RPM for PLM (Regulatory Procedure Management for the Product Lifecycle Management) in IRIS – Frequently Asked Questions and Answers

28 February 2025

Disclaimer

This document contains a direct record of frequently asked questions (FAQs) through Slido.com on regulatory procedure management transition to IRIS during the events over past months, complementing them. The FAQs are split per topic.

Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the RPM for PLM product team. The responses represent the expert view of the Product team and are not official statements by the European Medicines Agency nor its partners. For convenience, many technical terms are explained in the table of abbreviations at the beginning of this document.

For general inquiries, please contact the RPM for PLM team via the EMA Service Desk. For questions or comments around the content of this FAQ document, please raise a ticket via the EMA Service Desk.

Acronym key and glossary terms

API	Application Programming Interface
CAPs	Centrally Authorised Products
DCP	Decentralised Procedure
eAF	electronic Application Form
EMA	European Medicines Agency
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
NAPs	Nationally Authorised Products
PASS	Post-Authorisation Safety Studies
PLM	Product Lifecycle Management
PSURs	Periodic Safety Update Reports
SIAMED	Sistema de Información Automatizada sobre Medicamentos

Questions

Regulatory procedures' transition to IRIS

1. Which procedures is IRIS covering after January 2025?

From January 2025, all post-authorisation procedures submitted to the EMA on or after 20 December 2024 are managed in IRIS. The transition affects all Centrally Authorised Medicinal Products (CAPs) and Nationally Authorised medicinal Products (NAPs, MRPs, DCPs) for those procedures where the EMA acts as reference authority.

Post-authorisation procedures transitioned to IRIS are: Variations[1]; Article 61.3 notifications[2]; Marketing Authorisation (MA) Transfers; Periodic safety update reports (PSUR); Post-authorisation measures (PAM); Annual reassessments; Referrals; Post-authorisation safety study (PASS)/ Post-marketing surveillance studies (PMSS); Line extensions; Renewals.

Kindly note that the submissions steps are still done via the current systems, i.e., Gateway and PSUR repository, while **IRIS is used for procedure management only**.

2. Is the use of IRIS mandatory for CAPs?

The use of IRIS is mandatory for all products' EMA-led post-authorisation procedures submitted to the EMA on or after 20 December 2024.

3. What is the plan for transitioning additional regulatory procedures to IRIS?

The next procedures planned to transition to IRIS are initial marketing authorisation procedures for CAPs. A detailed updated roadmap with details on key milestones for 2025-beginning of 2026 will be released in March 2025.

4. Is the transfer to IRIS only affecting CAPs, or will NAPs/MRPs/DCPs be integrated in the future as well?

IRIS is designed for managing EMA-led post-authorisation procedures.

Post-authorisation procedures managed by EMA which include NAPs/MRPs/DCPs (e.g. worksharings with both NAPs/MRPs/DCPs and CAPs; single assessments of PSURs - which may exclusively pertain to NAPs; some referrals and PASSes) is managed via IRIS. For these specific cases, NAPs are also affected by the transition of post-authorisation procedures to IRIS.

In contrast, the PLM Portal operates differently, encompassing electronic application forms for both CAPs and NAPs.

5. Will MRP/DCP/NAP procedures transition to IRIS? If yes, when?

With the exception of the scenario mentioned in Question 3, management of MRP/DCP/NAP procedures will not be handled through IRIS.

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[1] For veterinary medicinal products, variations not requiring assessment (VNRA) are to continue to be submitted and managed via UPD

[2] For human medicinal products

6. What actions are required to perform in IRIS for submission of post-authorisation procedures on behalf of the MAH?

The process of submitting all regulatory procedures did not change and is still be performed via the current systems (i.e. Gateway and PSUR repository).

There is no submission creation in IRIS by industry users for PLM procedures. The submissions will be created by EMA based on the electronic application form included in eCTD sequence after technical validation and exposed to the industry portal under "Ongoing submissions". For more information please be referred to section 12 of IRIS guide for Applicants.

7. Does the transition to IRIS affect the linguistic review process?

There is no change to the linguistic review process itself. The MAH will provide the full set of annexes (as applicable) in all EU languages (incl. EN, NO and IS) to the Member States by Eudralink, with a copy to the Agency.

The MAH uploads the final translated documents through the IRIS portal at the end of the linguistic review process, rather than using Eudralink. The documents can be uploaded as separate files or as a zip-folder if the size of the document does not exceed 50 mb.

The translation timetable is visible within the IRIS portal in addition to the translations timetable document.

8. How are validation issues addressed in IRIS?

Validation issues are handled based on the nature of the issue. Some may be addressed within IRIS, while others may require additional steps such as submitting corrected documents/ additional information as per current process.

IRIS access & roles

9. What are the differences between the roles in IRIS?

As described in the chapter 5 of IRIS guide for registration and RPIs:

- **IRIS Industry Manager**: can create new applications, and edit, submit and withdraw the created applications or any other where the user has been specifically added as Industry Manager.
- **IRIS Industry Contributor** (this role is automatically assigned also to IRIS Industry Managers): can edit submissions where he/she has been added as a Contributor by a Manager.
- **IRIS Industry Coordinator**: users with this role can access any submission/application made on behalf of an organisation, and not only those where the user is the creator or has been added as a manager/contributor, with the functions of IRIS Industry Manager. Please note that this role does NOT allow to create new submissions of any kind: for that, it is necessary to also have the role of Industry Manager, for the same organisation.

10. Why do I need to request a role in IRIS if EC decision will still be shared via Eudralink?

All the communication related to the submitted post-authorisation procedures will be held with the "Submission Contact" (a.k.a. "Portal Contact") registered in IRIS. Only the EC decision will still be sent outside of IRIS to the MAH.

11. Can a single user have more than one type of role?

It is possible for one person to hold both "User Admin" and other roles, such as "Manager" or "Coordinator".

Please be referred to chapter 5 of IRIS guide to registration and RPIs.

12. Can a single user be affiliated with more than one MAH?

A single user can request affiliation to more than one organisation. For example:

- a user who works for a consultancy may request to be affiliated with his/her own consultancy organisations, but also to one or more additional pharmaceutical companies. This will allow the consultant to prepare and manage a submission on behalf of a pharmaceutical company.
- a user related to the mother company (HQ) has to be affiliated with MAHs which are local affiliates if the user is the contact person for the products related to the MAHs.

For further information please be referred to section 5.3 of the IRIS guide to registration and RPIs.

13. What role should I request in IRIS if I am a QPPV?

Any user who will be the main contact point to the procedure, also known as "Submission Contact" or "Portal Contact" should request IRIS Industry Manager role.

For more information please be referred to section 5.1 of IRIS guide to registration and RPIs.

14. How do I check what roles I have?

Please log in to the EMA Account Management Portal at https://register.ema.europa.eu. Click on "Manage Access". When "Remove access" tab is selected you are able to see your currently granted access.

15. I am not able to request a Manager role in IRIS, what do I do?

Please ensure your organisation already has IRIS Industry User Admin to grant you the role of the Manager. For further information please be referred of section 5.2 of IRIS guide to registration and RPIs.

IRIS and other portals

16. Does the IRIS transition mean variations submissions are made through IRIS platform rather than through the current EMA submission gateway platform?

No, IRIS does not replace the current submission Gateway. Both portals coexist, each serving specific functions. The current submission process through Gateway will continue.

17. Is IRIS replacing the PLM portal for all procedure types?

IRIS is not replacing the PLM portal. The two portals coexist and serve different functions. The PLM portal is for data submission, while IRIS is used for case management, including data interaction.

18. Is the web-based electronic application form part of the transfer of regulatory procedures to IRIS or is it a separate project?

It is a separate project. EMA has established the PLM Portal, which provides access to the web-based electronic application form for both CAPs and NAPs related procedures. The PLM portal hosts the form's creation and the submission package's gateway, whereas IRIS serves as the platform for the actual procedure exchange and work for CAPs, with the exception of the procedures mentioned in 3. As a result, distinct teams operate concurrently on the eAF and IRIS, even though they are both part of the Product Lifecycle Management Value Stream.

19. Do notifications related to Eudravigilance now go through IRIS, or do they still remain via Eudralink?

The processes related to Eudravigilance do not change and continue to be performed via the current systems.

20. Why are there different portals for creation, submission, and submission management?

The separate portals serve different purposes and have distinct protocols. We are actively working to enhance the user experience and streamline interactions between them to prevent duplication of processes and data input.

MAH contact point & communications on the procedure

21. What is the "Portal Contact"?

"Portal contact" (also known as "Submission contact") is the primary contact person from the MAH to whom all communication is sent by default for a given submission after Authorisation. For CAP products the default "Submission Contact" is the "Person/Company authorised for Communication between MAH and Authorities after Authorisation" as detailed in 2.4.3 of the application form within the current submission.

Only a single person can be designated as a submission contact for a case in IRIS. However, that individual can nominate additional Industry managers and reassign the "submission

contact" role as required, for example before a period of leave. For more information please be referred to section 2.4 of IRIS guide for Applicants.

As per previous practice, the Applicants and MAHs are required to notify the Agency of any upcoming changes to the following contact people as specified in the application form for initial marketing authorisation (sections 2.4.1-2.4.5 and 2.5.1.1). For human medicines, please be referred to the section 'Notifying EMA of changes to contact persons' of https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/contacting-ema-post-authorisation. For veterinary medicines, please be referred to the Notifying EMA of changes to contact persons (veterinary medicines) | European Medicines Agency (EMA).

22. Can the main "Submission Contact" be changed for ongoing procedure?

The "Submission Contact" role can be reassigned at any moment for ongoing submissions, and repeatedly, by any of the Industry managers associated to that submission but the EMA will send communications only to the default "Submission Contact" assigned in that moment.

For information on changing/adding a Portal contact to the existing Submission, please be referred to section 2.4 of IRIS guide for Applicants.

23. Can generic mailboxes be registered for "Submission Contact" (also known as "Portal Contact") and be used for communication?

IRIS does not support usage of the functional mailboxes. If your products currently list functional mailboxes, please update all product email addresses associated with responsible individuals within your organisation.

24. Can more than one contact person be allocated for a case in IRIS?

No, only a single person can be designated as contact person (Portal contact) for a case in IRIS. However, applicant can nominate additional Industry managers and reassign the "submission contact" role as required, for example before a period of leave of the "submission contact".

25. How are notifications managed in IRIS?

The IRIS portal/submission contact will receive an email notification from IRIS on successful case creation after the case is created in IRIS within 72 hours after the procedure submission via eSubmission portal.

In procedures where validation is performed, a notification will be dispatched once the validation outcome is available.

Whenever the EMA provides MAHs with a document (e.g. assessment reports, opinions) or a significant procedure milestone is reached, the designated contact person for a specific case receives an automatic email notification. This notification serves as a general alert indicating the presence of new documents or information that require their attention.

26. When will QPPVs receive notifications? What is their role in the procedure?

The QPPVs will receive notifications when they are the "Submission contact"/ "Portal contact" for the procedure (e.g. Referrals).

27. How will I receive communication on post-authorisation procedures in IRIS? How do I contact the EMA Procedure lead for ongoing cases?

The Applicants will receive all the communication related to the IRIS cases via email from the EMA IRIS email address EMA-IRIS@id.ema.europa.eu. The Applicant can contact the EMA Procedure lead by responding to the email sent by IRIS EMA corresponding to the ongoing procedure.

28. If a forwarding rule for notifications is set up within a company, can recipients still reply to EMA via email after forwarding? Is the token preserved?

The recipients of the forwarded email can still reply to EMA. When replying, please make sure to add the IRIS EMA email address (EMA-IRIS@id.ema.europa.eu) to the recipient list and not to delete the IRIS token (IRIS:XXXXXXXXXXXXX) from the subject line of the email.

29. Who will be the main contact point for PSUR procedures?

The main contact person for PSUR will be the contact person indicated in the submission of the PSUR and should have the IRIS Manager role in IRIS. For more information please be referred to section 5 of IRIS guide to registration and RPIs.

Documents in IRIS

30. How are document submissions managed in IRIS?

Users create electronic application forms within the PLM portal. These forms are then downloaded and submitted through the current submission process via the Gateway. Note that the eCTD sequence is manually linked to a specific IRIS case during case registration, so the link is not automatic.

The documents outside eCTD sequence should be submitted via the Industry Portal within the related case.

31. Can documents be submitted via IRIS after a case is closed?

Documents cannot be submitted after the case is closed.

32. How long do cases and documents stay available in IRIS?

Once a case is closed, you can still consult the documents submitted for that specific case. The retention of documents after case closure may vary.

33. How has the procedure number format changed in the IRIS system?

The procedure number format in IRIS has changed and now referred to as a "case number". The case number format in IRIS is:

{agency ID}/{process group type (case form)}/{unique case number (10digits)}

e.g.:

Human variations: EMA/VR/0000067181;

Veterinary variations: EMA/VRA/0000066521

Please refer to IRIS guide for Applicants for full list of case number formats per different type of procedure.

You can also see the column with the submission number. The submission number is equal to the case number for the PLM procedures with only one MAH involved in the case.

The submission numbers are different to the case number (the last 10 digits) for the PLM procedures with potentially more than one MAH involved in the case (e.g. PSURs, referrals). It allows each and individual MAH to manage individual submissions via Industry Portal independently for the same procedure.

34. What is PRD number in IRIS?

It is a new product identifier number in IRIS. The IRIS PRD number is a different number from the Article 57 database number.

Every product (authorisation product, medicinal product, packaged medicinal product(presentation)) has a unique PRD number in IRIS. PRD number is assigned when creating a new product in IRIS and remains permanent throughout the product lifecycle. There is no business meaning between the IRIS PRD number and IRIS case number.

Guidance & training

35. Where can I find training & guidance resources?

The **IRIS user guide** contains relevant information for Industry stakeholders to use effectively IRIS for Regulatory Procedure Management and will be constantly updated.

A **comprehensive training session** for MAHs took place on 12 November 2024 (presentation & recording available on event page).

Please note that you can also consult Public System Demo recordings where latest developed features are presented.

General information

36. How many days after submission via EMA Gateway will procedures be showing up on IRIS?

The notification on success/failure of the submission continues to be issued by eSubmission portal after the submission is performed. The IRIS portal/submission contact will receive a separate email notification from IRIS on successful case creation after the case is created in IRIS within 72 hours after the submission.

37. Are IRIS submissions created per MAH or per registration/country?

For worksharing procedures including both CAPs and nationally authorised products (MRP/DCP/NAP), one IRIS Industry submission is created for the lead CAP of the procedure.

For procedures with stand-alone submissions including nationally authorised products (MRP/DCP/NAP) (e.g., PSURs, referrals) IRIS Industry submissions are created per product.

38. How does the IRIS system handle data privacy and security concerns?

IRIS follows the same data privacy and security protocols as the EMA Account Management System (IAM). Only authorised roles within the organisation have access to specific case information.

39. Is there an API available for IRIS?

While there are discussions about potentially making an API available for specific uses by Industry, it is not currently available. The development team is exploring options.

40. Will the IRIS platform eventually replace the current repositories?

At present, the current repositories (incl. PSUR) will remain unchanged and separate. Future integration or changes will be evaluated as the transition progresses.