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Q&A Q4 2022 System Demo

Date: 21/12/2022

Location: Online, 09:00 - 12:00 Amsterdam time (CET)

Link: Quarterly system demo – Q4 2022 | European Medicines Agency (europa.eu)

Disclaimer

Below is a direct record of all questions asked through Slido.com during the System Demo and answers provided in writing.

Questions not asked through Slido.com were not captured. Questions that have no written answers below where either responded to verbally or did not receive a response during the System Demo event. Questions asked in the "General" room in principle did not address specific products and are not included below. Any product related questions asked in the "General" room were moved to the appropriate product room. Wherever this happened this is indicated in the question text.

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 Demo and are not official statements by the European Medicines Agencies or it partners.

Table of Contents

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Variations for Human Electronic Application web-form (eAF) – *formerly* "DADI" project & Product Management Services (PMS) – Product Lifecycle management Value Stream

Question	Reply
[MOVED FROM GENERAL] The data from xEVMPD to PMS- will that be validated data, i.e. data that may have been edited by EMA?	The Agency will migrate from xEVMPD to PMS the last non-nullified version of the product being submitted to xEVMPD database. This can be the last version being submitted by the user that has not been yet validated by EMA, unless the validated version is already available in the database.
[MOVED FROM GENERAL] The data from xEVMPD to PMS- will that be validated data, i.e. data that may have been edited by EMA?	*Not answered during the demo*
Authorization status: How is it transferred from xEVMPD (product level) to PMS (package level)? Will the same value be populated for all packages?	Depending on the authorisation country the authorisation is granted at pack level or medicinal product level. That means that MAH provides the records at this level as well. If records are provided at product level, only one pack will be created in PMS and therefore the Auth status will be the same for the pack and the product. In those cases where the records are submitted at pack level, the logic explained in the demo will apply.
Does the electronic variation form is now official and can replace the pdf form, or it still under demo?	The web-form can be used for official variations applications so it's more than a demo. However it is not yet required and we're not yet in the formal transition period as there are certain features that are not yet available in the web based eAF that are required in order to start the transitional period towards mandatory use. Only at the end of the transition period will the web form by mandatory and will the PDF no longer be available to use for variations. The transition will kick off in 2023.
Does the New MAH details immediately available on Portal or does it take time after variation approval?	The organisations come to the web eAF from OMS and normally these become available approximately 15 after the OMS update is made. With regards to newly authorised products, they will become available in the system once the status is our internal system Siamed is changed to 'valid' and indeed, there is some lag in between the authorisation of the product and the product becoming available in the system. I will add some information on this to the user guide. If you have a situation that you need submit a product that has been newly authorised and it is not yet available in the PLM Portal eAF, please use the interactive pdf form for now.
For the present and proposed, currently for the PI changes we show the changes with track changes. How does it work now as the text has to be entered in the box with very limited format possibilities? Thanks in advance for your response	In comparison to the interactive pdf eAF, the web eAF has some improved editing capabilities. It is possible to use all the most used editorial changes, such as different colours, bold, italics, underline, strikethrough and many more. It is, however, not yet possible to paste already edited text from different document into the form. Copy pasting edited text between present and proposed sections is possible. We are hoping to improve the editing process even further in the present and proposed sections.

Question	Reply
For variations: Will the MVP enable tracked change mode for the ePI? Or will the ePI updated after finalisation of the variation?	*Not answered during the demo*
I was wondering about the SPOR v2 API access (to PMS, SMS... i.e. read only on DEV to start) - as we only have SPOR v1 API access (to RMS, OMS) now.	*Not answered during the demo*
If we do not find our product in the eAF, what are the appropriate checks and corrections for the applicant?	For the moment, only Centrally Authorised Products can be found in the PLM portal eAF. A new data released is planned for the end of Q1 next year (2023) for Non-CAPs (MRPs, DCPs and NAPs). In the case you are not able to find your Centrally Authorised Product in the web eAF you should open a ticket in Service Now so we can investigate why the product is not linked to the correct MAH or what the issue is with the record. Please, remember that only Authorised Products can be found in the web based eAF through the PLM portal.
In relation to the implementation of the PMS, for national procedures, in which language should it be supplemented?	All the information can be found in Chapter 2 of the EU IG. Depending on the field, the language will be different. For example, full name or full indication text should be provided in the language of authorisation, but referentials and controlled vocabularies should be provided in English as captured in RMS. But as explained, all this information is provided in Chapter 2.
Is deactivating a form the same as deleting the incorrect form? Is there a way to delete a wrong form?	Deactivating the forms moves them to a different tab from where you can in future easily delete them. The deletion feature is not yet available in the system. The retention period for deactivated form is currently set to 1 year and forms in Draft and Completed status are set to 2 years. For now, the deactivated is the closest we have for deletion.
Is it possible to add a purchase order on the application?	Yes, indeed, under the Proof of Payment section has a field where the Purchase order number can be added. More information can be found from the user guide.
Is it possible to create an eAF including two different MAHs? For example for a shared MRP.	Yes, work-sharing applications with more than one MAH are possible. For now, we only have CAPs available in the system, but in future also NAPs including MRP/DCP products will be added. All MAHs need to be affiliated to the application in order to be able to add products from different organisations. Details on how to do this are available in the recently updated Portal Registration guide which is available in the Portal Forum.
Is it possible to create the form offline and upload as XML	For now, unfortunately this is not yet possible. The forms must be edited in the PLM Portal UI, and they cannot be changed outside the system. It is not yet possible to import XMLs into the system. We are looking to introduce some machine-to-machine functionalities in future.
It was said, that in PMS authorisation status is provided at package level. Is there a need to change something if we work on global level?	Even if you work at global level, PMS will require the submission of package information. This is already explained in Chapter 2 of the EU IG. For the moment there is no need to provide this information as we are not requesting enrichment of data. As soon as this information is needed, we will announce it and provide enough time to industry to perform the updates.

Question	Reply
it would be good to focus the demo on "what's new since the last demo". It feels like we've seen much of this before.	Thank you for sharing your feedback. We agree, that is the intention. However in the case of eAF much of the work has been fixes to existing features, hence we are retracing some of our steps.
NEWS folder - can this be devised into 2 parts? One for News, one for questions? In IRIS we have this 2 parts and it is very useful	Thank you for your comment. We're looking at how we can improve the communications and interaction features of the PLM Portal in the coming increment. We'll take your suggestion under advisement.
On slide 41, bullets 4 and 5 seem to be contradicting: what is the IDMP rule in terms of merge/split of medicinal products?	Points 4 and 5 are the current (4) and future (5) structure of the product. Right now, due to the structure in SIAMED, all the presentations are captured under the same MP. But those products are not following the IDMP rules as they need to be split based on the authorised full name. Once they are split, we will also assign the correct presentation to each of the new created products.
PMS: On slide 41, bullets 4 and 5 seem to be contradicting: what is the IDMP rule in terms of merge/split of medicinal products?	Points 4 and 5 are the current (4) and future (5) structure of the product. Right now, due to the structure in SIAMED, all the presentations are captured under the same MP. But those products are not following the IDMP rules as they need to be split based on the authorised full name. Once they are split, we will also assign the correct presentation to each of the new created products.
There should be a security measure when selecting the related MAH(s) and the products, so third parties cannot draw up and submit eAF without the consent of the MAH(s) affected.	In general, the PLM Portal eAF has very stringent access management features implemented. It could happen though that for companies where there are 'global' headquarters and colleagues have affiliation to multiple MAHs from different local MAHs, depending on their access levels, for example application coordinator, will be able to create a form for any of the MAHs that they are affiliated to. If no such affiliation is in place, it is not possible to create forms on behalf of other MAHs. If you have any specific case/concern where access to other organisations products is available, please raise a ticket via the service desk and we can investigate this case in detail.
Topic "Roles in Account Management and SPOR". For small and medium sized companies it would be good if there was a "super role", because in these companies often only one or 2 people take all roles.	Thank you for this feedback - the poll is now also open for you to comment.
When login in PLM portal we can only see MAH, we are affiliated to? So why we need to select MAH? Thanks	Good question, however, this was implemented as some business scenarios have multiple different organisations involved, for example work-sharing variations contain more than one MAH. Also, consultants and colleagues who work in global companies may have roles where they have more than 1 MAH available for them and it is important that they can indicate who the 'lead' MAH is for that given procedure.

Question	Reply
When PMS access (i.e. read only to Dev) will be provided to Software Industry?	PMS will be accessible via the User Interface or API connection. Both components with the complete set of functionalities (i.e. view, compare, edit, insert etc.) will be available based on the current plans by 2024. Nevertheless, as mentioned in a similar question, PMS data can already be seen through the DADI portal (only certain fields for CAPs products) and next year a new data released will expose also non-CAP products.
When PMS will be available for industry?	If you talk about the User Interface or API connection, this will be ready based on the current plans by 2024. Nevertheless, PMS data can already be seen through the DADI portal (only certain fields for CAPs products) and next year a new data released will expose also non-CAP products.
When trying to publish this eAF we get a Warning in Lorenz validator. Do we need to sign the form in PDF or we can submit as it is?	We are aware that some tools do indicate 'best practice' warnings when the web-based form is included. This is acceptable for now and it is not a reason for concern. We are not aware of any 'Fail' issues which would mean that an immediate change to the tools would be required. We are however, looking to update the validation criteria as soon as possible to remove the BP warning. With regards to the signature, we are currently discussing this with our legal colleagues, however, the use of signature is strongly recommended, but not mandatory. Forms submitted without signature for now will not be rejected. The exported forms can be signed using digital signature tools.
Why do I have to confirm if my product is orphan or not (Yes/No tick box)? As data is coming from PMS this should be already included as this information is part of PMS (as well as already xEVMPD).	It is not necessary, or even possible to confirm if the product is orphan or not. This data indeed is coming from PMS. The fields that currently relate to 'orphan' are under the additional information sections and they will be displayed when 'indication' is selected in the 'changes concern's'. The information relates to new indication and orphan market exclusivity. Unfortunately, for not, business rules to display these sections in more automated manner are not possible as it could be that new indication for existing product will add an orphan indication and on the other hand, these sections are not always required to be filled for orphan products.
why is the present section not pre-filled? EMA supposedly has all this information already in the database	The current version of the forms doesn't yet have the 'structured changes' sections implemented. However, in future, when we implement these sections, the present data will be prefilled where available and relevant, for example, manufacturers and ingredients, but of course many other details too.
Will further details of the upcoming releases including bug fixes be released on the EMA website? Can you confirm when it will be recommended to start using the new PLM eAF, once the majority of bugs have been fixed? Thank you!	At the moment details of releases are currently shared on https://esubmission.ema.europa.eu/cessp/cessp.htm and on the Forums of the PLM Portal. Releases and release notes, including bug fixes are shared through the Forum and published on the eSubmission website. We encourage you to try and use the form now. The moment where we formally recommend you use the form will be during the formal transition period. This will be in 2023.

Question	Reply
Will the Forum and Threads in PLM portal be monitored by EMA and queries answered or suggestions will be provided?	Yes, they will be, similar to the IRIS Platform. Note that for technical questions and issues with individual applications you should use the Service Desk though.
Will the industry be requested to verify/correct migrated data into PMS?	No. No verification will be required by Industry. Nevertheless, in case any discrepancies are found, industry will be able to make corrections to the data. During next quarter we are planning to give several webinars explaining the process to correct data in case it is needed.

Electronic Product Information (ePI) – Product Lifecycle management Value Stream

Question	Reply
Are there drop down fields (linked to RMS from SPOR) or only free text fields?	There are indeed drop-down fields for some elements, allowing users to select and re-use SPOR data.
Are there timelines available for implementation of ePI for CP, MRP/DCP and NP products?	ePI will be piloted in 2023, and an implementation phase will start in 2024. ePI will be rolled out for NCAs in a planned way, depending on readiness and resources starting with EMA/CAPs and early adopter NCAs. More precise timelines will be provided later in the project, as these depend on the progress of MVP development and the pilot.
As I understand, the Word files exported from the ePI editor do not contain tracked changes. If so, how could these exported word files be used for assessment? How do the Assessors recognise the changes?	In the MVP, we do not have track changes functionality, so a Word with track changes will still need to be provided for assessment.
As MVP will not have track changes and text comparison functionality: Will the tracked and annotated Word documents remain the master documents for Assessment and communication with Assessors?	Tracked and annotated Word documents will still be used for assessment.
Can changes made to the ePI be tracked? Track-changes are a must for proper review. Will it replace working documents in Word?	In the MVP, the working documents will still be used. As demoed today, the ePI could be created in the portal and exported to Word for submission in the working documents.
can several people (MAH) work on the same ePI (e.g. medical, PV)	Yes. We will be refining and explaining how to do this / any limitations before launch

Question	Reply
Can software vendors get access to the system	We will be determining access to the system in the pilot phase (H2, 2023), therefore please express interest by emailing ePI@ema.europa.eu
Can the FHIR upload capability (available in ePI) be shared with PMS and eAF for reuse, and efficiency?	ePI. eAF and PMS are all working in the same Agile value stream (Product Lifecycle Management) and all synergies are considered and indeed this functionality is under discussion.
Can we have different Co-authors for different languages?	Yes, indeed. An author can add different co-authors, to co-create the PI, or alternatively, some co-authors may be translators. However, co-authors are at the ePI level, and there are not different co-authors at the individual language level.
Can you give service provider access to the ePI section of the portal only, e.g. for them to provide a translation as ePI directly?	ePI specific roles can be assigned to service providers such as translators. One or more co-authors can be added to specific ePIs to provide translations directly.
Despite the modular structure is it also possible to work on a document as a whole?	There is a preview functionality, where the whole document can be displayed on a separate tab. If the section is edited in the editor, the preview tab can be refreshed to see the changes.
Does the the editor handle scientific notation	We have successfully tested various symbols and formulae with the editor.
ePI is only really delivering value when a significant majority of PI is in ePI format - Who will validate ePI if we create this for legacy products?	ePI can be created by the applicant for legacy products in the context of a variation. Once ePI is implemented, we intend to support creation as rapidly as possible to ensure a significant proportion of ePIs will be achieved as soon as possible.
For first compilation of the ePI, do we have to copy/paste all information, or can a structured product information, e.g. the Austrian accessible template, be used to upload in a structured way?	For the MVP, the information will need to be copy pasted or authored directly in the portal. An advanced feature of using a structured template can be considered in future.
For the Word rendition from ePI xml, what tech are you using, and will it be available as a service that can be called via an API?	It is currently not planned to make it available as a service, and the technology is being trialled and the final technology decision is not made yet.
For variations: Will the MVP enable tracked change mode for the ePI? Will the ePI updated after finalisation of the variation or will it replace the working documents?	Track changes is not possible in the MVP, and the working documents will still be used.
How are the timelines for ePI?	ePI will be piloted in 2023, and implementation phase will start in 2024. ePI will be rolled out for NCAs in a planned way, depending on readiness and resources starting with EMA and early adopter NCAs.
How can a version with track changes be created?	This is not offered in the MVP but is an advanced feature to be considered in future.

Question	Reply
How will epi connect to the application application form just demonstrated	The roadmaps are of course different, as eAF is live and ePI is in development, which will be followed by pilot. However, it is intended to maximise the synergies with ePI and eAF, we have started this by having both in the same PLM portal.
How you will know which coordinator to choose for next step? Will appear just one, when you will add your product in database?	There are two search tabs for selecting co-authors. The first tab will show users from your own organisation (who have an ePI role). You can select one or more. If you wish to add a co-author from another organisation, you would search under the second tab, using their full email address. As is the case with eAF, users will have to register in register.ema.europa.eu and request an ePI role
In a few words, what's the main purpose of the ePI initiative?	ePI will support point-of-need delivery of information on safe and effective use of medicines to patients and healthcare professionals. It will support, accessibility, analysis of PI data and administrative efficiency. ePI is an important factor in management of shortages and crises. This is well described in the ePI key principles: https://www.ema.europa.eu/en/electronic-product-information-human-medicines-european-union-key-principles
In ePI, is it possible to leave comments outside the actual PI text? Leaving instructions like „EVINN ADD DATA HERE" seem to bear a strong risk of accidentally being overlooked.	Indeed, users may not work like this, we have just done this for demo purposes to show 2 co-authors working on one ePI. For the MVP, comments cannot be added, but this can be considered for the future.
Interesting to see that the ePI has the ability to upload FHIR XML to populate the information. Could this same functionality be applied to the PLM DADI eAF portal?	All the synergies are considered, as eAF and ePI are working together in the same value stream and indeed this functionality is under discussion.
is anonymisation of the word document warranted?	Personal data is not stored in the exported Word file.
Is it also possible to upload word instead of FHIR for updating ePI?	This is currently not in scope of the MVP, as it is a very significant effort to convert from Word to the EU ePI Common Standard.
Is it expected/foreseen that some/many sections of the ePI will be directly populated by information from PMS (e.g. MAH, MA Number, Medicinal Product Name, Composition, Shelf Life...)?	In the MVP, ePI will be annotated with a PMS ID. Going forward the synergies with PMS will be optimised.
Is it planned to create APIs to allow company content handling systems to populate the data in the editor?	Creating the ePI via API will be considered and the outcome communicated in the future.

Question	Reply
Is it possible to add comments to an entry with the progress of editing?	We do not currently have commenting in the MVP, but it can be considered for the future.
Is it possible to compare two ePIs or will this be possible in future?	Document comparison is not in scope for the MVP. But indeed this would be considered as an advanced feature in future.
is it possible to reuse SmPCs by linking instead of copying them?	Please could you provide more detail on what is meant by linking?
Is the concept of creator and approver built into the system	There will be an approver role, and this is for the regulator. We will demo this in March.
Is the ePI editor using the draft standard in the background, and as such would it be possible to upload an ePI file created offline with another tool?	Yes, this is possible although (certainly at present) you must first create the ePI using the authoring portal. You can already create a completely blank ePI and export this as FHIR and subsequently upload a FHIR file that you may have created with another tool. Creating the ePI via API will be considered in the future.
Is the ePI tool available to all users now? If not, when it will be? Even in testing mode?	The tool is not currently available as we are actively developing it.
Is the system publically open for trying?	No, not yet. We are still actively developing the tool. To date, we have only opened it for a short UAT with a small sample of users
Is there a merge function in the editor, to allow uploading of offline revisions made in the MAH organisation's systems?	This functionality is not available in the MVP.
Is there no versioning in the Portal when uploading updated versions?	There is no versioning in the MVP, however this is an important functionality that is under consideration for future development.
Technically, the rich text we have seen in the editor, is Markdown?	We are using TinyMCE
The focus of the ePI MVP is upstream tasks (creation, update) to the SmPC. When will downstream processes be established, such as dissemination of the HA approved SmPC. Also will the dissemination to specific platforms be mandatory?	Indeed, it is correct that the focus is on creation. However, the MVP does also include the API for dissemination. We do not have specific details on dissemination to specific platforms at this point. However, maximising the dissemination of authorised information on medicines is a key benefit driving the implementation of ePI.
There is a possibility to import FHIR format, so the use of the online rich text editor is completely optional? One could create the FHIR resource offline in another system and then upload it.	Yes, using the editor is indeed optional. Certainly at present, you must first create the ePI using the authoring portal (to create the record). You can already create a completely blank ePI and export this as FHIR and subsequently upload a FHIR file that you may have created with another tool. Creating the ePI via API will be considered in the future.

Question	Reply
This is my first System-Demo. Can you please say again what MVP stands for? Thank you.	Minimal Viable Product. To be able to deliver a product that works and does what you need, advanced features which are ''nice to have" are not available. This increases the speed at which we can make a more basic product available.
Thus, we have to continue to prepare tracked Word files and use them as a template for updating the ePI? In conclusion, we have to maintain the classic working documents in Word and the ePI in parallel?	For the MVP, the ePI and classic documents will be maintained in parallel. In future, we are targeting a fully digital workflow.
We are heavily reliant on MS word for the creation and maintenance of SmPC and PL. MS Word functionalities like "track changes" and the possibility to compare documents are very important. Will we be able to continue to work with MS Word?	Yes, this is why we have implemented the Export to Word functionality. This will allow Word to be used for review, assessment etc.
What are the expectations from national competent authorities and the pharma companies with regards to ePI?	National competent authorities have endorsed the EU ePI Common Standard for use for ePI across the European Medicines Network. ePI will be implemented by EMA and early adopter NCAs initially. Then it will be rolled out across the network in a planned way considering readiness and resources of the NCAs. For pharmaceutical companies, in future applicants will be required to submit PI in ePI format.
What if multiple safety related variations ongoing parallelly, how to handle such situation in ePI?	The detailed business processes will be provided for use of ePI MVP in future iterations of the project, including handling of parallel variations.
What is ePI in context of PMS? Is it the same thing?	Both ePI and PMS use FHIR. However, PMS is fully structured product data, whereas ePI is a document, with all the aspects of a document: headings, content, document title etc. More details on ePI are available on EMA's GitHub site, and PMS on the EMA corporate website.
What is the purpose of System Demos if questions are ignored?	Sorry for the misunderstanding, the POs will try at their best to the questions in writing in herb. As we need to keep the timing as close as possible, so people have a chance to join and see the demo they are interested in. We will ensure next time we have more time for Q&As. Thank you for your understanding. Please feel free to enter your question, we are actively responding in Slido.

Question	Reply
What will be required by the applicant before submitting the first ePI variation for legacy products which do not have any existing ePI? e.g. a "baseline" submission of the current ePI?	The precise details of the variation where ePI can be introduced will be communicated in the implementation phase.
When submitting an ePI for a variation, will there be in future an automated comparison of old vs new text/tracking of changes, conducted in the back end?	This is not in scope for the MVP, but it is indeed recognised that it would be an extremely useful functionality for future consideration.
Who enter all the ePI in the database?	We are currently working on publishing to the repository and will demo this at the next PI.
Will ePI still be only text-base, or will it also allow explanatory animations/films, e.g. as instructions for use?	At present, and for the MVP, the editor currently caters for text, including sub and superscript, formulae, tables and images, although it does cater for links, i.e. a URL if the animation is published / hosted elsewhere. The use of different media will be explored, as it is a key benefit that ePI will offer. However, for the MVP, the ePI is simply the electronic version of the existing PI.
Will it be possible to include ePI into an existing RIMS system or does it have to be created online?	It is currently not possible to directly link to a RIMS. However, we have created an import FHIR functionality demoed today, with the intention of expanding this post-MVP.
Will maintenance of an ePI in the Portal supersede submission of SmPCs to EMA?	For the MVP, the plan is to introduce ePI just at the beginning and the end. In the future, we would aim towards a full digital workflow.
Will only the ePI editor be used in the future or will MS Word continue to be used for creation and maintenance of SmPC and PL?	For the MVP, Word/pdf are still used for eCTD submission and assessment. A full digital workflow is a future goal.
Will rather administrative sections, like MA-No, Productname, MAH be prefilled from SIAMED/xEVMPD/PMS?	In the MVP, we are using SPOR for aspects such as PI section headings, MAH, authority. The ePI will be annotated with a link to PMS. However maximizing the prefilling will be post-MVP.
Will the assessment of text changes be done using the ePI or will it continue to be done using Word files?	For the MVP, the assessment of text changes will be done using Word files as today. In future, a complete digital workflow is envisaged.
Will the edited ePI document exported to word show the changes made as track changes?	This functionality is not available for the MVP.
Will the ePI editor also offer functions like "track changes" and text comparison like MS Word?	Although we're aware of the importance of that feature, the MVP will not have a 'track changes' or text comparison
Will the ePI replace the hard copy SmPC and patient leaflet?	Replacement of hard copies is not in scope of the current project, which is focused on creation of the MVP for ePI creation and management.

Question	Reply
Will the ePI System effectively create a central database of approved EU PI? From where are the documents sourced (Article 57?)?	Currently a single FHIR ePI repository is being created for the MVP. The future repository structure is not yet decided. For legacy PI, ePI will need to be created for these, this could be done along with other changes in a variation.
Will the MVP or any subsequent version of it be linked to a submission in eCTD?	This is planned for the future.
Will there be guidance/instructions how the WORD file in the MAH system has to be prepared in order to get a FHIR message which could be uploaded into the ePI portal?	It is envisaged that applicants may wish to upload FHIR, and details of the FHIR file will be provided on the EMA GitHub site and in future guidance.
Will you be able to share the XML schema for ePI even if this will evolve	This is available on the European Medicines Agency GitHub page. Please note that the information on GitHub is currently under review and will be updated in Q1 2023 https://github.com/EuropeanMedicinesAgency/EU-ePI-common-standard
Will you make the ePI DEMO available after the webinar?	The EMA page will stay the same https://www.ema.europa.eu/en/events/quarterly-system-demo-q4-2022 and you should be able to re-wind the video in the YouTube window. I believe that the actual YouTube link will remain the same (and you can of course rewind / review / fast-forward) https://www.youtube.com/watch?v=AMX6-aydQxg
Would it not be safer if users would not change content of the ePI in Notepad++ (or any other editor), but instead can use in-house software that can than trigger an export of the changed FHIR message, to be uploaded in ePI again.	Indeed, as mentioned it is not envisaged that users would directly edit the FHIR, however today we have done this for demo purposes, to show that the file that Evinn modified was uploaded.

Emergency Task Force support – Research & Development Value Stream

Question	Reply
If PIP procedure had been entered it did not appear in the application form - has this issue been solved?	Thank you for inquiring. The issue is being handled by the development team and should be solved accordingly.
With the cases decreasing is mpox still a priority for the ETF?	The mpox was declared by WHO a Public health emergency of international concern. As such mpox is still listed as a declared PHE in IRIS - scientific advice submission forms which implies mpox is a priority. However, ETF can decelerate a procedure based on: premature evidence to address medical need, workload or lack of urgency. Therefore on a case-by-case basis the submissions related to mpox are accelerated or decelerated.

Inspections / Parallel Distribution – Monitoring Value Stream

Question	Reply
Access to the inspection was only for the registered person from the MAH is it now possible to have access for the administrator to all product inspections for the MAH?	Access to a given industry submission is granted to the MAH product contact/sponsor or QPPV once this is adopted at CHMP/CVMP. The Administrator can only approve access requests from your organization; however the product contact can add other managers to the submission who will be able to access the submission in IRIS. However, IRIS Industry Coordinator role has been implemented recently and this enables the user to access any submission/application made on behalf of an organisation once it is granted.
for parallel distribution it seems that the system is built to support leaflets with 3 languages. Are there cases with more than 3 languages?	Notifications for parallel distribution are submitted per product EU presentation and one country of destination or for several countries having the same official language(s). Product information therefore must be provided in the official language(s) of the country where the product is intended to be placed on the market. In the context of parallel distribution up to three official languages per country of destination (ex. Belgium) per notification are possible.
For Parallel import, only 3 languages can be selected to the documents. In Be, sometimes 4 languages are present...	Notifications for parallel distribution are submitted per product EU presentation and country of destination. In case of notification for distribution in Belgium, French, Dutch and German are considered the official languages required on the product packaging.
Is it planned to give access for originator MAH to view parallell importer submitted/approved information/documents for their CAPs in the portal?	It is not foreseen to grant such access for the MAHs.
Is the inspections portal Go live? Do we have to register to obtain notifications?	The IRIS inspections portal is live. The notifications are sent from IRIS system to the relevant inspectors and MAH product contacts or QPPV once the inspection is adopted at CHMP/CVMP.

Question	Reply
Which countries have 3 official languages?	In the context of parallel distribution trilingual EU member states are Belgium and Luxembourg
Will clinical trial inspections added in this portal? Will the clinical sponsors also get access?	GCP inspections as well as GMP and GVP are live in IRIS. Notifications are sent and access is granted to the product contact point and inspectors involved in the inspection, but not to clinical sponsors. For more information please see https://www.ema.europa.eu/en/documents/other/iris-guide-applicants-how-create-submit-scientific-applications-industry-individual-applicants_en.pdf

Veterinary Union pharmacovigilance (UPhV) Database MVP – Monitoring Value Stream

Question	Reply
To which users will the duplicate detection tool be available?	At the moment only EMA staff have access to the duplicate detection tool. Should wider access be needed, this is something that can be investigated.
Where we are aware of incorrect product mappings - what action should we take?	In the case of incorrect product mappings, please raise a Service Desk ticket.

Expert Database – Managing the Agency Value Stream

Question	Reply
Could this expert database be made accessible to industry members?	The Information that is in the expert database (DoI/CVs etc.) are available on the EMA website for medicines and management board and on the EC website for EXPAMED experts
sorry maybe I did miss this info. by when will the MVP be live?	The currently planned Go Live date is the 29th of March 2023.
The user interface has been demoed. Will there be also an API available, is so by when please? and also: only submit to EMA or also read? Can NCAs read all expert info related to their country?	There is not external API planed during the MVP. NCA contact points can export the list of experts that have been nominated by the NCA from the system at any time.
Which parts of the database will be made available to/usable for industry?	The Information that is in the expert database (DoI/CVs etc.) are available on the EMA website for medicines and management board and on the EC website for EXPAMED experts