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Q&A Q1 2023 System Demo

Date: 22/03/2023

Location: Online, 09:00 - 13:00 Amsterdam time (CET)

Link: Quarterly system demo - Q1 2023 | European Medicines Agency (europa.eu)

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. Where it was clear that a question asked in the "Plenary" room referred to a specific IT product it was moved to the appropriate product room. Wherever this happened, if anywhere, this is indicated in the question text below.

In principle this document will not be updated. Generally, the order of questions answered follows the order in which they were prioritised by the audience using the "thumbs up" feature of Slido.com.

The responses represent the expert view of the development teams at the time of the System Demo and are not official statements by the European Medicines Agency nor its partners.

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Product Lifecycle Management Value Stream

Electronic Application Form (eAF)[1] / PLM Portal

Question	Reply
The download protocol is torrents, as torrent protocols are somewhat obsolete and suspect from a security perspective. Is there any plan for a more modern protocol? (CESP, is not modern but works fine...)	There is no need to do Torrent downloads from the PLM portal to access the eAFs. I believe this question relates to the Common Repository torrent downloads. This is a separate product, and we are currently reviewing the Common Repository system in the view of future implementation of eCTD v4.0.
When will EMA share the updated implementation roadmap incl. structured data fields clarity?	We will be working on our planning with various teams during next week and subsequently, after the PI Planning ceremony, we will be updating the eAF Roadmap.
Is there a planned time for the release on veterinary medicines?	We have already started analysis work in preparations for the implementation of the MAA forms, this includes both human and veterinary forms. We are currently concentrating on delivering features that will enable the mandatory use of the forms for all human variation procedures, however, in parallel we are working in preparation for the veterinary forms. The timelines will be published as soon as we have reliable estimates available.
When the PLM/eAF form will be signed by your proposed way, the Adobe signature function, will it still contain a valid FHIR message?	When signatures are included in the exported pdf form the FHIR message doesn't seem to be affected. It is, however, important to confirm that the xml attachment is still present in the pdf after the signature (using adobe sign, a digital signature tool or image of a signature) is added.
PLM generates FHIR xml messages in v. 4.6.0 from the eAF pdf. When will other systems at EMA shift to this version of FHIR messages? I want to draw your attention that this version of FHIR is still prone to voting at HL7.	We are aiming to upgrade to 5.0.0 together with PMS as soon as it is out officially, which should happen this year
When will commercial confidentially information be removed from the FHIR message?	This will come in either q2 or q3 this year. The feature is planned and in technical design right now
Common repository downloads eAFs	The eAFs created using the new PLM Portal web-based form can be natively opened in the Common Repository web user interface without having to download them. Single documents can be downloaded without a torrent from the Common Repository.

[1] This IT product was formerly managed as part of the Digital Application Dataset Integration (DADI) project

Question	Reply
when do we get the information on which submission type we can use for submitting xEVMPD data for registration in an MRP/DCP procedure which do not have a MA yet	We are working on an approach and guidance for applicants for this and it will come in due course prior to the start of the transition period.
why isn't it possible to paste text which is in tabular format in the present and proposed section	We have a user story in the backlog to improve the usability of the present and proposed section and as a PO for the eAFs I keep on highlighting the importance of this function.
As signature is highly recommended now, as per recent published Q&A, how can an applicant sign the eAF? Will those steps be explained at some point in a guidance document?	Please refer to the PLM eAF Navigation Guide. The forms cannot be signed in the web user interface. If the user wishes to include a signature in exported pdf, this should be done using any external signature tool.
As signature is highly recommended now, as per recent published Q&A, how can an applicant sign the eAF? Will those steps be explained at some point in a guidance document?	If you want to sign it, please use the Adobe signature function, which allows an image upload or any other digital signature of your choice.
Could you please explain the context for the addition of the new tick box related to personal data? There is nothing similar in the current eAF. Thanks	This is correct, the interactive pdf doesn't contain these tick boxes as they are not part of the Notice to Applicant application form. These tick boxes are not displayed in the pdf output from the PLM Portal eAF either, however, they are mandatory fields to be ticked when the change concerns product information. This was implemented as a business requirement from the EMA procedural colleagues.
I have issue when filing information regarding contact person details - mail address is missing in pdf. Have you already identified this bug? When we can expect it will be resolved-validation questions are received.	We are currently not aware of a bug on missing contact emails. I have retested this just now and can assure you, that the email address for the MAH and the contact person are both in the PDF when they are entered. It may be that the applicant has not entered an email address and therefore not exported one. There is a story being implemented right now to make the contact details of the person mandatory which will reach production on the 3.3.2023
Is it allowed to sign the downloaded eAF with an image signature?	It is however possible to include an image of a signature in the exported pdf form. We have received forms containing an image of a signature for centralised procedure and signature included in this way doesn't affect validation or validity of the form and is also acceptable.
Is it allowed to sign the downloaded eAF with an image signature?	It will not be allowed to modify the content of the eAF manually once it is downloaded. If you want to sign it, please use the Adobe signature function, which allows an image upload or any other digital signature of your choice.

Question	Reply
What about the UAT for national procedures?	We will not be having a specific UAT on the National procedures as such, but we have a planned data release later in Q2 (dependency on PMS go-live). This data release will be supported by training and guidance, however, no UAT as the use is optional. There will be a larger external UAT later this year to confirm that all functionalities supporting both CAP and NAP procedures are available and once this UAT is passed, we will be launching the transitional period towards the mandatory use.
When will EMA share the updated implementation roadmap incl. structured data fields clarity?	The updated roadmap will be made available via the PLM Portal Forum and eSubmission website

Product Management Services (PMS)

Question	Reply
Can you please clarify the go-live date and if any action is required from Industries?	NAP data will be released during Q2. For the moment there is no action required by Industry
when do we get the information on which submission type, we can use for submitting xEVMPD data for registration in an MRP/DCP procedure which do not have a MA yet	This is a point of discussion that will be prioritised and addressed in Q2 2023. We are discussing this matter with the web-based eAF development team, in collaboration with the EMA Domain and Solution Architects. Overall, we are working to identify the most appropriate solution to implement.
What is the process to be followed to correct or enrich PMS data and where can we see PMS data? How is the MAH informed about changes made by EMA in the Art 57 database?	We are working on the different processes to be implemented in the Product UI and through API submission for enrichments, corrections, etc. This is not possible for the moment. In relation to the changes made by EMA in Art. 57, the process is the usual one, through the 3rd Acknowledgement.
You mention that XEVMPD data loading and mapping is complete in UAT, when will this be complete in Production?	The aim is to have this data release during Q2 2023
Are we able to update the product through the Product UI? We fear that some product data may not have been cleansed/merged corrected from the migration due to discrepancies of product data we have in house vs. what is in xEVMPD/SIAMED.	You will be able to do it as soon as the product UI edit pages are released.
Could you please provide an extract of SIAMED to anticipate the mismatching with XEVMPD?	Unfortunately, this is not possible for the moment.

Question	Reply
In some member states the NPs may not obtain the marketing authorization number for all packages approved, and this data is not in xEVMPD. Is there a guidance on whether the NP must include all approved packages in PMS?	We are migrating the data that we have in xEVMPD. So some products won't contain the correct number of packages. PMS will require at some point the submission of those packages (please, check Ch.2) but for the moment, this information is not needed
Can you please clarify the defining elements of the MPID since in Ch2 it is not clear (e.g. MA number is specified as a defining element, but in the example, they are being grouped together).	As explained in Ch2, we have different defining elements, but some of them are then group together to generate the MPID. If you have any specific question, you can raise a ticket in Service Now.
Is the Belgium special case with multiple languages and MA numbers assigned on Packaging Type level incorporated in the xEVMPD to PMS migration rules?	No for the moment. This use case was found a couple of weeks ago and we are discussing how we can implement this in PMS.
Regarding the authorisation status to Support DADI [ed. web-based eAF], would you be able to shed some light on how that will be set up? we are curious to know how we can ensure the pending product is in PMS. Howe will this process be facilitated?	The rules for the Auth. Status can be found in Ch 2 of the EU IG. For the pending products, this is a priority for Q2 so more information will be provided on how we implement this feature.
When will we be able to use EMA tool to correct PMS data?	We will provide more information on timelines as soon as possible taking into account that we need to have different enablers in place. Nevertheless, in case you see already wrong data in PMS, you can submit a ticket in Service Now.
Which version of FHIR will be used?	The version mentioned in the EU IG is the HL7 FHIR Specification version 4.4.0 (FHIR R5 Preview 3). We plan to move to FHIR R5 as soon as it is officially released.
Can corrections to PMS be submitted using another route other than by editing the FHIR record?	User Interface or API submission will be the different channels accepted.
Please explain why the PUI is part of PLM and not PMS?	This was a technical decision taken to allow the access and sharing of products data starting with PMS and eAF Product.
We are missing the context and the process. Could we have a demo on how all these portals are going to interact and are going to be used in practice? Various processes could be presented and use of portals within those processes explained.	Yes, this aspect will be addressed and demoed upon completion of the process discussions we need to finalise with the Product teams. Thank you for your feedback.

Question	Reply
What is EMA's position on the accuracy of retrospective PMS data provision? For older or transferred products, data is often not available, e.g. logistic data for the Marketing Start Date. Can industry be pragmatic here?	We will bring this topic to the SMEs to get an agreement from NCAs and Industry
what is the future of SPOR in the big picture (product lifecycle)? What is the plan to get there in terms of system connections and process changes?	We are building our data centric target operating model incrementally by developing the PLM Portal and PMS together and overall supported by SPOR services. The goal is to bring efficiencies, improve data quality and consistency and deliver a smoother user experience through related processes, enabled through interfaces with core regulatory systems. By delivering the PLM Portal and PMS, a stronger process links, quality and consistency will be built between EMA and NCA approved data and ensuring that industry submitted data is verified as approved and consistent at regulatory level. In 2023 we will make ISO IDMP-compatible product data (supported by the use of standardised SPOR data) available on authorised medicinal products, both centrally authorised products (CAPs) and non-centrally authorised products (non-CAPs). This will result from a data migration and continuous updates from the EMA database (SIAMED) and the xEVMPD (Article 57) database to PMS following the ISO IDMP standards.
When is it planned to enrich the data coming from xEVMPD to be used in PMS?	To be able to enrich data in PMS there are several enablers that are needed first. Additional information will be provided when the capability to enrich data will be available.
When will IDMP submissions start?	We need to have different enablers in place to allow submissions to PMS. We will provide more information as soon as we have a better idea of these timelines.
Will corrections to PMS data need to be performed using the FHIR interface?	Yes. But also API submission will be allowed
Is it planned to move the UI for SMS/OMS/RMS to PLM?	No, SOR services will be accessible via the usual SPOR portal accessible from the link: https://spor.ema.europa.eu/sporwi/ However as you can see from the System Demo in the PLM UI there is a link to SPOR portal for each SOR service you need to access.
When will Ch 3 of the IG be issued?	We are discussing the different processes with the SMEs and internally. Whenever we have more information, we would update this Chapter.
why this is in the PLM portal and not on the SPOR UI?	This was a technical decision taken to allow the access and sharing of products data starting with PMS and eAF Product.
will there be an extra UAT testing session for PMS	Yes, an extra UAT testing session in PMS is running with the scope to test with externals the xEVMPD delta functionalities.

Question	Reply
Will you show the xEVMPD EV Codes in PMS as well? This will significantly help Industry to map out the PMS IDs in their RIMS systems to later update data via the PMS API	Feedback received.

Product User Interface (UI)

Question	Reply
Do I need a specific role for accessing the Product User Interface? I logged in, but I do not see the Products Data Management tab	This question was answered live. Product data management tab is not visible due to the access and security protocol in place. The roles to access PLM will be communicated in due time. Overall to access PMS Product UI in PLM the roles mentioned at this link applies . Please also note that we are discussing this aspect with the web-based eAF development team.
Is the download in Excel also possible for all data fields in PMS. Currently you just see the general information also available in xEVMPD. But it would be good to have an overview on what is populated and what is missing.	Thank you for your feedback. We will consider this aspect for future activities.
Is It planned learning sessions on how to use PMS before go-live? When?	Yes, a training plan for external and internal users is planned. Further details will be communicated in due time throughout the EMA official channel.
why this is in the PLM portal and not on the SPOR UI?	This was a technical decision taken to allow the access and sharing of products data starting with PMS and eAF Product.
How is ePI expected to interlink with the PI in the eCTD?	From the ePI team: at the moment the Minimal Viable Product will touch as little as possible the current business processes. It will still be necessary to include the PI documents in the eCTD. The ePI portal has an export to Word functionality, which could be used to generate documents for eCTD submission. Further integration with other systems and processes, including eCTD, will be developed post Minimal Viable Product.
Will Product UI be directly linked to ePI creation tool?	Product UI can support the creation of ePI. For the moment, specific discussion have not yet occurred on this regard however we do not exclude to discuss this aspect in due time with the ePI team.
Is it planned to move the UI for SMS/OMS/RMS to PLM?	No, SOR services will be accessible via the usual SPOR portal accessible from the link: https://spor.ema.europa.eu/sporwi/ However as you can see from the System Demo in the PLM UI there is a link to SPOR portal for each SOR service you need to access.
Is it possible to get an example of FHIR message to start building the template for RIM data extraction? Thanks	This point is considered for future development. Overall, we plan to build in Q2 2023 the FHIR profile as part of the EPIC FHIR adaptor. Thank you

Question	Reply
Will it be possible to know who did what change on an entry?	This point will be addressed as soon as we start working to the PRDUCT UI EDIT functionality feature. For the moment, as explained at the System Demo, we are working to develop the VIEW functionality feature.
Export: which formats are foreseen?	FHIR format is foreseen however additional formats can also be considered. We will further explore with our PMS Subject Matter Experts this aspect.
Is it planned that the PLM Portal will be used in future for any veterinary use-case?	At the moment we did not have received any request of discussions on this specific aspect with the UPD team. Thank you
would ePI use any SPOR master data?	Kindly address this question to the ePI team to receive the most correct answer. Overall, SPOR data can also be used to support ePI Product. Thank you
When will the API specification be ready?	Next week we will define the PMS planning at the Agile Product Increment even. Upon agreement, information on the planned timelines and activities will be communicated via the usual EMA channel.
Who can see all the data on a medicinal product? Is the authorisation to do so linked to the account? Or can anyone see all the data?	The level of accessibility to product data will be based on the access rights assigned as per usual registration to IAM to PMS and eAF roles. Additionally, only data classified as non-confidential (i.e. medicinal product full name) will be visible to the public. We are working on this aspect.
For Initial MA applications through PLM in the future, what will be used to insert new product data in PMS, PI or PLM? PLM product data is accessible by PI as indicated now, will this be for variation and initial MA applications?	We are still working to address regulatory variations. Initial MA will be addressed at later stage. Overall the user will be able to submit product data via API and / or UI.
How can we register to Product user interface?	Please refer to the previous question. This question was answered live. Product data management tab is not visible due to the access and security protocol in place. The roles to access PLM will be communicated in due time. Overall to access PMS Product UI in PLM the roles mentioned at this link apply (link: https://www.ema.europa.eu/en/documents/other/boarding-users-substance-product-organisation-referentials-spor-data-services_en.pdf). Please also note that we are discussing this aspect with the web-based eAF development team.
How is ePI expected to interlink with the PI in the eCTD?	Kindly submit this question into the ePI section in Slido (this is the PRDUCT UI section) in order for the ePI colleagues to provide you the most appropriate answer. In the meantime have informed the ePI team about this question. Thanks
will PLM be linked to UPD?	At the moment we did not have received any request of discussions on this specific aspect with the UPD team. Thank you
Will the manufacturers item also be visible in the PMS UI?	In PRODUCT UI the entire PMS dataset will be reproduced and therefore data made available (based on the applied confidentiality rules).

Electronic Product Information (ePI)

Question	Reply
When planning the timelines, has consideration also been given to large generic companies, for whom it will not be easy to provide an ePI for the entire product portfolio?	Yes, indeed consideration will be given to the time it will take for companies to adapt to providing ePI, particularly companies with large portfolios.
The ePI creation tool is designed for small companies. However, the ePI is to be mandatory for all pharmaceutical companies. Will the EMA also offer a tool for large companies to be able to handle the large number of PIs?	At the moment, we are working on the minimal viable product, and we will certainly be considering various options for advanced tools and features going forward.
When is ePI integration with PMS targeted to go live?	For the Minimal Viable Product, ePI documents will be annotated with a PMS ID. Further integration of ePI and PMS data is foreseen post Minimal Viable Product. Details are in the documentation published on EMAs GitHub page.
What do pharmaceutical companies with a large product portfolio need to do to be able to provide an ePI?	There are (will be) two ways to create ePI: 1) via the authoring portal 2) via upload of FHIR XML file (in the EU common standard for ePI) European medicines regulatory network adopts EU common standard for electronic product information | European Medicines Agency (europa.eu)
who makes sure that the latest template of the EPI is available	The regulator will make the latest template available in the portal.
Are you planning any interactions with Pharma Ledger for the accessibility of the ePI?	ePI will be made accessible through a publicly available API, and we are hoping that stakeholders such as IMI projects and medicine information providers will engage with the ePI API.
Can a PI in word or PDF format be uploaded and the system automatically recognizes the sections based on the bookmarks and puts the text in the right boxes?	Conversion from Word/pdf to ePI is not in development. However, once ePI is created in the portal, it is possible to export to Word.
What is the timeline for the Vet industry to also start using ePI?	For the Minimal Viable Product, the focus is on human medicines, but all the tooling and standard development takes into account future inclusion of Vet medicines also. This is under discussion, and we do not yet have a fixed timeline.
Will there be a tool/software from EMA that makes it possible to import the PI available in Word into the ePI creation tool, or is it perhaps also envisaged that the ePI creation tool will be equipped with such a function?	Reply copied from another question: Conversion from Word/pdf to ePI is not in development. However, once ePI is created in the portal, it is possible to export to Word.
are there already roles available for the ePI?	The ePI roles have been created but are not yet available to external users. We will be making roles available to a small number of applicants in the upcoming pilot phase.

Question	Reply
Is each heading documented with the MA variation(s) number that make it up? Indeed, we used to declare these notifications so that traceability was ensured. At what level: in the metadata + locally (at the heading level)?	In the Minimal Viable Product, each ePI is associated with a procedure number. However this is at ePI level and not at heading level.
Is the ePI which will be made available via a publicly available application program interface the same as the ePI from the ePI creation tool?	Yes, it is the same ePI (as demoed today when Evinn accessed the ePI from the API that I had created).
The name of the medicinal product will be in free text, or will there be a link to PMS for instance?	Although the tool's field for Medicinal Product allows for free text, there are plans to link with PMS IDs. We connect with SPOR where data is available (and where there is benefit in doing so) and will continue do link to mastered data incrementally.
Will the electronic/digital version of the package leaflet created via the ePI creation tool be the version provided to the patient later?	Reply copied from other question - - This is currently not in the Minimal Viable Product and is in discussion.
Could ePI be automated by extracting data from the SmPC?	Conversion of current pdf/Word to ePI is possible and has been investigated in a proof-of-concept but is not currently part of the Minimal Viable Product being developed.
Once ePI portal is available, does that mean that the applicants will not have to include PI in the eCTD anymore? Or will there be duplication: applicant will have to create PI for the eCTD and in addition create ePI?	The Minimal Viable Product business process will touch as little as possible the current business processes. It will still be required to include PI in the eCTD. As the ePI portal has export to Word functionality, the exported document could be used as the basis of the eCTD submission.
The name of the medicinal product will be in free text, or will there be a link to PMS for instance?	(perhaps also of interest - copied from another question) For the Minimal Viable Product, ePI documents will be annotated with a PMS ID. Further integration of ePI and PMS data is foreseen post Minimal Viable Product. Details are in the documentation published on EMAs GitHub page
What is available in PLM UAT concerning ePI?	If this is referring to the UAT environment, ePI will be available in the UAT environment for users with ePI roles assigned.
When is ePI integration with PMS targeted to go live?	Thanks for your question Kepa, Hope you're keeping well, best wishes, Kerstin
Will EMA provide a platform for patients to access the electronic/digital version of the PL?	This is currently not in the Minimal Viable Product and is in discussion.

Question	Reply
Assuming it becomes legally okay to provide an electronic PL to patients instead of the paper version found in the packaging. Will this be the PL created via the ePI Creation Tool?	In the future we envision that there will be multiple ePI creation/conversion tools available on the market. So the PL could be created using the ePI authoring tool or with other tools on the market. The fundamental aspect of an ePI is that it is compliant with the EU common standard regardless of where it was created.
How are the headings related to a CA addition foreseen, e.g. national prescription & dispensing conditions in the SmPC, if the DRD would require us to keep it in that place? Do we have the freedom to modify the template accordingly?	Currently ePI is the electronic format of the current QRD template. Blank subsections can be added to the template, or templates extended according to NCA requirements when they are implementing ePI.
Is it possible to take part in the pilot? How?	We are working on the pilot in the upcoming PI and will share more details in due course.
Is there already a date from which the ePI should/will be mandatory for all pharmaceutical manufacturers?	There is no date yet. There will be a limited Pilot (2023 to 2024) before moving to a non-mandatory implementation phase. Only after these phases are complete would ePI become mandatory.
We had a so-called mutant PI format compiling all the particular situations, e.g. text with all the xml entities + image in each heading up, so as to check in 1-time different formats rendition from XML: is this foreseen?	If I understand the question correctly, we do indeed have a test PI in which we have all the rich-text editing requirements compiled, that we use for testing.
Who is supposed to enter all the data for ePI?	The applicant will be responsible for creating and submitting ePI.
Why ePI planned to implement only for Minimum Viable products? What is plan for other products?	Minimum viable product refers to the development of the ePI portal. We will release an Minimal Viable Product for creating and editing ePI then develop more advanced feature in the future
Will EMA provide a tool for pharmaceutical manufacturers to import documents into the ePI-creation tool? If not, from where can this be obtained?	There are (will be) two ways to create ePI: 1) via the authoring portal 2) via upload of FHIR XML file (in the EU common standard for ePI) European medicines regulatory network adopts EU common standard for electronic product information | European Medicines Agency (europa.eu)
Will minor updates without variation be documented and linked to major variations ones? e.g. creation of presentation VERSUS typography, layout often asked by industry or required by NCA.	All the details of the business processes are in development. Versioning is also a post-Minimal Viable Product feature under consideration.

Question	Reply
Any information you can provide on planned pilots with ePI? Timelines? Which markets will be involved?	We are working on the pilot planning in the upcoming PI and will share more information in due course.
Are third parties already working in consultation with EMA to develop ePI software for larger product portfolios?	This is not currently the case, as we are working on a minimum viable product. We will facilitate interested third parties by publishing information about the EU ePI Common Standard on EMA's GitHub page.
ePI - will there only be the option to work in the system or will there be an option e.g. 'open in word' with full word functionalities?	This option is not available, as the portal is not based on Word online.
Is the EMA ePI FHIR XML standard finished now (XML Schema)? when will it be? Important for companies so they can adapt their systems accordingly…	We are planning to publish updated information on GitHub in the coming weeks.
Please explain the relationship of the data in ePI and PMS? Is industry responsible for the alignment of data reflected in ePI and the SmPC or does EMA have a verification process that reviews these records in conjunction with PMS data?	For the Minimal Viable Product, ePI documents will be annotated with a PMS ID. Further integration of ePI and PMS data is foreseen post Minimal Viable Product. Details are in the documentation published on EMAs GitHub page.
Should the industry first wait for the ePI workflow to become concrete or can something already be done to be prepared in time?	Thank you for thinking about preparing for ePI implementation. Even at this early stage, as we move toward piloting the Minimal Viable Product, it is a good idea to keep up to date with the progress and to share the technical details of the EU ePI Common Standard, which are published on GitHub, with technical colleagues. We anticipate updating the GitHub documentation in the coming weeks.
Should the pharmaceutical industry or software providers in this field start developing software for the creation and maintenance of ePIs for large companies with a large portfolio of products, or will such software be provided by EMA?	It is anticipated that vendors/software providers/companies will develop tools for managing ePIs.
The ePI creation tool (Minimal Viable Product) is not suitable for large pharmaceutical companies. This is because ePI creation will be pure manual work. The MVP must have an integrated document converter to enable efficient ePI creation (docx -> ePI/FHIR).	The purpose of the Minimal Viable Product is to enable the initial introduction of the EU ePI Common Standard into regulatory processes. Advanced tools and functionalities are anticipated to be developed by vendors as well as regulators as ePI becomes widely adopted.

Question	Reply
The ePI creation tool currently has a limited range of functions. Complex PI with tables, figures and diagrams cannot be reliably created. However, as of July 2024, the implementation of ePI is planned, how should such cases be handled?	PI with tables and images can be reliably handled in the tool.
Will EMA provide a tool for pharmaceutical manufacturers to import documents into the ePI-creation tool? If not, from where can this be obtained?	While an API for import is not included in the Minimal Viable Product, it is certainly an identified need from companies and will be considered for prioritisation for further development.
Will the ePI eventually make the exchange of Word/pdf of SmPC obsolete, and when?	For the time being, and until advised otherwise, ePI would be in parallel to Word / PDF. What you will be able to do with the ePI authoring tool, is prepare and maintain PI in its electronic format as the main source. Word and PDF can be generated from this electronic version. The tool provides these functionalities. (We envision continued exchanges of Word documents)
Will the headings or information in one document heading repeated identically in other documents, e.g. SmPC and Labelling, Annex II and Package Leaflet, etc. be linked in the ePI documents to avoid oversights or inconsistencies in updating?	Linking of documents as you describe will not be possible in the Minimal Viable Product but is an advanced feature that can be considered for future development.
Will the PL created via the ePI Creation Tool be the version patients are expected to use in the future instead of the paper version (found in the box)?	EMA will comply with current and future legislation regarding the paper package leaflet.
Will the system allow Post authorisation Changes due to unforeseen additional approval processes of NCAs where Text may have undergone corrections	The NCA Subject Matter Experts in the project are involved in testing and review, providing requirements according to their business processes so that the tool will meet such needs.
Will there be a central platform for downloading ePIs (preferably via EMA, rather than each member state creating its own portal). The portal should be valid and mandatory throughout the EU.	Yes, all published ePIs in the EU e.g. CAPs, NAPs, and MRP/DCPs will be available via a publicly available Application Program Interface (API)
Can you please give more information on the pilot test? Schedule, participants, CAP, NAP, MRP/DCP?	We will be focusing on pilot planning in the upcoming PI and will share details in the coming weeks and months.

Question	Reply
How can PUs prepare for the upcoming ePI workflow?	It is recommended to keep up to date with the progress of the project and upcoming pilot. In addition, for technical colleagues, an update to the documentation in GitHub is planned in the coming weeks.
How should the situation where ePI is updated more recently than printed SmPC be managed? What expectations are being communicated to patients and HCPs?	This is a situation that already exists today with PIs published in pdf format. Patients and HCPs as well as all stakeholders will be included in communication and change management activities.
How will the mass update that NCAs do today in the case of Holder transfers, for example, be done?	Mass updates will not be possible in the Minimal Viable Product but is an advanced feature that can be considered for future development.
is it possible to select multiple countries in case of MRP/DCP?	In the ePI portal, MRP/DCPs are treated as individual procedures for each authority. This is because each national text can be approved and published at different times. We will be looking to enhance this feature in the future
Is the EMA ePI FHIR XML standard finished now (XML Schema)? when will it be? Important for companies so they can adapt their systems accordingly…	For reference: https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard More complete answer to follow
It is planned to provide an ePI at the start and end (approval). Would it not be completely sufficient to provide the ePI only at the end (approval) - this would save time and capacities on all sides?	As answered by E. Scanlan The business processes are under review and we will of course avoid introducing unnecessary steps / delays. We would like Applicants to be familiar with the portal / epi authoring tool so that ePI can be submitted without delay when products are approved, hence the reason to engage at an early stage. More information will follow when the business process reviews are complete.
The new regulations regarding ePI should be the same across the EU. It would be very bad for the sake of harmonisation if every member state had different regulations.	Agreed, harmonisation and interoperability across the EU are key principles for ePI.
There is some excitement around the industry about ePI. On the one hand, many are excited about the potential of ePI, but on the other hand, too much is still unknown, especially on the subject of the creation and maintenance of the ePI.	We share the excitement around the potential of ePI and development is progressing in line with the agreed ePI key principles to ensure future benefits are realised. In order to move forward as efficiently as possible, we are focusing on Minimal Viable Product development and piloting. With this approach, we acknowledge that many aspects are not yet determined. With continual improvement and Agile processes, we will bring ePI into business sooner.

Question	Reply
When should we expect structured data to be implemented in the editor?	Reply copied from another question: Although the tool's field for Medicinal Product allows for free text, there are plans to link with PMS IDs. We connect with SPOR where data is available (and where there is benefit in doing so) and will continue do link to mastered data incrementally.

Regulatory Procedure Management – Variations Procedure on IRIS Platform

Question	Reply
What would be the scope for industry provision of content via upload in IRIS versus transmission via eCTD?	Thank you for your question! All eCTD/NeeS submissions, including responses will be still performed via the Gateway (using Delivery UI xml). However the goal is to abolish sending and receiving documents via Eudralink. This often includes draft responses and other documents exchanged during procedures, which may be included into eCTD/NeeS as relevant.
Is it foreseen to do the procedure management for all variations (CAPs and NAPs) in IRIS? In the moment there are lots of national procedure management portals and it would be nice to have only one portal to handle.	Thank you for your question! The project will replace and improve EMA procedure management system and EMA`s interaction with relevant stakeholders, on centrally managed procedures.
if the applicant can upload responses in the IRIS portal, does that mean that we will have to upload responses in the portal and also submit responses in eCTD via CESP?	Thank you for your question! All eCTD/NeeS submissions, including responses will be still performed via the Gateway (using Delivery UI xml). However the goal is to abolish sending documents via Eudralink. This often includes draft responses and other documents exchanged during procedures, which will be included into eCTD/NeeS as relevant.
As the Initial MA application form is generated on PLM in the future, will the IRIS system pull the application as well as product data directly to create the relevant procedure in the IRIS system?	Thank you for your question! Indeed, this is the along the vision we are advancing towards
When you say variations in IRIS do you mean PLM portal?	No, indeed we don't! We'll make sure to clarify this wherever we can. https://iris.ema.europa.eu/ is the secure online platform for handling product-related scientific and regulatory procedures with EMA, including variations and initial marketing authorisations. https://plm-portal.ema.europa.eu/ is the secure online portal for managing electronic Application Forms, electronic Product Information (ePI) and authorised product data (PMS) in the European Union, in collaboration with the European Medicines Regulatory Network.

Question	Reply
Will Health authority questions and responses also be handled in the system?	Thank you for your question! Only related to sharing of documents from EMA to Industry, collaboration between EMA and rapporteurs/assessors (Network) and submission of draft/working documents by the industry users. The goal is to decommission sending documents via Eudralink. Importantly, all eCTD/NeeS submissions will be still performed via the Gateway (using Delivery UI xml). Subsequently, the procedure information will be exposed to the Network and Industry portals.

Union Product Database (UPD)

Question	Reply
Will the file size that can be uploaded be extended in future? 10 MB is not much for some documents.	We asked users for examples and the largest files (PuAR, SPC, PL, labelling, etc.) provided were between 6MB - 8MB. As contingency we decided to extend to 10MB. This excludes the size of the VNeeS file. For VNeeS file the maximum size allowed soon will be extended to 6GB.
When will VNRA information be available using the API?	We are currently working on this and expect to be ready in Q2 2023.
Could the NCA be contacted via UPD for incorrect entries? Maybe that would increase the quality of entries	Yes, we kindly recommend to contact directly the UPD national contact points, available in the HMA website. The quick link to the document can be found here.
relationship between UPD and ePI, are documents available in ePI	For the ePI Minimal Viable Product, only human products are in scope, but all the tooling and standard have been developed so that ePI can be extended to vet products in the future.
Has the logout timer been tested with several tabs open of the UPD UI?	Automatic reset of the counter (logout timer) across several tabs open is not possible. The counter only "listens" to the events happening in the currently viewed UPD tab (and not across the browser tabs). Even if the user has two screens, 1st screen with UPD opened, 2nd screen with a different webpage, the counter will not restart when clicking on the 2nd screen.
what is the difference between VNRA status and submission status?	VNRA status is the status of each product + VNRA belonging to a VNRA submission: can be 'Pending, Approved or Rejected'. Submission status is the status of the complete submission (that can contain several products + VNRA codes). If we have at least one product + VNRA with status pending, the Submission status will be 'Pending'. If all products + VNRAs are approved - submission status is 'Approved'. If all products + VNRAs are rejected - submission status is 'Rejected'. If there are no product + VNRA with pending status but contains 'Approved' and 'Rejected' - submission status is 'Partially approved'.

Improved Regulatory User Journey for EMA Stakeholders

Link to user journey survey: https://ec.europa.eu/eusurvey/runner/UserJourneyMappingSurvey2023

Question	Reply
One item that would greatly improve the User Journey would be publish clear roadmap and timelines and to communicate changes e.g. in 2022, PLM eAF UAT phase 2 announced, then delayed, no longer taking place.	This is a general need across all product teams and is being progressed within each value stream. The importance of clear communication on timelines, releases and impact for industry and regulators is fully recognised and we are committed to sharing these as early as possible. Note that roadmaps are generally communicated at a product level in targeted events to the affected stakeholders, via the change and communication channels for that product.
Do you want survey responses per organization or from individuals?	Individual responses are desired to ensure that we get the richest learning from this exercise. We seek to understand what the user experience is like for a day-to-day user of the systems.
Are you considering to expand the scope outside of IRIS, to include all the PLM products?	This is an initial phase with a limited scope, already including some products outside of IRIS. Based on our experience and learning from this phase, our intention is to expand to other product teams and use cases in future. As User Experience is so important to successful digital transformation, we are investing to ensure that we can incorporate customer feedback and good practices across all the product teams.
Is EMA public website included in this user journey as well?	This is not currently in scope of this phase. The corporate website is managed outside of the Agile way of working at present. Note, however, that we work closely with colleagues in the teams responsible for the corporate website to benefit from expertise and design guidelines.

Monitoring Value Stream

European Shortages Monitoring Platform (ESMP)

Question	Reply
Will the ESMP data be integrated with IDMP (especially "Risk of supply shortage" and "Risk of Supply shortage comment")? How is EMA avoiding redundant submissions of data?	Data submitted to the ESMP will comply with the standards developed by the International Organization for Standardization for the identification of medicinal products and be based on the domains of master data in pharmaceutical regulatory processes, namely substance, product, organisation, and referential data, and with it avoiding redundant submission of data.
Ispoc is named in iris. Are there plans do also do the shortage submissions in Iris?	Shortage submissions would be done through the ESMP, which a standalone IT platform integrated in IRIS.
Is EMA working on an EU-wide process for notifying authorities (EMA/NCAs) in case of Risk of Supply Shortages?	Indeed, the scope of EMA's extended mandate focuses precisely on that. More information can be found on the EMA website: https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-management
Shortage of supply related data is in the scope of PMS for future implementation, will ESMP submission feed into the PMS update?	The ESMP will be using PMS data, including information on manufacturing and other relevant data elements.
In the future is there a plan for structured data import with schemas that can be used for validating, submit by an API	Indeed, interoperability will be a big focus for the ESMP and is already considered as part of the product's roadmap. The analysis on the interoperability will be started by the end of the year, along with the best means of achieving it.
Is it possible to update directly on the platform? Or only through the submission of the excel?	Submissions on the platform via a webform will also be possible. This was demonstrated in the Q3 2022 public demo, available online.
Is this for human only? For veterinary products this is already included in UPD	Indeed, this is only for human medicines
Why ESMP planned to implement for critical medicines only? Is there any plan for rest other product's shortages?	EMA has a mandate for monitoring shortages in the context of both crisis and preparedness - more information can be found on the EMA website: https://www.ema.europa.eu/en/about-us/what-we-do/crisis-preparedness-management

Critical Medical Devices Shortages (CMDS) Reporting System

Question	Reply
The integration between Eudamed and EMA is interesting, CTIS as well as CMDS, Will Actors be mapped to SPOR organisations, and will CMDS have UDIDI from Eudamed. Is there an API for CMDS allowing a NCA to download data?	Currently the development of an API is not foreseen for the first release version of the CMDS Reporting System. However, data from Eudamed will be gathered and used. more detailed functionalities can be explored and discussed for future developments of CMDS. In Article 22 of the Regulation (EU) 2022/123 it is explicitly mentioned, that, "to the extent possible, relevant information on critical medical devices and related manufacturers shall be gathered from Eudamed once it is fully functional". Therefore, relevant features will be developed. This will be part of a release beyond the first go live release of CMDS.

Veterinary Union Pharmacovigilance (UPhV) Database

Question	Reply
Will there be an updated user manual for the DWH?	Yes, indeed the user manual will be updated to include the new features.

Managing the Agency Value Stream

Experts Management Tool

Question	Reply
No questions received for this IT product.	