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Q&A Q1 2026 System Demo

Date: 26 March 2026

Location: Online, 09:30 - 12:45 Amsterdam time (CET)

Link: https://www.ema.europa.eu/en/events/quarterly-system-demo-q1-2026

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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Monitoring Value Stream

EudraGMDP

Question	Reply
are there any actions expected by Industries?	*Question answered verbally during the demo.*
Would it be any changes in the publication of the GMP-Certificate? Download options for industry or other NCAs?	*Question answered verbally during the demo.*
Will EUDRAGMPD link with PMS?	*Question answered verbally during the demo.*
Is it possible to perform search on operations/activities?	*Question answered verbally during the demo.*
Is there the possibility to download massive data from EUDRA-GMPD? Thank you	*Question answered verbally during the demo.*
Which signatory details can be edited bei the NCAs? Name of NCA? Name of Person signing?	*Question answered verbally during the demo.*
Who is responsible to provide the data on database?	*Question answered verbally during the demo.*
When will the test/UAT environment be available for NCA?	*Question answered verbally during the demo.*
is this linked to ESMP?	*Question answered verbally during the demo.*
Will there be an API to automate customer authorization check and supplier qualification?	*Question answered verbally during the demo.*
Access for MRA-Partners? Any change to expect? Specifically for the gateway to exchange data	*Question answered verbally during the demo.*
Will it be easier for NCA to add autorised user	*Question answered verbally during the demo.*
Will It be possible to enter national legislation as legal basis for the MIA?	*Question answered verbally during the demo.*
Will there be a link to UPD?	*Question answered verbally during the demo.*
What about the list of planned inspections	*Question answered verbally during the demo.*
Would it be any changes in the publication of the GMP-Certificate? Download options for industry or other NCAs?	*Question answered verbally during the demo.*
are alternative names in SPOR valid for EudraGMP scope?	Yes, all alternative names in SPOR (OMS) will be consumed and will be visible in the EudraGMDP documents.

European Shortages Monitoring Platform (ESMP)

Question	Reply
Where all this information about the manufacturers are pulled from? In PMS there is no information about production capacity etc., or at least it's not requested by the current enrichment activities	*Question answered verbally during the demo.*
In the case of an unexpected increase in demand leading to a short-term shortage (approximately two weeks), is it necessary to update ESMP and/or IRIS, or would national shortage reporting alone be sufficient?	*Question answered verbally during the demo.*
As per ISO IDMP data model marketing status can be provided at Product level. However, EMA PMS data model restricts the Marketing status at Pack level. When EMA will implement Marketing status at product level?	Currently data on the marketing status is not entered and held in PMS, but in IRIS for CAPs, and in the case of a crisis and MSSG-led preparedness in entered in ESMP for NAPs only for products in scope of that monitoring. The EMA will be working on establishing a single submission pathway for the marketing status in the future.
Does the MAH will received a messege if ESMP is empty in some field of manufacturers??	*Question answered verbally during the demo.*
Which shortages information becomes publicly available and when?	*Question answered verbally during the demo.*
When will the pre-populated template be available?	*Question answered verbally during the demo.*
Can you show us the new 'Readable IDs' improvement that is to be deployed in April?	*Question answered verbally during the demo.*
How the backup manufacturers are populated in ESMP?	*Question answered verbally during the demo.*

Research & Development Value Stream

Clinical Trials Information System (CTIS) modernisation

Question	**Reply**
In case of a CT sponsorship transfer, will data in CTIS be transferred to the new sponsor or doctor new sponsor needs to enter the data?	*Question answered verbally during the demo.*
Is there a link between CTIS and IRIS?	*Question answered verbally during the demo.*
Will there be an official document that shows the finalisation status of the ASR for storage in the TMF. Currently the only evidence we can save is a screenshot	*Question answered verbally during the demo.*
How will be RFI handled?	In the new module, the RFI process will differ from the current system. The sponsor user will access incoming RFIs directly from the RFI tab, download the RFI document, and prepare the response outside the system. Once the response is finalised, the sponsor can upload the completed document and submit it through the module.
Will the sponsor receive a notification in case of RFI	Yes. The sponsor will receive an email notification both when an RFI is issued and when the ASR is finalised. In addition, all notifications will also appear in the Notice Centre, which will be included as part of the new Safety Module.
when this module b applicable?	The planned date is by the end Q2, but this is currently under revision.

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
What is EMA downtime process and policy for submissions and where can I find this?	*Question answered verbally during the demo.*
Will the new UPD document repository allow to address documents with a specific URL	*Question answered verbally during the demo.*

Electronic product information (ePI)

Question	Reply
will there be sufficient time for voluntary submission in the transition period for non-CAPs? in order for non-CAP MAHs to gain experience before mandatory requirements	Even before voluntary submission, ePI roles will be available for companies, so that they can enter the portal and create draft ePIs in order to gain experience. This will add to the time companies have to prepare for mandatory submission.
what do we have to do if we want to participate in the UAT?	Please keep an eye on the PLM portal, where we will publish a call for participants in advance of the UAT
Will the EMA PLM ePI platform be ready on time, even if additional NCA interoperability development is required? As per directive: The system shall be available at the latest by [6 months before transposition of this Directive]	The PLM portal-ePI for CAPs and non-CAPs is already operational and has been used in regulatory procedures during the pilot by EMA and the NCAs of Spain, the Netherlands, Sweden and Denmark.
What are the criteria for the readiness of the NCA?	These will be presented and discussed with the NCAs at the planned June workshop.
by when is in plan to apply this also to NAPs?	We will present the roadmap in a few minutes.
Can we assume that the NCAs (NL,DK, ES, SE) that participated the first ePI pilot in 2023 are fully ready for ePI implementation?	The assessment of NCA readiness is progressing this year with various analyses and activities that will enable the definition of the NCA roadmap including timelines for each NCA.
is in plan to apply this also to NAPs?	Yes. ePI is for all EU authorised medicines, including CAPs and non-CAPs.
please clarify which actions are expected by Industries. Thanks	ePI submission by companies will be voluntary until the new pharmaceutical legislation comes into application. Please consult the legislation and the ePI guidance area of the PLM portal for more details.

Question	Reply
Please give us some adventages for ePi?	As a starting point, please consult the Key principles: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf
So WHEN will the Directive be implemented?	Please see https://www.ema.europa.eu/en/about-us/what-we-do/reform-eu-pharmaceutical-legislation and the website of the European Commission for information on this topic.
When will the reflection paper on linking ePI from medicine packages be finalised?	Several important aspects of the concept of linking ePI to the medicine package are still under consideration. The updated reflection paper will be published in due course.
Where is a difference beetwen ePI base and PI pdfs on EMA site?	ePI is a structured, harmonised, electronic format compliant with the EU ePI Common Standard. It offers significant advantages for accessibility and dissemination of information over current pdf formats.
will a bulk import API be developed before MVP go-live for CAPs?	API for upload will not be developed before go-live for CAPs.

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

Question	Reply
When does eCTD 4.0 come into force? What impact does it have on SPOR?	*Question answered verbally during the demo.* eCTD v4.0 is in Optional use for new CAP MAAs. Pilot for eCTD v4.0 for CAP products with existing lifecycle has been announced.
What is the link with ICH M4Q(R2) ?	*Question answered verbally during the demo.* Once the M4Q quideline has been updated, the ICH M8 will make the necessary updates into the eCTD v4.0 specification. The ICH M8 has confirmed that M4Q changes will not be reflected in eCTD v3.2.2.
Will it be possible to submit eCTD 4.0 for nonCAP's in Q4, or it will be necessary to submit both formats?	*Question answered verbally during the demo.* We are planning to start a technical pilot for non-CAP new MAAs soon. The actual optional use go-live is dependent on the decision on the Central Repository.
Can NCA's use EMA EURS next for NAP eCTD 4	*Question answered verbally during the demo.* This depends on the outcome of the decision on the Central Repository implementation.
Have any CAP MAA's in eCTD 4.0 been received so far on voluntary basis?	We are still waiting for the first eCTD v4.0 application in production. Applicants are warmly invited to contact the eCTD v4.0 team for support.

Electronic application form (eAF)

Question	Reply
Many of our products appear under the HQ MAH instead of the subsidiary MAH in PMS, preventing correct MAH selection in the web based eAF. How long will the PDF eAF remain available?	*Question answered verbally during the demo.* Please, review your MAH in XEVMPD. The data from PMS is coming from XEVMPD, so you should check what information you have captured there.
Follow up on Question conc. products which appear under the HQ MAH in stead of correct subsidiary Org: Data is correct in XEVMPD. Refer to RITM[redacted]. Thanks.	Thank you for the ticket number, we will review this case and provide an update via the ticket.
will the Annual Update fields be added to the interactive PDF eAF in parallel?	*Question answered verbally during the demo.* Yes, we will add the same feature in the interactive PDF eAF as well.
Any news on the use of the eAF for new MAA?	*Question answered verbally during the demo.*
Any possibility to have a "collaborative editing" in the portal?	*Question answered verbally during the demo.* Concurrent editing in the PLM Portal eAF is currently not possible, however, co-authors can be invited to edit the form where needed. We are currently looking at different options to improve co-authoring.
Related to the question about organisation incorrect in PLM eAF proposed, the ticket is opened already from some times with no answer.	Please send me an email, and I will follow-up with the relevant team (it is not the eAF team can address)
An organisation change legal entity name but not address, in OMS only the name is updated. In PLM eAF there is an option of including the old name manually in the current, but in the proposed only the old name is visible. Is there a fix?	*Question answered verbally during the demo.* Please raise a service desk ticket, and the Proposed organisation table will be updated accordingly.
DCP procedure: some national approvals of CMS are missing, so that we cannot provide in xEVMPD and therefore not available in PLM to prepare a variation for this DCP in PLM. How long is it possible to provide the eAF outside PLM?	*Question answered verbally during the demo.* That is not the case. XEVMPD allows the submission of products when the RMS has granted the approval but in the CMSs the product is under the national phase. Please, review Chapter 3.II of XEVMPD for additional information on how to submit these pending products: https://www.ema.europa.eu/en/documents/other/chapter-3ii-xevprm-detailed-user-guidance-electronic-submission-information-medicinal-products-human-use-marketing-authorisation-holders-ema_en.pdf
when will it be mandatory to use LOC-ID for manufacturers in the eAFs?	*Question answered verbally during the demo.* In the PLM Portal web based eAF the use of OMS data is mandatory. This rule is not reinforced in the interactive pdf Human eAFs for non-CAPs upon a request from NCAs.
When will the issues with missing or incorrect data (e.g., MA numbers, withdrawn application details, and CMS information) be resolved?	Please check that the relevant information is available in xEVMPD. If the xEVMPD entry is correct, however, details are missing in PMS and hence in the PLM eAF, please provide more specific details through a service desk ticket.

Question	Reply
Is it possible to get the eAF list via API ? When yes, where can I find the api commands !?	*Question answered verbally during the demo.* Currently there is no API implementation planned for PLM eAF. We will take into consideration for future quarters.

Product Management Service (PMS)

Question	Reply
1.20. Manufacturer reference (under Medicinal Product) Manufacturer of finished product – process operations of medicinal products Manufacturer responsible for batch release is this correct relationship ?"	*Additional context needed to be able to answer the question.*
5.4. Manufacturer reference (under Packaged Product) Examples: Primary packaging manufacturer Secondary packaging manufacturer is this relationship correct right ?"	*Additional context needed to be able to answer the question.*
5.12.6. Manufacturer reference (under Manufactured Item) Example: Manufacturer of finished product – process operations of medicinal products is this relationship correct ?"	*Additional context needed to be able to answer the question.*
Kindly confirm in which relationship correct to place/ linked QC-related manufacturer information under 1.20. Manufacturer reference (under Medicinal Product) or 5.12.6. Manufacturer reference (under Manufactured Item) ?	*Additional context needed to be able to answer the question.*
If Old eAF the low level terms of manufacturing operations not mentioned so in that case we will use high level terms right?	*Question answered verbally during the demo.* if you have the information available in your dossier or you know it, we recommend submitting the most granular information. If you don't have it, then, high level terms are accepted.
the network portfolio roadmap is updated, can you please comment on the planned XEVMPD decommission and the full write API capabilities	*Question answered verbally during the demo.* As reported in https://www.ema.europa.eu/en/documents/other/network-portfolio-roadmap_en.pdf the work related to the XEVMPD decommissioning is planned to start in mid 2028 and to continue until mid-2029. While we are working on full write API functionality and FHIR upgrade to support the SIAMED decommissioning (CAP-EMA user only).
Is PMS data enrichment required only for marketed or for non marketed products as well?	For all authorised products. Doesn't matter if they are in the market or not.

Question	Reply
Subsidiary MAH is not retrievable in PMS and some products completely missing, preventing use of eAF and blocking enrichment deadlines for critical products. We have a pending EMA ticket. When can we expect this is solved?	*Question answered verbally during the demo.* Please share the ticket Id or directly follow up in service desk
As Per EU IG Ch3 & PMS FAQ, manufacturer data in eAF should go to PMS. But PMS Data Matrix - PLM tab shows legend 'N' in column 'Is it used?' for web eAF manufacturer elements. Is this intentional or a typo?	EMA is working to enable structured changes. So manufacturers from PMS will appear in the eAF in the future.
when will be available chapter 4 and updated PMS QA document?	*Question answered verbally during the demo.* The release of Chapter 4 is no expected at the end of 2026 while the updated version of PMS QA document is released on a quarterly basis. FAQ will be updated in a couple of weeks. We are waiting for some deployments to happen to provide the most updated information.
We don't see CEP details placeholders associated with PHP/Ingredients. When will see them in UI?	This is not available at the moment. Once full enrichment capabilities are introduced, users will be able to submit all product data in accordance with PMS DM Chapter 2. The PUI team is now focused on building other processes in the UI. Whenever this section is relevant for the process, it will be built. As there is not data yet for this field, it is not a priority.
If there are no Reference substance for Active Ingredient, guideline ask to add the same data again as reference (Ex Adalimumab). What is the rationale to have this redundant data or duplication of data? Can you rethink on this again.	*Question answered verbally during the demo.* We can rethink it. We can discuss this with the SMEs, but if this is the information in Chapter 2 and Chapter 8, this has already agreed with the network and there is a rationale behind, most likely to have reference substances for all products so we can use homogeneous information.
manufacturer details should be captured in following relationships: Manuf reference under Medi Prod, maufactured item, active sub... QC sites for both the med prod and the active sub are not explicitly referenced in the this relationships?	*Question answered verbally during the demo.* The complete manufacturer relationship is not yet available in PMS. Once full enrichment capabilities are introduced, users will be able to submit manufacturer data at any level, including establishing relationships in accordance with PMS DM Chapter 2. In the meantime, all required manufacturer information can be reported at the medicinal product level.
How different is the plan to validate the submitted FHIR in PMS, from current xEVMPD levels of assessment(MDN received/2acks/3rd acks). Is there any plan already or if when we will have the concrete information on this	*Question answered verbally during the demo.* There is no plan yet. This will be part of the TOM implementation and we will need to discuss the process with the network. We have received already the feedback that the same process as the one from XEVMPD should be avoided. We will take this information into account but so far it is not decided.
which will be the accessible data by public in PMS?	Please, review Annex A of Chapter 5. You have the information for each field in PMS, which ones are public and which are confidential.

Question	Reply
When enriching data in PMS PUI for MNF, which MIA reference should be provided? The most up to date one in EudraGMP (even if possibly not submitted in the dossier) or the one provided in the dossier at the time of the MNF site approval ?	*Question answered verbally during the demo.* MAHs are required to maintain their product data updated in PMS. Thus the latest available MIA information can be submitted.
we noticed that PMS PUI data Incident tickets now are being converted into Request tickets via the PMS Data Quality Enquiry-Employee Center form. Could you kindly clarify when this change took effect, where official guidance is available?	If the issue is not related to PUI but to the data of the product, then, you need to open a ticket for SPOR and PMS. Only if the issue is related to the PLM Portal or the UI, then, the issue is for the PMS PUI.
Is it possible to get the "change list" (My Workspace) via API ?	No, it is not for the moment.
Manufacturing Operation Start Date: Which date should be provided in case of Manufacturing Name change? Approval of the variation (as done currently for CAP) or is the definition different?	The date when the manufacturing operation started as the name indicates. if the manufacturer changes the name, they are still performing the same activity so no need to change the date.
As per ISO IDMP data model marketing status can be provided at Product level. However, EMA PMS data model restricts the Marketing status at Pack level. When EMA will implement Marketing status at product level?	PMS is not used for marketing status reporting so this question should be raised to a different team.
which are pharmacovigilance impacts (if any) Companies should consider by the decommissioning of xEVMPD?	The main impact will be that products will have to be submitted to PMS instead of XEVMPD. But apart from that, ICSRs, PSURs, etc, will still work as usual. We are only decommissioning XEVMPD, nothing else.
For a CAP var, only site address chng(org+role unchanged)but PMS UI upd the Start Dt to the var approval date.Per EUIG Ch2 start dt=dt when the manufacturing op is approved.Why is start dt upd when only address chng and no new op was added?	We would need to check with the SIAMED colleagues, which are the ones that include this information. I would say this is the case because there might be a new LOC ID, so it is a new entity and that is why they include this information in SIAMED and therefore, PMS is capturing the same information.
We got a 3rd Ack from XEVMPD where the EMA Steward had changed the Package Description into all capital letters. This is not in line with the syntax used by EMA in PMS. Which is correct, all capital letters or not?	EMA data stewards don't change the text to capital letters. This is something the system is doing. It also happens with the name parts for example. It is OK for PMS and we don't need you to make any changes or open any ticket.
in which relation QC operations linking like which section under medicinal product section?	Please, review Chapter 3 for all the information about the submission of manufacturers and in which sections.
When would PHPID, MPID pllaned to be populated in PLM?	There are no plans yet for their implementation. There is still data missing in order to be able to populate these fields.

Question	Reply
We see that the version of the PMS ID is recently created (Last Updated in 2026), but the MedDRA coded version for Indication still show 21.1. May we know why?	As explained in the FAQ document, RMS captures the version when the term was last changed. That is the same version we are displaying in PMS.
Who should be contacted when quality issues are detected in PMS, like e.g. duplicated packs due to multiple languages for products from the ULCM?	This is not an issue. This is explained in Chapter 9 of the EU IG. In multilingual countries you will have as many packages as EV Codes for the same package. So no need to raise any ticket. As explained also in this demo, we are investigating now how we are going to merge these packages. We will provide additional information.
Who should be contacted when quality issues are detected in PMS, like e.g. packs with multiple pack sizes for products from the ULCM?	First you need to check if in XEVMPD you have splitted the packages. That is something you need to check internally. If you confirm this is the case and you still see wrong packages, then, please open a ticket for SPOR and PMS team.
Package PMS ID: How is the Package PMS ID created for BE, LU, FI when there is more than one language for the same pack size? Will there always be one per language or will it be merged into on ID regardless of the languages?	Please, read Chapter 9 of the EU IG. It is explained how multilingual countries are managed in PMS.
We cannot enter the structured packaging enrichment data since February. The Validate button is not active and the data is not saved. After the DB maintenance it is not ever better. Is it a global error or related with our profile?	We confirm the edit function in PUI is working correctly and as designed. Please note that in PMS PUI you can add the pack size and manufacturers data only. If you are encountering issue in submitting this data please open a PLM PUI Incident ticket type by reporting the ORG ID and type of roles you have been granted so the team can investigate.
Ticket number for Subsidiary MAH not retrievable in PMS and some products completely missing: RITM[redacted]. Thanks.	This ticket is related to alternative names in OMS. eAF already allows the use of alternative names, so I would suggest you to liaise with them so you can explain how to select these names. The problem is that in PMS, we only show one company name. The ticket is assigned to a different team (not PMS) but I will try to have a look.
Please confirm that a medicinal product registered in a specific country (e.g. HR, HU, IT) with 4 different presentations (same strength) should have one PMS ID. A ticket was opened some months ago but still not resolved.	If the product has the same information in all the grouping elements as described in Chapter 9 of the EU IG, then yes, only one product with 4 packages should be created.
As manufacturers must be updated in PMS by the end of 2026, should we submit via PMS from January 2027, or can we continue to use XEVMPD ?	Manufacturers can be submitted only through PMS. So manufacturers should be submitted and maintained through PMS. XEVMPD is still in place, and products should be submitted and maintained through XEVMPD.
MIA: we understand that we should use the latest MIA version. How is this field expected to be maintained? Should the information be updated (for all products affected!) every time a new MIA of a specific manufacturer is issued ?	In PMS should contain the most updated date information as also per XEVMPD database.
If the dossier and the AF (submitted long time ago) do not have low level	Low level terms are always preferred than high level terms.

Question	Reply
MBO details but we know them anyway, should we enrich with the low level axtivities or stick to the high level terms of the old AF?	

Product user interface (PUI)

Question	Reply
we noticed that PMS PUI data Incident tickets now are being converted into Request tickets via the PMS Data Quality Enquiry-Employee Center form. Could you kindly clarify when this change took effect, where official guidance is available?	*Question answered verbally during the demo.* If the issue is not related to PUI but to the data of the product, then, you need to open a ticket for SPOR and PMS. Only if the issue is related to the PLM Portal or the UI, then, the issue is for the PMS PUI.
Are the short MBOs name now the only ones selectable or can we choose between long and short names?	Short names only as per page 15 https://www.ema.europa.eu/en/documents/other/process-electronic-submission-medicinal-product-information-chapter-3_en.pdf
The current MIA should be used for manufacturers. How is this field suppose d to be maintained? Updated every time a new MIA is issued for all products affected?	MAHs can updated their products as soon as the new MIA is issued.
For most of our pdt, Presentation strength name is updated instead of Concentration strength name as strength is in "mg/ml". Please clarify if this is an EMA Known issue or Ticket need to be raised to get it updated in PMS PUI.	*Question answered verbally during the demo.* What do you mean with Presentation strength name?
May I ask you to repeat the direkt link to PMS ID again? Especially the get-variable of the link. Thank you	here you can find the direct link: https://plm-portal.ema.europa.eu/medicinal-product-read-only/?pmsid= (+add the relevant PMS ID)
What is the rule to create the Package PMS ID? Is the assumption correct that there will be one Package PMS ID created for every language? So that there will always be 3 Packaged PMS ID for Belgium	*Question answered verbally during the demo.*
Should manufacturers be enriched for both the product and substance, or is the product manufacturers sufficient?	MAHs can report manufacturers data also referring to the substance to support the data structuring as well as the ESMP and eAF use cases.
As Per EU IG Ch3 & PMS FAQ, manufacturer data in eAF should go to PMS. But PMS Data Matrix - PLM tab shows legend 'N' in column 'Is it used?' for web eAF manufacturer elements. Is this intentional or a typo?	*Question answered verbally during the demo.* EMA is working to enable structured changes. So manufacturers from PMS will appear in the eAF in the future.

Question	Reply
FAQ documents has a known issue with Q4 resolution date: "Some updates submitted to XEVMPD are not reflected in PMS" because some older version of EV code data is migrated. Can you confirm if this is resolved now?	The bug was fixed. However if you still notice discrepancies you can open a ticket so the team can investigate and perform the required data fixes.
are Manufacturing Operations referred only to Manufacturers reported in the dossier?	*Question answered verbally during the demo.*
Are there any updates on bulk removal in PMS PUI?	This is not yet available as work is still ongoing.
For the ManufOp 100000160466 "Storage and/or distribution of medicinal product" to be included in the PMS, what level of detail regarding storage and distribution is required from the MA holder?	Please follow EU IG Chapter 2 business rules. as based on the type of operation specific fields are required to be populated.
How to manage if we find incorrect merge of records occurred and resulted in multiple PMS ID generation?	Please raise a ticket PUI incident to request the relevant investigation and fixes.
For the ManufOps 100000160466 "Storage and/or distribution of medicinal product" to be included in the PMS, does this requirement include all authorized 3PL and 4PL providers, as well as the MAH own warehouses and subcontracted warehouses?	MAH should report the authorised sites responsible of the storage and/or distribution of medicinal product.
Please note the dynamic export do not pull the product with valid suspended authorization status (at product level).	*Question answered verbally during the demo.* We will provide this info to the team. Please, make sure you have no filter in the reports.
During CAP manufacturer data verification, we found discrepancies in PMS PUI, with some sites missing or appearing as additional. Should we raise a ticket for this?	*Question answered verbally during the demo.* Yes, for the PMS team so we can discuss it with SIAMED. Please, provide the missing or extra manufacturers, when they were approved, etc so SIAMED colleagues can review this faster.
Could you advise which catalogue should be used to raise PMS PUI data issue or discrepancy tickets? Tickets raised under "Incidents" are being moved to the "PMS Data Quality Enquiry". Has EMA shared any update regarding this change?	If the issue is related to PMS data and not an issue with the PLM Portal or the UI, then, you need to raise a ticket for SPOR and PMS, not for PMS PUI.
"We got a 3rd Ack from XEVMPD where the EMA Steward had changed the Package Description into all capital letters. This is not in line with the syntax used by EMA in PMS. Which is correct, all capital letters or not?"	In PMS capital letters are also accepted.

Question	Reply
do you think that the update of PMS for Manufacturing Operations should be tracked in the Quality system? do you consider this as GxP impacted?	For the purpose of PMS submission of structured manufacturers data, authorised manufacturers also included in the quality system can be submitted. For questions related to GxP we recommend to consult the relevant inspection officer.
Is MIA currently mandatory to be enriched to PMS?	As per EU IG Chapter 2 section 2.6, it depends on whether if the manufacturing site is located in the EEA. If so then the Authorisation number is to be extracted from section 1 of the Union format for Manufacturer's Authorisation or from "MIA number" column in EudraGMDP can be reported in section 2.6
Is it possible to add Package PMS ID as one of the filter type to the main page in PMS PUI?	We will check if possible. Thanks

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

Question	Reply
We would like to reiterate our request to have a single button to download an entire IRIS case folder (not document by document, or screenshots as this is the case now). EMA acknowledged this as enhancement under review. Where do we stand?	*Question answered verbally during the demo.*
Can EMA provide a clear process flow on document level (eCTD/gateway versus IRIS)?	*Question answered verbally during the demo.*
Communication: are there any more EMA Q&A webinars planned for iMAA feature? Are there further regular meetings planned with industry representatives? How is EMA going to communicate about developments?	*Question answered verbally during the demo.*
Is contact management already on IRIS production? If not, when it will be available?	*Question answered verbally during the demo.*
Can EMA please clarify their plans about e-business pipeline being handled in IRIS?	*Question answered verbally during the demo.*
For Orphans, Paediatrics, SA, PRIME, there is a section in the IRIS webform asking for an upcoming submission MAA date. This can create confusion, when several procedures run in parallel for the same product. How will EMA improve this?	*Question answered verbally during the demo.*
When will the new useful feature for the product contacts go life?	*Question answered verbally during the demo.*