. How and when will EMA remediate these data inconsistencies?	Please follow up in the ticket to receive the most appropriate answer.
We have a manuf thats correct in oms in terms of loc id but in pms its still the old name. We were told its a synchro issue. Should we wait for pms team to correct it or enrich it with old name? Will it be corrected automatically in pms ?	Please refer to question 3.13 of the FAQ document.
Will NCAs be able to see pending products?	In principle yes, but it is to be further discussed if there is any value.
How should CIS and CIP authorisation numbers be entered in XEVMPD so both display correctly in PMS, given its single field and France-specific guidance? Also, how can products link to the active MAH OMS organisation after an address change?	If you are questioning about the national MA number, the national MA n can be specified in the pack description of each PRD record. Unfortunately the second question is not clear. Please submit a question via service now with additional context.
Does it means it's required to create a product manually only for the new MA granted instead of submit via EVMPD?	In future yes, when XEVMPD will be decommissioned.
You mentioned that "Cleansing of duplicated packages for NAPs" is completed - when will this exercise be completed for MRP/DCPs?	yes these are included as Non CAPs.
Thank you for the demo. Is this functionality to support planned SIAMED decommissioning next year? Next questions is what about existing line extension for CAP? Can it be created in PMS UI but it might not need another PMS ID	Thank you for your interest. No, this functionality will support TOM in the context also of XEVMPD decommissioning. Yes also Line extensions can be created using this functionality however the full process will be tackled at later stage.
Is the PUI going to substitute the registration of DMP / AMP in xEVMPD?	Yes, the plan is to decommission XEVMPD and use PMS.

Question	Reply
Why is a withdrawn Luxembourg product appearing under a valid product with a different MA number, preventing the MA number from displaying at medicinal product level as expected? How can this be corrected?	Kindly open a ticket as we need more context.
When does the demonstrated PMS UI UAT tool become productive. Is there any planned timeline?	There is no plan for the moment.
we have non cap non ulcm products, how do we use pui write MPV bulk update to enrich manufacturers ? are there any demo ?	Please use this guide https://plm-portal.ema.europa.eu/guidance-and-help/article/?artid=KA-01048 and watch any recording available on You Tube EMA channel or directly on PMS events hosted (links and recoding are retrievable by searching in EMA/Event page)
Could you please share an up-to-date roadmap with the future data required for MAH. We need to have visibility on the workload in the next months/years.	Thank you for you comment. We always aim to share the most updated information with external stakeholder. For the moment this is the most updated one: https://www.ema.europa.eu/en/documents/other/product-management-service-pms-roadmap_en.pdf
For CAPs kindly confirm whether Service Tickets remain the standard process for update or enrichments on existing CAP product? Furthermore, is there a roadmap for when full field-level editing capabilities will be enabled for users?	CAPs products are not subject to enrichment process. There is no roadmap for when full field-level editing capabilities will be enabled for users. However this will be communicated in due time.
Will the data entered be validated against the data received from Siamed?	Data entered in PUI are validated across the business rules implemented.
Quantity Operator 'Quantity Sufficient' substances, how to update Concentration or presentation strengths? In Chapter 8 Page 48 Quantity Operator of excipient 'Water for Injection' in 'to volume'. In RMS, 'to volume' value is not there?	In RMS there is a term 100000165006 quantity sufficient to use. Please also note that Ch8 is under revision hence examples will be added and existing ones updated.
Now since eAF is mandatory, please clarify what data will be sync through eAF & what is still subjected to enrichment in future for CAPs	This is a question to pose to eAF team. Thank you
We have some e-mail tickets opened about PUI correction with Mor Ethan 1 month for an answer - normal ?	Please follow up on Service Now
Why do the whole indication text required in PMS?	As per Ch 2 business rules.
We raised CR C-049365 for enrichment but are facing a PMS Synchronization Issue (Version Mismatch Preventing Validation). Despite INC [REDACTED], no resolution has been provided. Could you confirm the root cause and expected timeline?	Please follow up in the ticket itself to receive the answer.

Question	Reply
For certain CP products, duplicate records were created in PMS PUI, while the XEVMPD submissions are correct per migration rules. What is the recommended approach to resolve these CP PMS duplicates? (RITM██████)	Please follow up in the ticket itself to receive the answer.
The submission of pending products is already mandatory? And if yes, for all procedure (CP,DCP,MRP,NP)?	no, MAH cannot submit pendign product. The scope of the demo was to show the pages we have been working on and how we implemented the business rules to prepare the systems for future use.

Electronic Common Technical Document version 4 (eCTD v4.0)

Question	Reply
When can we expect mandatory use for the eCTD4 for CAPS? Also any insights into the expectations for NAPS?	<i>Question answered verbally during the demo.</i>
Does the eCTD 4.0 require a new validator? Asking due to the forward compatibilty or does the existing validator work in this case?	
Will document reuse be possible for NAPSs?	<i>Question answered verbally during the demo.</i>
Are there plans for eCTD 4.0 to align with the evolving ICH M4Q(R2) document structure and the structured submission standards being developed under ICH M16?	
EU member states have local archival regulations that demand we have the files locally, is this taken into consideration when building the system supporting this?	<i>Question answered verbally during the demo.</i>
Can we already apply for participation in the NAPs Pilot?	<i>Question answered verbally during the demo.</i>
When will the implementation of minor variations using eCTD 4.0 through PMS be introduced as pilot was done as defined in last Demo, and what is the expected implementation timeline?	<i>Question answered verbally during the demo.</i>
As forward compatibility is on hold and will resume in mid November; is there any requirement to re-generate delievery file.	<i>Question answered verbally during the demo.</i>
We have still pending issues with FC Pilot Phase 2 with follow-up sequence to be submitted. Will it be accepted and processed by the EMA, or do we need to wait for Q4?	

Question	Reply
Are there plans to revise eCTD4 in light of the change of document structure in ICH M4Q	
Will a baselining be necessary? Or can the existing eCTD can mainly be used?	<i>Question answered verbally during the demo.</i>

Electronic product information (ePI)

Question	Reply
When will become ePI mandatory?	<i>Question answered verbally during the demo.</i> ePI will become mandatory for new applications on the entry into application of the new pharmaceutical legislation.
Should the SmPC and PIL be provided as word documents in the working documents folder in the sequence in addition when e-PI is referred in the sub file?	<i>Question answered verbally during the demo.</i> Yes. The requirements for providing Word and PDF documents will stay the same.
How it is ensured that ePI content remains consistent, traceable and up to date across EMA, NCAs, MAHs and national systems when the same product is authorised in multiple Member States and changes are approved at different times?	If a change to an ePI is authorised at different times, the ePI will be published by the regulatory agency at the time of authorisation.
How and when will the ePI be made available to external requesters like Apps or other tools so they can be shown on Smartphone screens on demand or imported into decision support systems.	<i>Question answered verbally during the demo.</i> ePI data will be available to external requesters from go live via an API.
Will the info regarding ePI also be available in the cesp xml file when this will be introduced for NAPS as well?	<i>Question answered verbally during the demo.</i> The feasibility of applicants entering the ePI details in the CESP delivery file is currently being assessed, there is currently no timeline for when this functionality will be available.
How confident are you the voluntary phase will start on time? any planned modification after the UAT?	In case of changes to published timelines, these would be communicated through the usual channels.
Is the UAT to test the platform for importers and exporters too? As on the EMA website it only mentions pharmaceutical companies	<i>Question answered verbally during the demo.</i> Importers/exporters are not included in the upcoming UAT.
Is UAT for Industries for CAPs or is it also for NAP?	<i>Question answered verbally during the demo.</i> The UAT is for all industry participants, independent of the authorisation type.

Question	Reply
If you join the UAT, do you have to use the ePI for the published products after the testing period even though this option is not yet officially available for NAP?	<i>Question answered verbally during the demo.</i> No. The external UAT we are running is for testing purposes only. Any ePI created will be in the test environment and will not be used in future.
Could you please advise how we can get UAT access for ePI?	<i>Question answered verbally during the demo.</i> The call for participants in the upcoming external UAT is published on the EMA and PLM websites.
What about parallel importers and epi?	EMA's current ePI roadmap does not specifically cover parallel traded medicines in its current scope. Extending the scope will require additional development, planning and resourcing to further address the specifics of the parallel trade, to be scheduled once ePI is implemented in general for non-parallel traded medicines, both CAPs and NAPs.
what is the road map for labelling types. Meaning currently expectations are for SmPC or PIL and will the IFU (instructions for use) for healthcare professionals be planned for?	Currently only the Human PI QRD template is planned in the roadmap.
Can you create Word files from ePI?	Yes. At the PLM portal, ePI can be exported as Word or FHIR format.
Will the sub file for CAPS be available for download of sequences from CR(Eurs next)?	
When can we expect the new EU legislation come into force for ePI?	Details on the new pharmaceutical legislation are provided on the EMA website: https://www.ema.europa.eu/en/about-us/what-we-do/reform-eu-pharmaceutical-legislation
What are requirements for UAT? Is FHIR readiness mandatory?	Technical experience in working with structured data and FHIR XML is optional for participation.
In the past it was said that if an ePI is created for a product, the process stays with the electronic product information and has to be updated and used from then on. Does this also apply to ePIs created for the UAT?	No. The external UAT we are running is for testing purposes only. Any ePI created will be in the test environment and will not be used in future.
in the FHIR UAT which system was used from the companies to create FHIR xml, which then were uploaded in PLM?	This is a question for the companies.

Union Product Database (UPD)

Question	Reply
[No questions received]	

Monitoring Value Stream

EudraGMDP

Question	Reply
When will be implemented an integration between EudraGMP and PMS for the population of manufacturers' certificate?	<i>Question answered verbally during the demo.</i>
After EudraGMDP is decommissioned, how will existing authorisations, GMP/GDP certificates, historical records be migrated and accessed in the modernised system and what actions you propose to MAH should plan before/ during the transition?	<i>Question answered verbally during the demo.</i>
Will foreign authorities, outside of the EU, be informed on the changes? Numerous authorities check or receive EUDRA GMP (Certificates).	<i>Question answered verbally during the demo.</i>
Will foreign certificates be available as well?	<i>Question answered verbally during the demo.</i>
Will QP declaration for manufacturing of Active Substances have to be prepared through this new platform ?	<i>Question answered verbally during the demo.</i>