Update webinar on Regulatory Procedure Management for Product Lifecycle Management on IRIS (13 February 2024) – Questions & Answers

Date: 13/02/2024

Location: Online, 10:00 – 11:30 Amsterdam time (CET)

Link: Update webinar on Regulatory Procedure Management for Product Lifecycle Management on IRIS | European Medicines Agency (europa.eu)

Disclaimer

This document contains a direct record of all questions asked through Slido.com during the Update webinar on Regulatory Procedure Management for Product Lifecycle Management on IRIS and their oral or written answers.

In principle this document will not be updated.

The responses represent the expert view of the Product team at the time of the webinar and are not official statements by the European Medicines Agency nor its partners.

Acronym key and glossary terms

API	Application Programming Interface
CAPs	Centrally Authorised Products
DCP	Decentralised Procedure
eAF	Electronic Application Form
eCTD	Electronic Common Technical Document
EMA	European Medicines Agency
ePI	Electronic Product Information
EU	European Union
FHIR	Fast Healthcare Interoperability Resources
IT	Information Technology
MAA	Marketing Authorisation Applications
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedures
NAPs	Nationally Authorised Products
NCA	National Competent Authority
PASS	Post-Authorisation Safety Studies
PLM	Product Lifecycle Management
PMF	Plasma Master File
PMS	Product Management Service
PSURs	Periodic Safety Update Reports
PSUSA	Periodic Safety Update Report Single Assessment
RPI	Research Product Identifies
RPM	Regulatory Procedure Management
RSI	Request for Supplementary Information
SIAMED	Sistema de Información Automatizada sobre Medicamentos
UAT	User Acceptance Testing
UI	User Interface
VNeeS	Veterinary Non eCTD electronic Submission

#	Question	Reply

1	How can a MAH know if one of their products has been selected by EMA for the first transition to IRIS? (in total there are 67 human generic products and 44 veterinary products)	Contact points from MAHs with selected products were approached directly regarding the transition of their products. MAHs which did not receive a communication were not impacted by the 1st roll-out.
2	Will it be possible to participate to the UAT before the roll-out for all CAPs?	All seven Subject Matter Experts from Industry are actively involved in the UAT sessions that are being handled before the rollout. Additionally, meetings with them are in place every 2 weeks to present and gather requirements for further developments.
3	Should the IRIS communication have a standard subject and/or standard email address to ensure auto forward works efficiently?	Yes, and we will provide in the IRIS guide the subject template of the emails.
4	If the person who submits is not the MAH contact person, how can they work on IRIS?	The MAH contact person, i.e. the user stated in MAA eAF section 2.4.3 - for the product becomes the default portal contact and submission manager in IRIS for the procedure to: • receive all EMA notifications/emails on the submission; • access the submission in the IRIS Industry Portal and follow the case until closure; • change the submission contacts and add users as managers/ contributors to access/ modify submission. Only individual email address of the MAH contact person is accepted in IRIS. Generic emails (e.g. regulatory@namecompany.com) are not accepted. Auto-forward rules will need to be set up within every organisation. Several other IRIS roles can be assigned within the organisation with different access roles (IRIS eAF Industry User Admin, manager, contributor, coordinator) to work on a procedure.
5	Will the submission of variation dossier via EMA gateway still be in place?	MAH's submission and responses to RSI continue via ECTD/VNeeS submissions. Only the documents which are currently exchanged via Eudralink are to be uploaded via the Industry IRIS portal.
6	What is the retention time of the EMA documents output in IRIS? Can these documents be accessed for finished procedures?	Following case closure, the documents on the EMA output folders will be set as records and will be available on the IRIS Industry portal.
7	Is the 1st roll out a phase test?	The first roll-out is not a phase test, it's a live implementation for a sub-set of 67 Human and 44 Veterinary centrally approved products.
8	How is the New Fee Regulation tied in with IRIS development and	The New Fee Regulation implementation represents a regulatory requirement. We do

	roadmap and why is this regulation deadline important for the deliverables of procedural handling on IRIS?	not plan to spend resources on making the necessary updates in the current systems where it can be avoided. Therefore, the aim is to have IRIS ready to accommodate the New Fee Regulation in time. Additionally, IRIS is extremely more adaptable to handling this implementation compared to EMA's current systems.
9	Will submission of regulatory procedures remain through Ectd/VNeeS?	The eCTD/VNeeS submissions of regulatory procedures remain as per the current process. However, documents exchanged currently via Eurdralink, following an initial submission, will be uploaded via the IRIS Portal. Following receipt of a successful submission, the EMA will create a case in IRIS, which will be visible to Industry and Network via the designated portals. The Industry users will interact with EMA on the relevant case via email and the Industry portal to: - view case status, - withdraw a case, - update case contacts/ contributors/ managers - retrieve documents sent by EMA and submit non-eCTD(NeeS) documents.
10	Can we have a general button to download the whole submission, including all documents, for archiving purposes?	Currently, there is the possibility to download all the documents from the Portal, together with the possibility to download a list of the outcomes.
11	How will IRIS support NCA processes to work with IRIS?	The RPM for PLM team meet with NCAs Subject Matter Experts on a regular basis to provide updates on developments for them to evaluate the impact on the national systems. A technical webinar will be held with NCA IT staff to explain this matter further and for them to take into consideration the IRIS new way of working into the national systems.
12	Will the MAH contact person need to manually add users to each submission to be able to read communications in IRIS?	There are different types of roles with different types of involvement within a procedure. Different roles need to be assigned to each individual submission, whereas the Industry coordinator is assigned to the company as such and has access to all submissions related to that organisation. For further information, please consult the guidance document.
13	What is the accurate definition of a Lead Product?	A Lead Product, whose concept is used for purpose of fees and portal contacts, is a product belonging to the MAH, which should receive the invoice, and that automatically includes in the portal the contact person indicated as the main contact. The contact can be changed anytime in the

		portal once information about the submission is received.
14	What is the plan to include more products to be managed on IRIS? Is the subset the selected products going to change soon?	At the moment, no further plan is in motion; the impacted MAHs will be contacted should the situation change.
15	Will the IRIS portal contact (i.e. person listed on the eAF) have to assign other users to access the procedure each time a new submission is made?	The portal contact is per procedure, per submission. There is however another role which can be assigned across the company that can view and access all submissions.
16	Is the IRIS portal only intended for CAPs?	In 2024, IRIS portal is only intended for CAPs. However, from next year, the IRIS portal use will extend to all centrally approved products and MAHs of NAPs if they are involved in a PSUSA, Referral, PASS, which are led by EMA.
17	How do you get a submission number for an upcoming procedure, and is that number automatically available within the gateway?	For Worksharing and type IA procedures including more than one product, the MAH will request a placeholder case number, in line with the current process. In the Cover letter, the MAHs are requested to indicate the "Lead product" within the procedure in order to assign the correct Industry portal contact and set up a lead MAH for payment-related activities. This number will be available for selection in the eSubmissions delivery UI.
18	Are the documents uploaded by the MAH immediately available to the Rapporteur?	Yes, the documents uploaded by Industry are visible to Rapporteurs and EMA immediately.
19	Will the linguistic review process change?	The linguistic review process stays as it is with a final upload on day 25 to the EMA via the Industry folder.
20	Will the product data (i.e., 'packaging", 'pack size') be sourced from PMS?	Yes, the product data comes from PMS via the IRIS view. A snapshot of the version of the product present at the time of submission will be shown.
21	Will the temporary out of stock reporting also become part of IRIS? Or will we continue to send the filled form via Email to EMA?	This is not part of the current implementation. Regarding the marketing status and supply chain issues, there are plans and currently ongoing implementations to move them to different portals and IRIS. More information on the matter will be provided in upcoming webinars.
22	Are there updates on how the ongoing move from submission documents to structured data submissions will integrate with the enhancement and scope-widening of IRIS?	This will be part of phase 3. We are currently waiting to have visibility for implementation and FHIR standards which will impact IRIS in phase 3, where we will improve and enhance our integrations and the way our systems communicate.
23	When a variation is submitted via eCTD, does it have to be linked to	The eCTD/VNeeS submissions of regulatory procedures remain as per the current process

	IRIS (i.e., upload the variation form)?	(including the eAF in the eCTD/VNeeS). Following receipt of a successful submission, the EMA will create a case in IRIS, which will be visible to Industry and Network via the designated portals. The Industry users will interact with EMA on the relevant case via email and the Industry portal to: • view case status, • withdraw a case, • update case contacts/ contributors/ managers • retrieve documents sent by EMA and submit non-eCTD(NeeS) documents.
24	For which processes is RPI fundamental?	For none, as the RPI is not used for our case management. It might have relevance in the future, when marketing authorisation application will be implemented.
25	Which contact person will be addressed in IRIS in case of PSUR (and other types of submissions) where there is no submitted application form?	For procedures with multiple MAHs which are standalone entities, unlike for worksharing, there will be a contact per MAH per submission.
26	Is there any change foreseen to the process and data related to the substance and research product identifiers?	This process is not covered by RPM.
27	Is there a maximum size of the documents to be uploaded by the Industry (for instance for big variations, with many updated documents)? Does the VNeeS folder need to be zipped to decrease its size?	There is no maximum number of files or global size. There is however a limit of 15 megabytes per file and it is recommended to upload individual files for each document instead of a single file. There is also a recommended file as the container for literature references if there are any. All the documents which are submitted to the VNeeS or eCDT will stay the same. For these applications, there will not be the need to reupload the documents; currently, there is only the need to upload the documents exchanged via Eudralink. For further information, please consult the Guidance Document.
28	How can we address the case numbering in IRIS mismatch with the way Procedures are dealt with in a lifecycle perspective?	There is a lifecycle on the eCTD so there is a clear sequencing on the submissions. On the portal, you will have the possibility to filter the cases and put together a lifecycle even if you do not have the same case number.
29	Are approval letters and final annexes uploaded to "Output from EMA" folder when the case is closed with positive outcome?	Yes, the output documents (i.e., outcomes documents, opinion assessment report…) will not change and they will be uploaded into the Industry folder instead of being received via message.
30	What will be the first procedures to be submitted via new IRIS	We are already managing procedures in IRIS for a subset of products (67 human and 44

	process? When is the cut-off date for submitting via this new process?	vet products. We started on 23 January 2024, so for the companies which are affected by this new way of working the procedure management in IRIS is already taking place. For the wider MAH group, the submissions in IRIS Q4 2024.
31	Will a functionality be developed for the NCAs to exchange IRIS case information, preferably in an automatic way?	The NCA users have a different access to the Network IRIS portal, from which they can access all information. Additionally, the active notifications will remain to the Rapporteurs or to any other case-related team members (i.e., core operators), who will also be able to access information from the portal. Improvements in terms of collaboration can also be included at a later stage.
32	Will the MAH be notified via email in case of updates within the IRIS portal (i.e., correspondence has been received, notification of the start of the procedure) or will the user need to monitor IRIS to determine if there are any updates?	The MAH will receive an email notification regarding the procedure status and, in addition to that, the MAH can also access the Industry portal and view the status and details of the cases.
33	Which role must have the contact by default?	Within the current set of contacts, it has to be an Industry portal contact authorised for all post-authorisation procedures. This is the portal contact as indicated in the electronic application of the initial marketing authorisation application under the section 2.4.3. Moreover, this contact will have an Industry manager role, and then industry users can decide if they would like to change the portal contact (i.e., in case of holidays or absences).
34	In the context of preparing for Human Variation Web based eAF: which field names will be affected by the new updates?	If it is related to the Lead Product concept, we are liaising with the eAF team to understand if in the electronic application form there is the need or requirement to indicate the Lead Product.
35	Will there be a difference in access to information based on Role for CA's when it comes to Rapporteur and Concerned (i.e., can everyone edit a report in IRIS?)?	IRIS has an integration with SharePoint system and working on SharePoint allows all users who have access to the application to edit and work on the documents. This will allow Network users and the EMA to work simultaneously on the same document and save time, and to always work on the latest available version of the document. Benefits are therefore increased, since currently there is only the possibility to work individually on a system and then a person needs to collect all the comments and feedback together.
36	Can PSURs for a medicinal product be submitted via IRIS? Will the Synplicity portal be	No, submission requirements will not change for the procedure types since IRIS is only a case management system.

	replaced by IRIS?	
37	Will response to RSI be submitted via IRIS by the MAH or via the gateway in eCTD format?	The eCTD/vNeeS submissions of regulatory procedures remain as per the current process. Following receipt of a successful submission, the EMA will create a case in IRIS, which will be visible to Industry and Network via the designated portals. The Industry users will interact with EMA on the relevant case via email and the Industry portal to: • view case status, • withdraw a case, • update case contacts/ contributors/ managers • retrieve documents sent by EMA and submit non-eCTD(NeeS) documents.
38	Issues regarding mismatched numbers are still present for inspections numbers (regulatory number *versus* inspection). Is it possible to avoid the double numbering new standards?	This issue is being targeted as to only have one case number, as explained in the Guidance Document. It would be formed by EMA slash code for procedure and random number. For PSURs we will need to understand if there will be a double numbering (one for procedure and one for case management), but this topic will be addressed later on when more clarity is provided.
39	For CAPs with one EU MAH and multiple local representatives: will the country regulatory functions have a view on access, on status of ongoing variations, etc. for the CAP they have in the country?	Typically marketing authorisation holders submit via Service Desk one form with all the product contacts, which correspond to the marketing authorisation application 2.3, 2.4, 2.5 contacts depending on the case. 2.3, is the contact for post-authorisation procedures: this contact is the default one for your submission. if you want to grant access to other colleagues (e.g., your national affiliates), they need to be affiliated to the marketing authorisation holder in IAM, and then they can be granted the role of contributor, but it has to be an individual action, case by case, from the marketing authorisation side.
40	How is the contact person reassignment in IRIS linked to obligations for the SIAMED portal?	The contact person for SIAMED portal is the portal contact for the product and will be by default on the case. On the IRIS portal this SIAMED product contact will have the liberty to update the contact of the manager for the case and the coordinators for the respective procedures.
41	Can the assigned manager/ contributor be from another company?	If this is a particular care in which there are two different companies working on the same case, the answer is yes, they can be assigned by the Industry administrator to that particular case). The only requirement is for the person to be associated with the company for which they

		would like to access the submission on the IRIS Industry Portal.
42	Does the IRIS super user have access to all submissions?	There is no such role for Industry, while the IRIS Industry coordinator has access to all submissions related to the organisation.
43	Will the PSUR repository continue to be available and in use?	Submission requirements and the EMA legal requirements will not change. We will move only the case management of these procedures to IRIS.
44	Will IRIS contain documents from NAPs, such as the case of PSUSA?	Yes, the normal case management documents (i.e., assessment reports, etcetera), will be shared from the EMA through the IRIS portal. However, the submissions from other companies will remain separate so that each company has access to their submissions only. If documents are shared, that will happen via IRIS Industry portal.
46	IRIS retains a connection with the current Common Repository. Will that connection stay in place (including the API), and how will that evolve considering eCTD 4.x?	IRIS is only a case management system, the submissions via the common repository eCTD/VNeeS will remain in place. There is no direct connection, we will refer to the submission in our IRIS case so that the connection to the related documents can be made.
47	When will the slides of this presentation become available?	The slides will be made available on the EMA website on the event page together with the recording of the webinar.
48	In case of any error in a document, do we need to reupload the submission or is it possible to correct the error in real time?	If the need to correct a document arises, it needs to be reuploaded since there is no possibility to access the document directly from the IRIS portal and work on it. Moreover, uploading a new document triggers a communication which is sent to the EMA, which was already working on the document containing the error.
49	Can MAHs do a full download of a closed case, including documents, emails, timetables, etc. from IRIS?	These requirements have been considered and will be prioritised accordingly in further improvements and developments.
50	Is IRIS for any procedure that the EMA is responsible for (i.e., submissions from NAP for PSUSA, SIGNALS, referrals)?	The case management will be in IRIS, meaning that the details will be available in the Industry portal for MAHs, while the submissions will remain the same via various means (eCTD, VNeeS…).
51	How is the PLM portal connected to the IRIS portal?	There are a few points to be considered: • the IRIS portal is mainly an EMA-oriented portal for EMA-led procedures for centrally approved products or nationally and centrally approved products depending in case of PSURs or referrals and which are managed by the EMA and visible in the Industry IRIS portal; • the PLM has a wider use as it is also a place for daily work for MAHs and other

		stakeholders related to NAPs and CAPs; • the PLM portal can be used to create electronic application forms, which are part of the eCTD submissions submitted via the gateway and received by the RPM Team. Only after the receipt of a successful submission the EMA will create a case in IRIS for the procedure, which are led by EMA for centrally approved products and refers PSURs and PASSs; • the PLM portal can also be used to create the pilot for the ePI, and it contains the product user interface.
52	Will PIP correspondence also be managed via IRIS since it currently involves Eudralink?	It depends on the context and what stage of the PIP you are at: Paediatric procedures are ongoing and onboarded onto IRIS, while when submitting a PIP as part of the regulatory procedure, this will be handled via the respective procedures.
53	Does the RPM affect also PMF exchanges?	Not at the moment, but we are looking into it; it is a priority-based sequencing but it is already present in the longer-term roadmap.
54	If a PSUSA procedure will be moved to IRIS as a case, will assessments template be available in both? Where will the assessors elaborate the report?	The case management will be in IRIS, which includes the documents and the collaboration on them. However, we will be mindful of the requirement of document storage and PSUR repository.
56	Will the invoice portal remain as it is or will it be replaced by IRIS as well?	IRIS is only a case management system, so submission and other systems will not change at this time.
57	Will the contact person mentioned in the eAF become the portal contact for only that particular variation or for all other variations as well for that procedure?	The contact person mentioned by the eAF for the product will become a portal contact for the procedure when this product is set up. For all variations where this product is set up as a Lead Product, the contact person will have access to all notifications and become by default an Industry manager. More than one manager can be assigned to the submission, and other roles with different responsibilities can also be assigned to that case. However, there is only one person and one email address as a portal contact, and their contact is shown on the EMA website and used for all communications. This allows the set-up of as many people as needed to manage the procedure and of several roles with different access rights to these submissions.
58	Considering IRIS is only for case management, will there be a link connecting IRIS and PSUR repository or will these two systems be independent?	The submission will happen outside of IRIS with the common repository. The case management, which includes working on the collaboration and on the assessment reports within the Network, will happen in IRIS.