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

26 August 2026

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.

Please note that the screenshots provided herein are sourced from a testing environment and are not representative of actual live cases."

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
NAP	Nationally Authorised Product
PASS	Post-Authorisation Safety Studies
PLM	Product Lifecycle Management
PSURs	Periodic Safety Update Reports
RPM	Regulatory Procedure Management

Questions

Regulatory procedures' transition to IRIS

1. Is the use of IRIS mandatory?

Human and Veterinary domains

As of 1 September 2026, the use of IRIS is mandatory for **all EMA-led PLM procedures**. This requirement excludes ongoing procedures currently managed outside the system and variations not requiring assessment (VNRA) for veterinary medicinal products are to continue to be submitted and managed via UPD.

2. What is the plan for transitioning to IRIS?

Human and Veterinary domains

A detailed updated roadmap with details on key milestones for 2026-2027 can be accessed here.

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

Human and Veterinary domains

IRIS is designed for managing all EMA-led 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) are 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.

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

Human and Veterinary domains

With the exception of the scenario mentioned in Question 4, management of MRP/DCP/NAP procedures will not be handled through IRIS.

5. How shall I submit my PLM procedures for IRIS?

Human and Veterinary domains

The process of submitting all PLM procedures did not change and is still to 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/VNeeS 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.

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

Human and Veterinary domains

Until the further notice, there is a very minor change to the linguistic review process itself. The MAH continues providing 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.

Only the final translated documents are uploaded by the MAH 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.

7. How are validation issues addressed in IRIS?

Human and Veterinary domains

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 and other portals

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

Human domain

No, 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.

9. Is IRIS replacing the UPD portal for all procedure types?

Veterinary domain

No, IRIS is not replacing the UPD portal. The two portals coexist and serve different functions. The UPD portal is to submit, create, manage, analyse and maintain data on veterinary medicinal products and other related specific regulatory activities including variations not requiring assessment, volume of sales data for veterinary medicinal products and access to the Antimicrobial Sales and Use platform for collection of data on the volume of sales and on the use of antimicrobial medicinal products used in animals. While IRIS is used for product-related scientific and regulatory procedures management including scientific advise, veterinary signal management and post authorisation procedures.

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

Human and Veterinary domains

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

11. How PLM regulatory procedures are handled in IRIS, noting that gateway/eCTD/VNeeS submissions remain unchanged?

Human and Veterinary domains

Overview of the Process

1. Submission via eSubmission Gateway / PSUR Repository

- Document submissions—including eCTD/VNeeS sequences (e.g., variations, renewals, PSURs)—are still performed using the existing systems: the eSubmission Gateway or PSUR repository. IRIS does not replace these submission channels.

2. Case Creation in IRIS

- After submitting via Gateway, the EMA creates the case in IRIS using the eAF and dossier provided by the applicant. For PSURs submitted via PSUR repository, the cases are created few days before the planned start date of the procedure.
- These cases appear in IRIS under "Ongoing Submissions".

3. Managing Submissions in IRIS

Once the case is available:

- You can view and manage it under the "Ongoing Submissions" tab, assign managers or contributors, and track status.
- Non-eCTD/VNeeS documentation (e.g., additional documents outside the main submission) can be exchanged directly through the IRIS Industry portal.
- All IRIS-generated notifications (e.g. case creation, validation outcomes, assessment communications) are sent via email from **EMA-IRIS@id.ema.europa.eu**. Tokens in subjects must be retained if replying.

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

Human and Veterinary domains

The PLM Portal and IRIS operate as separate projects. The EMA established the PLM Portal to provide access to web-based electronic application forms for both CAP and NAP procedures. While the PLM Portal hosts form creation and the submission package gateway, IRIS serves as the platform for the actual procedure management and exchange for EMA-led procedures.

13. 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.

IRIS access & roles within the procedures

14. What IRIS Access do I need to obtain to use IRIS?

Human and Veterinary domains

Depending on your role in the PLM procedures, you must first obtain IRIS access for each organization (MAH ORG ID) on whose behalf you will be acting. Please secure one of the following access types:

- **IRIS – eAF Industry User Admin:** Can only assign/revoke the roles listed below to users requesting them for the organisation;
- **IRIS Industry Manager:** This role is mandatory for all MAH contacts who will act as the primary and default contacts for specific procedures in IRIS.
- **IRIS Industry Contributor.** This role allows users to assist the IRIS Industry Manager with specific submissions.

- **IRIS Industry Coordinator**. This role enables users to coordinate submissions at the organizational level. Coordinators can access any submissions or applications made on behalf of an organization, assign submissions to managers, and reassign submission or portal contacts.

  Additionally, Coordinators can view and manage contacts for their assigned organization's products.

  More details can be found in Chapter 5 of IRIS guide for registration and RPIs.

15. Why is IRIS access approval required prior the submission of the procedure?

Human and Veterinary domains

Once the IRIS–eAF Industry User Admin grants an MAH representative the IRIS Industry Manager role for a specific product, the EMA can assign them as the default MAH contact when creating procedures in IRIS.

This role also enables PSUR submissions via the eSubmissions portal, where the MAH contact person's IRIS registration is verified before the delivery file is generated.

16. What are the IRIS roles for the specific procedures?

Human and Veterinary domains

- **IRIS Procedure Manager:** An MAH representative holding the **IRIS Industry Manager** role for the product's MAH, assigned to a specific procedure. This user can view submission details, access documents shared by the EMA, submit procedure-related documents to the EMA, and request submission withdrawals. They can also assign other Procedure Managers or Contributors and reassign submission and portal contacts. Multiple IRIS Procedure Managers can be assigned to a single submission.
- **IRIS Procedure Contributor:** An MAH representative holding either the **IRIS Industry Contributor** or **IRIS Industry Manager** role for the product's MAH, assigned to a specific procedure. This user can view submission details, access documents shared by the EMA, and submit procedure-related documents to the EMA. Multiple IRIS Procedure Contributors can be assigned to a single submission.
- **Submission contact/Portal contact.** One IRIS Procedure Manager is designated to act as the Submission Contact (or Portal Contact), to whom all communications are sent by default for a given submission after authorisation. This role does not need to be requested via the EMA Account Management System; it is automatically assigned to the primary and default IRIS Procedure Manager assigned to the procedure.

  The Submission Contact (or Portal Contact) can be changed for any ongoing procedure by an IRIS Procedure Manager or IRIS Industry Coordinator at any time once the submission becomes available via the IRIS Industry Portal. Before a user can be designated as the new Submission Contact (or Portal Contact) for a procedure, they must first be assigned as an IRIS Procedure Manager for that submission. Each submission can have only one Submission Contact (or Portal Contact) assigned at a time.

  For more information please be referred to section 2.4 of IRIS guide for Applicants.

17. Can a single user have more than one type of IRIS access?

Human and Veterinary domains

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

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

Human and Veterinary domains

Yes, a single user can request affiliation to more than one organization.

To ensure successful IRIS access, the user's IRIS access role for the MAH ORG ID must match the product's MAH as registered under the PMS ORG ID.

19. What IRIS access should I request in IRIS if I am a QPPV or Regulatory Contact point (RCP)?

Human and Veterinary domains

Any user designated as the primary IRIS Procedure Manager or the Submission/Portal Contact for a procedure must request the IRIS Industry Manager role.

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

20. How do I check what IRIS access I have?

Human and Veterinary domains

Please log in to the EMA Account Management Portal at https://register.ema.europa.eu. Click on "Manage Access" and you will be able to see your currently granted IRIS access.

21. I am not able to request the IRIS Industry Manager role via EMA Account Management Portal, what do I do?

Human and Veterinary domains

Please ensure that your organization has an assigned **IRIS Industry User Admin** who can grant you the **IRIS Industry Manager** role. For detailed instructions, please refer to **Section 5.2** of the IRIS guide to registration and RPIs.

22. Why am I unable to see the submission even though I have IRIS access?

Human and Veterinary domains

There could be several reasons why a submission is not appearing on your IRIS portal account:

Mismatched Credentials: The email address you used to log in to the IRIS portal does not match the email address associated with your authorized IRIS access.

Solution: Ensure you are logging in with the correct credentials.

Missing Procedure Assignment: You have not been assigned a specific role for that procedure.

Solution: Contact your IRIS Procedure Manager or IRIS Industry Coordinator for the MAH to have them assign you to the specific submission.

Organization ID Mismatch: Your IRIS access is linked to an MAH ORG ID that does not match the MAH ORG ID associated with the product (as registered in PMS/OMS) for that procedure.

Solution: Request IRIS access for the correct MAH ORG ID, then ask your IRIS Procedure Manager or Industry Coordinator to assign you to the submission.

Procedure Not Yet Created: The EMA has not yet created the submission in the system.

Solution: Wait for the official email from the EMA regarding case creation or the start of the procedure (sent prior to the start date) before checking the IRIS portal.

Communications on the procedure

23. To whom at the MAH are all communications and notifications sent for a given procedure?

Human and Veterinary domains

All procedure-related communications and automated system notifications are sent to the email address of the MAH's designated Submission Contact / Portal Contact assigned to that procedure.

If the MAH Submission/Portal Contact copies other email addresses in their correspondence to the EMA, the reply from the EMA will only be sent to those individuals who hold active, registered IRIS access.

24. Can functional mailboxes be registered as a Submission Contact/Portal Contact" and used for communication?

Human and Veterinary domains

No, IRIS does not support the use of functional mailboxes. In line with EMA Account Management requirements, any MAH representative with an IRIS Procedure role must be registered with an individual email address. If your products currently list functional mailboxes, please update all product email addresses to those of the responsible individuals within your organization as per Chapter 2.17. Managing centralised product contacts of IRIS guide for applicants.

25. Can more than one MAH contact person receive emails and notifications for a procedure?

Human and Veterinary domains

No, only a single person can be designated as the Submission Contact / Portal Contact for a case in IRIS. However, the applicant can nominate additional IRIS Procedure Managers and reassign the Submission Contact role as required (for example, prior to a scheduled period of leave). Setting up automatic email forwarding rules within your internal email system is also recommended to ensure continuous coverage.

26. How are emails and automated notifications managed in IRIS?

Human and Veterinary domains

The designated Submission/Portal Contact for the procedure will receive an automated email notification from IRIS **within 72** hours of submission via the eSubmissions portal, confirming successful case creation. For procedures requiring validation, a notification will be dispatched as soon as the validation outcome is available. **For PSURs**, the initial email to the Submission/Portal Contact is sent just prior to the planned start date of the procedure.

Whenever the EMA shares a document (e.g., assessment reports, opinions) or a significant procedure milestone is reached, the assigned Submission/Portal Contact will receive an automatic email alert. This notification serves as a general notice indicating that new information requires their attention. A document shall be deemed received on the date the EMA transmits the notification email indicating its availability in the IRIS portal. This provision is without prejudice to the rules set out in Council Regulation

(EEC, Euratom) No 1182/71 of 3 June 1971 determining the rules applicable to periods, dates, and time limits.

27. How is the receipt date of documents defined?

Human and Veterinary domains

A document shall be deemed received on the date the notification email is sent by the EMA to the Applicant's/ MAH's IRIS **Submission contact/Portal contact** indicating that a new document is available in the IRIS portal. The foregoing is without prejudice to the provisions set out in Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits.

28. How does Applicant/MAH contact the EMA Procedure lead for ongoing cases?

Human and Veterinary domains

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 replying to the email sent from IRIS corresponding to the ongoing procedure by keeping the IRIS token (IRIS generated number at the end of the email subject: IRIS:XXXXXXXXXXXXXX).

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

Human and Veterinary domains

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:XXXXXXXXXXXXXX) from the subject line of the email.

30. Who will be the default Submission contact/Portal contact for PSUR procedures?

Human domain

The main contact person for PSUR will be:

For CAP product - Person authorised for communication between MAH and Authorities after Authorisation (referred in section 2.4.3 of the application form) for the CAP product;

For NAP product - the contact person indicated in the PSUR submission form with approved IRIS Industry Manager role. For more information please be referred to section 5 of IRIS guide to registration and RPIs.

31. Who will be the default Submission Contact / Portal Contact for Worksharing procedures led by the EMA?

Human and Veterinary domains

For EMA-led Worksharing procedures, the default Submission/Portal Contact will be the primary **IRIS Procedure Manager** associated with the **lead product** (or lead MAH) selected for the procedure.

Lead product is based primarily on the company responsible for the applicable payment, as indicated in the Electronic Application Form (eAF) and supported by the accompanying submission

documentation and correspondence. As part of this process, EMA verifies both the information provided in the application form and financial information on SAP customer ID number to ensure the correct lead assignment. These checks are done when application is submitted.

Where there is any uncertainty or inconsistency, EMA contacts the applicant directly to confirm the intended lead product before proceeding. This dual verification process helps ensure that the submission is assigned accurately and that the appropriate company and contact are associated with the procedure.

If you have a specific preference regarding which product should be designated as the lead product and who should act as the primary contact, we recommend clearly stating this in your Letter of Intent. Please note that the designated lead / preferred contact person should always be linked to the product belonging to the Marketing Authorisation Holder (MAH) that is responsible for the subsequent invoicing associated with the procedure.

Documents in IRIS

32. How are documents managed in IRIS?

Human and Veterinary domains

The documents outside eCTD/VNeeS sequence should be submitted via IRIS Industry Portal, uploading them under "Documents from Applicant" folder within the related case.

Documents sent from EMA are available under "Documents from EMA" folder within the related case.

Both folders are accessible when clicking on the arrow on the right of the screen for every case and selecting "View/Edit submissions" button for Ongoing submissions (Figure 1) and "View" for Completed submissions (Figure 2).

Figure 1

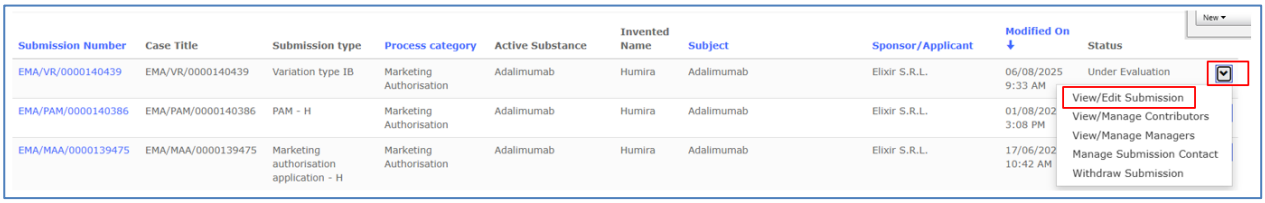

Figure 2

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

Human and Veterinary domains

There is no retention period set up for the cases on IRIS Industry Portal so far.

The retention period for the documents after the case is completed may vary as per EMA Records management and archives policy.

Procedure number in IRIS

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

Human and Veterinary domains

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.

Users can also view the Submission Number column. For PLM procedures involving only one MAH, the submission number is identical to the case number.

However, for PLM procedures that can potentially involve multiple MAHs (e.g., PSURs, referrals), the submission numbers will differ from the case number (specifically regarding the last 10 digits). This architectural setup allows each individual MAH to independently manage their specific submissions via the IRIS Industry Portal for the same overall procedure.

35. What is a PRD number in IRIS?

Human and Veterinary domains

The **PRD number** is a new, unique product identifier within the IRIS system. It is entirely separate from the Article 57 database number.

Every product (including authorized products, medicinal products, and packaged medicinal products/presentations) is assigned a unique PRD number upon creation in IRIS. This number remains permanent throughout the entire product lifecycle. Please note that there is no relational or business connection between an IRIS PRD number and an IRIS case number.

Guidance & training

36. Where can I find training & guidance resources?

Human and Veterinary domains

The **IRIS guide for Applicants** and **IRIS guide to registration and RPIs** contain relevant information for Industry stakeholders to use effectively IRIS for Regulatory Procedure Management and will be constantly updated.

All **training sessions** for MAHs (presentations & recordings) are available on EMA event page.

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

General information

37. What is the expected timeline for a procedure to become visible in IRIS following submission via the EMA Gateway?

Human and Veterinary domains

Procedures are systematically generated and visible within the IRIS Industry Portal within 72 hours of transmission through the eSubmissions gateway. Confirmation of successful case creation is systematically dispatched via an automated email notification to the authorized Submission Contact / Portal Contact.

Exception for PSURs: For Periodic Safety Update Reports (PSURs), the procedure will appear in the IRIS portal just prior to the planned start date of the procedure, rather than immediately after submission.

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

Human and Veterinary domains

For worksharing procedures that include both Centrally Authorised Products (CAPs) and Nationally Authorised Products (MRPs/DCPs/NAPs), a single IRIS submission is created for the lead CAP of the procedure.

For procedures involving standalone submissions of Nationally Authorised Products (e.g., PSURs, referrals), separate IRIS submissions are created per individual product..

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

Human and Veterinary domains

IRIS adheres to the exact same stringent data privacy and security protocols as the EMA Account Management System (IAM). Access to specific case or product information is strictly restricted to authorised roles within the designated organisation.

40. Is there an API available for IRIS?

Human and Veterinary domains

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.

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

Human and Veterinary domains

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