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Q&A – Quarterly System Demo Q2 2026

Date: 25 June 2026

Location: Online, 09:30 - 12:40 Amsterdam time (CEST)

Link: https://www.ema.europa.eu/en/events/quarterly-system-demo-q2-2026

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 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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Table of Contents

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

Union Product Database (UPD)

Question	**Reply**
Will the summary cards be available for export?	The summary card cannot be exported, but the product search result within the UPD UI can be exported for the whole search result.
Why was the information on the error report reduced? And is it now available again?	This 'system redaction' is necessary to prevent MAH users that do not have roles for all the organisations included in the submission file, from seeing confidential data from organisations to which they may not have access permissions granted. The access to the error CSV report files will be enabled on the afternoon of 26 June 2026.

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

Question	**Reply**
Will we receive now also the EC decisions via IRIS? Meaning will the Commission now use IRIS as well instead of Eudralink/emails?	*Question answered verbally during the demo.*
If would be great if you can make the presentation available for your recent webinar "Updates to industry contact management for authorisation products (IRIS)" from 11 June. It is still not posted on the event website. Thanks.	*Question answered verbally during the demo.*
Is there any chance for CDP as it is shown on the road map? When will it be explained or introduced?	*Question answered verbally during the demo.*
Would it please be possible to provide in IRIS a "Download" button for downloading the complete submitted information, eg for archiving etc?	*Question answered verbally during the demo.*
The question about deputy for MAH contact was about cross-product contact who receives the EC decision. Can there be a deputy?	*Question answered verbally during the demo.*
Now that we have the same number for both pre-and post-authorisation, how will the difference be made between products in the pre-submission/with their initial application just submitted and in the post-authorisation?	*Question answered verbally during the demo.*

Question	Reply
For submission of withdrawal, Why does it say I confirm submission on behalf of sponsor instead of on behalf of applicant. It can get confusing if entities are different	*Question answered verbally during the demo.*
It would be great if it is technically possible to nominate a deputy for the role "Person/Company authorised for Communication between MAH and Authorities after Authorisation" ie 2 contact persons	*Question answered verbally during the demo.*
There is a new button "New Product Conversation" on product level. Can you please explain the purpose of this new button?	*Question answered verbally during the demo.*
Looking at the slide on change mgmt activities, does that mean that to submit Eligibility request and LoI, the Applicant will first need an RPI? There will be limited time between the IRIS guide release and the go-live of pre-sub activities	The following communication was sent to Industry contacts: In preparation for the go-live for pre-submission activities in IRIS, we would like to inform you that a valid Research Product Identifier (RPI) will be required in order to proceed with newly created submissions for the following procedures: Eligibility, Letter of Intent, Pre-submission Interaction, Notification of Change, and Accelerated Assessment. If no appropriate RPI currently exists for a single medicinal product, a new RPI must be requested via IRIS, following the procedure available here: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration-rpis_en.pdf
Will the pre-submission activities/requests stay the same content-wise in IRIS as they are in the Service Desk currently?	While the content remains largely the same, the overall design and infrastructure of the IRIS portal provide a different user experience than the current process. It is recommended to get familiarised with the system ahead of the submission deadlines.

Electronic product information (ePI)

Question	Reply
When linking the product from PMS, the linking is to be done at product/strength level?	*Question answered verbally during the demo.*
For the next UAT, can you share more info on exact timeline and duration?	*Question answered verbally during the demo.*
Will you in this process upload a pdf of your smpc?	*Question answered verbally during the demo.*
The linking is mandatory only for centralized procedures? Or also for DCP or MRP?	Linking an ePI to the authorisation medicinal product is only mandatory for centralized procedures. For non-CAP products the individual ePI documents can be linked to the product in PMS, but this is optional.

Question	Reply
How will it be possible to attach these documents to eCtd	After creation of ePI, the applicant can export to Word from the PLM portal. The exported Word automatically includes the correct QRD convention styling. The exported Word can be submitted in the Working documents folder and used as the basis to create PDF. In the future, export to PDF will also be enabled.
How are changes after publication handled? How are the procedures that come after the initial application that changes information within the document handled?	In a post-authorisation procedure affecting the PI, the applicant creates a new ePI at the PLM portal and selects the option 'Update existing ePI'. The ePI to update can then be selected. This action loads the existing ePI into the portal and updates can be added in the editor or by importing.
Will the ePI also include PIL? Is it expected to upload the "formated" pdf (User Readability tested) or will only the word version be provided? Are the "layout" criteria going to be removed from the requirement of PIL User Testing?	The ePI does include the package leaflet. PDFs/Word files are not uploaded. An ePI is created by the applicant, either using the editor in the PLM portal or by uploading FHIR XML files created elsewhere. ePI contains minimum styling and layout information. Styling/formatting are added afterwards for display of ePI.
It is currently a requirement for CP texts that users insert non-breaking spaces in Word in places like "6 ml" to ensure that "6" and "ml" always remain together. Will this change in the future with an smart feature in the PLM portal?	There is no plan for a smart feature to add non-breaking spaces.

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

Question	Reply
How do you see continuing eCTD life cycle in the 4.0 version ?	*Question answered verbally during the demo.*
Are there sandbox/test environments available for organisations to validate eCTD 4.0 submissions?	*Question answered verbally during the demo.* Test submissions are warmly welcomed. Please contact EMA through: eCTD4consultation@ema.europa.eu or by raising a ticket with a request for eCTD v4.0 test submission and we will contact you to make the necessary arrangements. To speed up the process please indicate in your request your eSubmission Gateway routing ID and the email address of the person whose account this new test root folder should be added to. It is possible also to use the B2B Gateway for the testing, in this case please provide the relevant certificates.
How to let you know if we want to participate in the tests	*Question answered verbally during the demo.*
Could you organise a demo with the user interface? How will it be organised for dossier issuers compared to 3.2.2?	*Question answered verbally during the demo.*
Do you foresee need for baseline submissions for transitioning from 3.2.2 to 4.0 based on the forward compatibility testing so far?	*Question answered verbally during the demo.*

Question	Reply
Will this information also be published in the news section of the eSubmission webpage?	*Question answered verbally during the demo.*
will it be possible to use "all manufacturers" as a keyword rather than having to list all applicable site names in the manufacturer keyword? This keyword will be vary liong if 5-6 sites are listed.	Keywords are optional. If one document applies to multiple contexts of use (e.g., multiple manufacturers), maintain a one-to-one relationship between the context of use and the keyword. Do not use generic keywords such as "all". When needed, list the specific names directly in a single keyword field by concatenating them (e.g. for manufacturers: Uranus Ltd + Jupiter GmbH + Neptune Oy). More details can be found in EU eCTD v4.0 - Practical Guidance (Chapter 2.1.1) https://esubmission.ema.europa.eu/eCTD%20NMV/docs/EU%20eCTD%20v4.0%20Practical%20Guidance%20v1.pdf

Electronic application form (eAF)

Question	Reply
We recently faced a tech validation error with the MEB in a DCP procedure because the additional AFs with scanned signature included in country-specific folders was invalid. Could you please improve the NCAs education about PLM usage?	*Question answered verbally during the demo.*
There is an IRIS sync issue with the organization with respect to the web eAF. Should that be considered as a reason not to use the web eAF, there is any risk of rejection?	*Question answered verbally during the demo.*
We experience problemen wit incorrect Linking of Products in the eAF, support is dlow	*Question answered verbally during the demo.*
Why is the transition period of the non-cp products only 3 months not 6?	*Question answered verbally during the demo.*

Product Management Service (PMS)

Question	Reply
Manufacturing details are in Submitted status and visible in PMS IDs, but they are not appearing in Dynamic Export after 48+ hours. Is this an expected delay or a known synchronization issue?	*Question answered verbally during the demo.*
We have ULCM products awaiting MAT transfer to our company. How will this affect MOB enrichment if approval is close to or after the June deadline?	*Question answered verbally during the demo.*

Question	Reply
Is there any option to remove/delete the extra records which are Cancelled in my workspace during enrichment? Also, please confirm if there are any plans to introduce such functionality in the future?	*Question answered verbally during the demo.*
Are there plans to expand the search capability in the public API to include other data fields, as for example, legal status (Rx/OTC)? It would be useful for integration with our public database	*Question answered verbally during the demo.*
sorry why suddenly (after all the work we have done) MBO's are not mandatory anymore??	*Question answered verbally during the demo.*
Is there any plan for submission on MIA data on manufacturer level not product, per current process we have to manually enter 600 time the same MIA data? Any optimisation or connection with Eudra?	*Question answered verbally during the demo.*
It's very difficult to update a lot of pack sizes details using bulk action (little window too small for about 60 pack sizes, only 10 results by PMS ID appear, long time to load, etc...). Is an improvement planned to be more user-friendly?	*Question answered verbally during the demo.*
Any update in increasing the number of products to be selected for bulk enrichment for more than 50 limit?	We have increase it to 100. Investigating how we can do it for more.
I requested access to the public API. The request has been rejected, the helpdesk sent me the guideline how to request access to the restricted (!) API, and I am still waiting. Frustrating.	Replied in writing.
We have several splitted products after the pack split submission. We have opened tickets. When this issue will be solved? Thank you.	As explained, we are working on this and should be fixed in the next couple of weeks.
What would be the ideal source of truth to be considered for Ingredients - SmPC or module dossier? Any detailed guidance is planned to provide more clarification to the Industry?	Right now, as explained in Chapter 3.II of XEVMPD, both can be considered as source of information. It is up to the MAH to decide. It is important that is is consistent.
What are the process to submit an Account PMS API if we already have the 1st Super user, however she is not able to Approve our account requests.	Please, contact the IAM team explaining your situation. They will provide the necessary feedback.
In Packaged Medicinal product in PMS, how should we capture combination packaging materials (e.g., OPA/Al/PVC) when they are not available in SPOR	We are not able to reply to this question for the moment. We will discuss with the subject matter experts (SMEs) whenever materials are to be submitted to PMS.

Question	Reply
Why does excipient information differ between Medicinal Product and Packaged Medicinal Product in PMS, when data is sourced from SiAMED (EMA) and pushed into PMS?	The difference might be between the manufactured item and the pharmaceutical product. For the first one the data is coming from SIAMED, for the second, from XEVMPD.
Package type: "In PMS, does 'Package Type' cover only primary packaging or also secondary/tertiary? If all, how are multiple package types captured?	It refers to all packages. Please, see the examples in Chapter 2.
Will it be mandatory to upload the Manufacturing autorisations (Annex5.6), GMP certificates (Annex 5.9.), Flow charts (Annex 5.8.) Or QP declarations (Annex 5.22) ? IF yes when? We've already seen these fields available in the MBOs section.	No for the moment.
When viewing API data from postman, can we get the data field names instead of values? example authorised dosage form where we can see oral or other instead of RMS identifier?	We are working on this as a nice to have feature in the future.
Where can I find the link of the PLM API. I already have the credentials. I need the hppt link. Thank you	Please, review the technical documentation in Chapter 6 of the EU IG.
Can you suggest any use case where MAH could look into PMS public data?	If you need to access data for other products approved in other countries for example for analysis of the market. There are some use cases for MAHs in this case.
If a manufacturer changes name or loc ID will it be reflected in PMS or we have to submit it again?	MAHs will have to update PMS.
Information about manufacturers is confidential. Will it be handle accordingly?	Yes, only MAHs and NCAs can see this information. In the public API this information is not provided and in the restricted area, only MAHs have access to their data.
Which manufacturers have to be filled in? Cutting Sites or Labs for herbals are Not relevant for supply problems. Do we have to provide them when mentioned in the Dossiers?	Please, check Chapter 3. There you have the activities that should be provided to PMS.
How can address Problems due to repeated Migration of wrong data e.g. Housenumbers can be solved?	Open a ticket in ServiceNow.
In some countries, like Spain, the authorization number has a point in the middle (for example 43.245). What is the correct way to update that information in PMS? With the point or without the point?	As stated in the SmPC.

Product user interface (PUI)

Question	Reply
sorry why suddenly (after all the work we have done) MBO's are not mandatory anymore??	*Question answered verbally during the demo*
Is there any plan to enhance the bulk upload/cloning functionality, as it currently appears more suitable for MBO and manufacturer enrichment rather than for pack size updates, particularly in cases involving multiple package sets?	*Question answered verbally during the demo*
It's very difficult to update a lot of pack sizes details using bulk action (little window too small for about 60 pack sizes, only 10 results by PMS ID appear, long time to load, etc...). Is an improvement planned to be more user-friendly?	*Question answered verbally during the demo*
Will chapter 2 be updated to reflect the change of conformance for certificate's number from "Conditional" to "Optional"?	*Question answered verbally during the demo*
Did I misunderstand the 'Quantity Operator' is now required for Structured Pack Size? According to the current version of Chapter 3 "For the moment, the quantity operator is not required.". Request for EMA to kindly clarify.	*Question answered verbally during the demo*
A product with 1 MA no for all pack sizes was updated via xEVMPD Gateway to insert all pack sizes with individual EV Codes. But in PUI the products appears now under 2 different PMS ID. They should be combined in one. Why?	*Question answered verbally during the demo*
If MIA details will continue to be optional for the enrichment due in december 2026 for the entire portfolio? or just for UCLM?	*Question answered verbally during the demo*
What trigger a different PMS ID for same MA Number?	Please, check Ch 9 of the EU IG. For each country, there are different rules on how EV codes are migrated to specific products.
In Packaged Medicinal product in PMS, how should we capture combination packaging materials (e.g., OPA/Al/PVC) when they are not available in SPOR	We have not discussed yet how materials should be captured so we can't reply to this question. Whenever this information is to be submitted to PMS we will discuss with all stakeholders and check if we need to provide more info in RMS or not.
It's very difficult to update a lot of pack sizes/MBO details using bulk action; only 10 results by PMS ID appear, and it takes a long time to load with the issue due to the pending version increment. Will the function be improved?	*Question answered verbally during the demo.*

Question	Reply
Will the "non-mandatory" status for the additional manufacturers information just be a temporary technical solution to enable incomplete submissions, or will the guidance be adapted accordingly?	*Question answered verbally during the demo*
Is there a way to edit the same PMS ID that CR submitted and finalized already?	*Question answered verbally during the demo*
Temporarily optional means the products in ULCM are supposed to be enter with data (true or recommended by ema dummy data) and after 30th june it will become completely optional for to enter MIA/GMP DETAILS?	*Question answered verbally during the demo*
In chapter 3 is still written quantity operator is not required (16/06/2026 version)	*Question answered verbally during the demo*
A product is not showned in PMS, but is valid in XEVMPD. How to proceed?	*Question answered verbally during the demo*
Will you update chapter 2 to change the certificate number's conformance from conditional to optional?	*Question answered verbally during the demo*
PMS ID is no longer available in PMS PUI, however it was available from the previous Change Request submitted. How to proceed with this?	*Question answered verbally during the demo*
Please kindly clarify the meaning of the different STATUS Submitted CHANGE REQUEST (CR).	*Question answered verbally during the demo*
How to proceed if the CR Status is INTEGRATION FAILED.	*Question answered verbally during the demo*
If you correct a CAP backside in pms, will it stay corrected if you have a new approval and update in Siamed?	*Question answered verbally during the demo*

Monitoring Value Stream

EudraGMDP

Question	**Reply**
Thank you for the presentation will the test phase be opened for MRA Partners Swissmedic?	*Question answered verbally during the demo*
is there plan to link EudraGMDP to PMS in future?	*Question answered verbally during the demo*
Would EUDRAGMDP data available in PMS, so that we do not have to include in PMS MIA number etc	*Question answered verbally during the demo*
Previously, the completed document was displayed before it could be submitted. Will this option be available again?	*Question answered verbally during the demo*
Could the PDFs generated as GMP certificates from the EudraGMDP system could be eCTD compliant, please? Like PDF version not lower then 1.4 (currently it is 1.3 which is not acceptable for eCTD submissions) and Fast Web View activated?	The generated pdf in the new EudraGMDP won't be lower than 1.4

Research & Development Value Stream

Clinical Trials Information System (CTIS) modernisation

Question	Reply
when new safety module be implemented in CTIS	The new Safety Module is scheduled to go live at the end of September 2026
For which ASR types is the Multi-Trial functionality supported in the new CTIS Safety Module? and is the model Substance Group–centric or Clinical Trial–centric?	*Question answered verbally during the demo.* For Substance Group (SG)–centric ASRs, the sponsor can link multiple clinical trials to a single ASR. In contrast, Clinical Trial (CT)–centric ASRs are limited to one clinical trial per submission, and it is not possible to link multiple trials to a CT-centric ASR. The Clinical Trial–centric ASR submission route is intended for academic sponsors
can we choose substance group centric type if the ASR is multi trial ? or CT centric only we should select - advice	*Question answered verbally during the demo.* Please refer to the response above
will we get notified for ASR RFI in new safety module?	*Question answered verbally during the demo.* Both sponsors and Member States will receive notices in the Notice Centre of the new Safety Module. In addition, sponsors will also receive notifications via email.
1/3: We require an API for the management of internal procedures (e.g. allocation to the competent NCA staff, communication and consolidation with the competent ECs, internal controls to ensure compliance with the dual-control principle).	*Question answered verbally during the demo.* Noted, however, the management of internal procedures and APIs was not in the scope of the Safety MVP.
2/3: Without an API, time-consuming workarounds are necessary, meaning that the system would not meet the requirements of CTR article 80 ("technically advanced and user-friendly so as to avoid unnecessary work").	*Question answered verbally during the demo.*
3/3: Having said this, the system should not go live, especially since the current system is stable, i.e. there is no urgent need to implement the new system. Please comment.	*Question answered verbally during the demo.*
We are a German Pharma company would like to ingest the CTIS/CTR data into our company internal platforms. What is the official way to integrate the CTIS data? Is there a bulk ingestion method? Whom we can contact for this request? Thanks!	*Question answered verbally during the demo.* We understand that this will require a Sponsor API, which is currently in the pipeline. However, the delivery timeline remains uncertain due to the need to implement the new requirements in CTIS as outlined in the recently published Biotech Act.
Can the Notice Tab be exportet to an Excel?	*Question answered verbally during the demo.* No, it is not possible to export the Notice tab to Excel. However, sponsors will receive notifications via email.

Question	Reply
Why are the RFIs submitted as Word files and not as PDFs since these are not so easy to change in terms of content?	*Question answered verbally during the demo.* Currently, it is not possible to generate RFIs as PDF documents; however, this need will be assessed after go live.

Technology Lifecycle Management and Information Security Value Stream

EMA Account Management

Question	Reply
Where can i retrieve all tke role for one user	*Question answered verbally during the demo.* The "Revoke Access" functionality is available at the following url https://register.ema.europa.eu/identityiq/plugins/pluginPage.jsf?pn=emaaru It allows to list all users belonging to the managed organisations, export them and revoke their access. Documentation of the functionality is available here:https://register.ema.europa.eu/identityiq/help/useradmin.html#listusers
Could you consider an improvement in user experience: Title 'Revoke access' is confusing when this is the only section where one can check all users for an organisation. Revoking is only one functionality within this section.	We will consider changing the name to a more meaningful name.
The functionality being demoed showed no title and no path where to find this functionality on the Account Management site. I missed the first seconds of the demo and consequently can't find the place on the site. A site map could help.	The functionality is part of the "Request Access for Organizations" available at https://register.ema.europa.eu/identityiq/plugins/pluginPage.jsf?pn=emarfo
is there any change in CTIS role	*Question answered verbally during the demo.* There is no change with regards to existing high level administrators but in the context of the go-live of the upcoming new Safety Module by the end of September, the MS role "ASR Decision Maker Submitter" has to be assigned in EAM.
If submitted with multiple roles on different Application, how is it approved by bulk? or if Denied for application only, would the bulk account submitted will be all denied too? and how to proceed?	*Question answered verbally during the demo.* Each request requires an independent approval, if several requests are submitted at the same time each request is assessed individually.
Is it also planned to improve the approval step in IAM? E.g. by allowing the approval for a list of requests at once, instead of one-by-one?	*Question answered verbally during the demo.* The improvement of the approval functionality to aggregate items for the same organisation is in our backlog, this functionality is not planned to be implemented in Q3 2026 and it will be revaluated for Q4 2026.

Question	Reply
How long is the time turn around for the Account Request?	*Question answered verbally during the demo.* On average of 235 requests per month are evaluated by the service desk, the median wait of 1.6 days for approved and 7 days for rejected requests with an approval rate of 90%. Other roles are approved by the appointed User Administrator of each organisation with a median wait of 1.9 days for approved and 11 days for rejected request and an approval rate of 95%. Requests are valid for 30 days and expire afterwards.
after the fist admin role is approved, the next user should not share the Letter of afiliation. But is requested.	*Question answered verbally during the demo.* By default after the first user of an organisation is approved subsequent requests are directed to it. Few EMA platforms always require EMA approval as an exception. The default approval model is explained in here: https://register.ema.europa.eu/identityiq/help/useradmin.html#OrganisationAdmin
Currently when submitting an account request, the interface is showing In-progress and no confirmation if the request is Submitted. But the Approver already confirmed that they received it.	*Question answered verbally during the demo.* The different state of a request in EMA Account Management are explained in here: https://register.ema.europa.eu/identityiq/help/requestaccess.html#trackrequest
What is the best browser to use to submit an account?	The application is designed to work with any modern browser, the vendor of the solution suggest the following browsers on their latest version: Google Chrome, Microsoft Edge, Safari, Firefox.