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

29 August 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 or raised via other EMA platforms over the 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.

The screenshots provided in this document are used from the IRIS system testing environment and do not represent the real-life 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
NAPs	Nationally Authorised Products
OMS	EMA's Organisation Management Service
PASS	Post-Authorisation Safety Studies
PLM	Product Lifecycle Management
PSURs	Periodic Safety Update Reports
SIAMED	Sistema de Información Automatizada sobre Medicamentos

Questions

Revision history

Date	Description
29/08/25	Updated all questions, indicating whether they pertain to human or veterinary domains. Revisions focused particularly on IRIS access.

Regulatory procedures' transition to IRIS

1. Which procedures is IRIS covering after January 2025?

Human and Veterinary domains

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.

2. Is the use of IRIS mandatory for CAPs?

Human and Veterinary domains

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?

Human and Veterinary domains

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 2026 has been released and can be accessed here.

4. 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 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/PMSSes) 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.

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

Human and Veterinary domains

[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

With the exception of the scenario mentioned in Question 4, management of MRP/DCP/NAP procedures continue to be handled by the relevant National Health Authorities and will not be handled through IRIS.

6. How shall I submit my post-authorisation procedures?

Human and Veterinary domains

The process of submitting all regulatory procedures has not changed 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 or after receipt of letter of intent for worksharing procedure.

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?

Human and Veterinary domains

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 procedural timetable document.

8. How are validation issues addressed in IRIS?

Human and Veterinary domains

Validation questions to MAHs sent by e-mail from the IRIS system and are handled based on the nature of the issue. Some may be addressed within IRIS, by replying via e-mail or uploading the documents on IRIS portal, while others may require additional steps such as submitting corrected documents/ additional information via submission Gateway as per current process.

IRIS and other portals

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

Human and Veterinary domains

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

10. 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 manages electronic Application Forms (eAFs), electronic Product Information (ePI), and authorised product data for the EU regulatory network, focusing on post-authorisation and product data management. In contrast, the EMA IRIS Portal is a dedicated platform for scientific and regulatory procedures and it is also a key submission management system for certain applications. While the PLM Portal handles product data and eAFs, IRIS serves as a centralised portal for a broader range of scientific requests and new submission processes.

11. 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.

~~11.~~ 12. 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.

13. How Product Lifecycle Management (PLM) regulatory procedures are handled in IRIS (EMA), noting that gateway/eCTD/VNeeS submissions—including PSURs via the eCTD repository—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. (iris.ema.europa.eu, European Medicines Agency (EMA))

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.~~ 14. 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

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 Question 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.

~~13.~~ 15. Do notifications related to Eudravigilance now go through IRIS, or do they still remain via Eudralink?

Human domain

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

Veterinary domain

For veterinary domain, UPhV is part of IRIS. The process for veterinary signal management is managed in IRIS and the notifications are sent from there accordingly.

~~14.~~ 16. Why are there different portals for creation, submission, and submission management?

Human and Veterinary domains

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.

IRIS access & roles in the procedures

~~15.~~ 17. What IRIS access do I need to obtain to use IRIS?

Human and Veterinary domains

Depending on your role in the PLM procedure first you need to obtain one of the following IRIS access for each and every organisation (MAH ORG ID) on whose behalf you will be acting:

- **IRIS ~~eAF~~/ PLM Industry Admin:** Can only assign other roles as below to those who request then for the organisation. Cannot access IRIS.
- **IRIS Industry Manager:** this role is **mandatory** for all MAH contacts who will be acting as a primary and default contacts for the specific procedures in IRIS.

- **IRIS Industry Contributor.** This role allows to assist the IRIS Industry Manager with the specific submissions.
- **IRIS Industry Coordinator**. This role allows to **coordinate the submissions at the organisation level**. Coordinator can access any submissions/applications made on behalf of an organisation, (re-)assign submissions to managers;

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

~~16.~~ 18. Why is IRIS access approval required before submitting the application?

Human and Veterinary domains

Once the MAH representative has IRIS Industry Manager role granted by IRIS~~ eAF~~ / PLM Industry Admin for the MAH of the product, then he/she can be assigned to the specific PLM procedures in IRIS by EMA as default MAH contact when EMA creates the procedure in IRIS after submission is received from the MAH.

For PSURs the approved IRIS access allows the PSUR submission via eSubmissions portal where registration to IRIS for the MAH contact person is verified before generating the delivery file.

~~17.~~ 19. What are the roles of IRIS in the PLM procedures?

Human and Veterinary domains

- **IRIS Procedure Manager~~:~~**

  The MAH person with **IRIS Industry Manager** access for the MAH of the product assigned to the specific procedure; Can view the submission details, access documents shared by EMA, submit procedure related documents to EMA, request the withdrawal of the submission. Assigns other Procedure managers / contributors, reassigns submission/portal contact. One case can have multiple IRIS procedure managers assigned.

- **IRIS Procedure Contributor.**

  The MAH person with **IRIS Industry Contributor or IRIS Industry Manager** access for the MAH of the product assigned to the specific procedure; Can view the submission details, access documents shared by EMA, submit procedure related documents to EMA. One case can have multiple IRIS procedure Contributors assigned.

- **Submission contact/Portal contact.**

  One of **IRIS Procedure Managers** indicated to act as a **Submission contact/Portal contact** to whom all communication is sent by default for a given submission. This role does not need to be requested via EMA Account management system, and it is automatically assigned to the primary and default **IRIS Procedure Manager** assigned to the procedure. **Submission contact/Portal contact** can be changed for all ongoing procedures by the IRIS Procedure Manager any time once the submission becomes available via IRIS Industry portal. Prior to being assigned as a new **Submission contact/Portal contact** for the procedure**,** the person needs to be assigned as IRIS Procedure Manager to that submission. One case has only one Submission contact/Portal contact assigned at a time**.**

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

~~18.~~ 20. Who is the default IRIS Procedure Manager and Submission contact/Portal contact to be assigned to the PLM procedure?

Human and Veterinary domains

The default IRIS Procedure Manager and Submission contact/Portal contact for the start of the procedure are one and the same MAH contact with IRIS Industry Manager role for the MAH of the product. It is assigned by EMA at the time of the procedure creation in IRIS and depends whether it is CAP or NAP product.

For CAP products (Human and Veterinary domain) – Person authorised for communication between MAH and Authorities after Authorisation (referred in section 2.4.3 of the application form);

For NAP products it depends on the type of the procedure:

- For PSURs~~,~~ (Human domain) -MAH contact person of the email address indicated in the PSUR submission form
- For referrals~~:~~ (Human and Veterinary domain) - QPPV registered in Art 57 database or UPD; Regulatory contact point (RCP) registered in the Eudravigilance database (Human domain); MAH contact point at national level; MAH contact point assigned to the procedure by the MAH (e.g. referrals triggered by MAH).

As per previous practice, the Applicants and MAHs are required to notify the Agency and NCAs of any upcoming changes to the above-mentioned contact people. Guidance on how to update different product contacts are available under "*Important checks for marketing authorisation holders (MAHs) to prepare the transition of post-authorisation procedures in IRIS"* available in the Home - news · IRIS

~~19.~~ 21. Why do I need to request a role in IRIS if EC decision will still be shared via Eudralink?

Human and Veterinary domains

All the communication related to the submitted post-authorisation procedure will be held with the Submission Contact/ Portal Contact assigned to the specific procedure. Only the EC decision will still be sent outside of IRIS to the MAH as per current process.

~~20.~~ 22. Can a single user have more than one type of role?

Human and Veterinary domains

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.

~~21.~~ 23. Can a single user be affiliated with more than one MAH?

Human and Veterinary domains

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 successful IRIS access, **user's IRIS access for the MAH ORG ID should match the MAH of the Product as in PMS ORG ID.**

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

~~22.~~ 24. What IRIS access should I request if I am a QPPV or Regulatory Contact point (RCP)?

Human and Veterinary domains

Any product contact who will be the main IRIS Procedure Manager and/or Submission contact/Portal contact to the procedure, should request **IRIS Industry Manager role**.

Any other product contact who supports the main IRIS Procedure Manager can request **IRIS Industry Contributor role.**

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

~~23.~~ 25. 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.

~~24.~~ 26. I am not able to request ~~a~~an IRIS Industry Manager role ~~VIA~~via EMA Account Management Portal, what do I do?

Human and Veterinary domains

Please ensure your organisation is registered EMA's Organisation Management Service (OMS) and/or your organisation has IRIS/PLM Industry User Admin to grant you the role of the IRIS Industry Manager. For further information please be referred of section 5.2 of IRIS guide to registration and RPIs.

~~25.~~ 27. Why cannot I see the submission even though I have IRIS access?

Human and Veterinary domains

It could be several reasons why the submission is not available on your IRIS portal account:

1. Email address you connect to IRIS portal is different to the email address you have IRIS access.

Solution: ensure you are connecting with the correct credentials.

2. You do not have any IRIS procedure role assigned for the specific procedure.

Solution: liaise with your IRIS procedure manager or IRIS Industry Coordinator for the MAH to assign you for the specific submissions.

3. Your IRIS access is associated to the MAH with different ORG ID in comparison to the MAH ORG ID associated to the product (as per PMS/OMS) in the procedure.

Solution: request IRIS access for the relevant MAH and liaise with your IRIS procedure manager or IRIS Industry Coordinator for the MAH to assign you for the specific submissions.

4. Submissions are not yet created by EMA.

Solution: wait for the email from EMA on the case creation or start of the procedure to be sent before the start date and then check the IRIS portal;

Communications on the procedure

~~26.~~ 28. To whom at the MAH all communication and notifications are sent for a given procedure?

Human and Veterinary domains

All procedure related communications ~~and automatic system notifications~~ are sent via email to the MAH's Submission contact/Portal contact ~~email address~~ assigned to the procedure.

In case if the MAH Submission contact/Portal copies any other email addresses in his/her email to EMA, the reply email from EMA can only be sent to the email addresses for the contacts who are registered with IRIS access.

~~27.~~ 29. Can functional mailboxes be registered for Submission Contact/Portal Contact" and be used for communication?

Human and Veterinary domains

IRIS does not support usage of functional mailboxes. In line with EMA Account Management requirements, any MAH representative with IRIS Procedure role needs to be registered with individual email address. If your products currently lists contacts with functional mailboxes, please update all product email addresses associated with responsible individuals within your organisation as per EMA procedure on Notifying EMA of changes to contact persons published on EMA website or check *Important checks for marketing authorisation holders (MAHs) to prepare the transition of post-authorisation procedures in IRIS"* available in the Home - news · IRIS.

~~28.~~ 30. Can more than one MAH contact person receive emails for the procedure in IRIS?

Human and Veterinary domains

No, only a single person can be designated as a Submission Contact/Portal Contact for the case in IRIS. However, MAH can nominate additional IRIS procedure managers and reassign the Submission Contact/Portal Contact as required, for example before a period of leave of the Submission Contact/Portal Contact.

~~29.~~ 31. How are emails and automated notifications managed in IRIS?

Human and Veterinary domains

IRIS Submission contact/Portal contact for the procedure will receive an email from IRIS on successful case creation within 72 hours after the procedure submission (except PSUR) via eSubmission portal (considering working days).

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

For PSURs the first email to Submission contact/Portal contact will be sent just before the planned start date of the procedure.

Whenever the EMA provides MAHs with a document (e.g. assessment reports, opinions) or a significant procedure milestone is reached, the assigned Applicant's/ MAH's IRIS Submission contact/Portal

contact for a specific procedure receives an automatic email notification. This notification serves as a general alert indicating the presence of new documents or information that require their attention. A document shall be deemed received on the date the notification email is sent by the EMA to 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.

~~30.~~ 32. 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.

~~31.~~ 33. How can Applicant/MAH contact the EMA procedure team for ongoing cases in IRIS?

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).

~~32.~~ 34. 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:XXXXXXXXXXXXX) from the subject line of the email.

~~33.~~ 35. Who will be the default Submission contact/Portal contact for PSUR procedures?

Human domain

The default Submission contact/Portal contact for PSURs will be:

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

Documents in IRIS

~~34.~~ 36. How are documents managed in IRIS?

Human and Veterinary domains

The documents outside eCTD 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

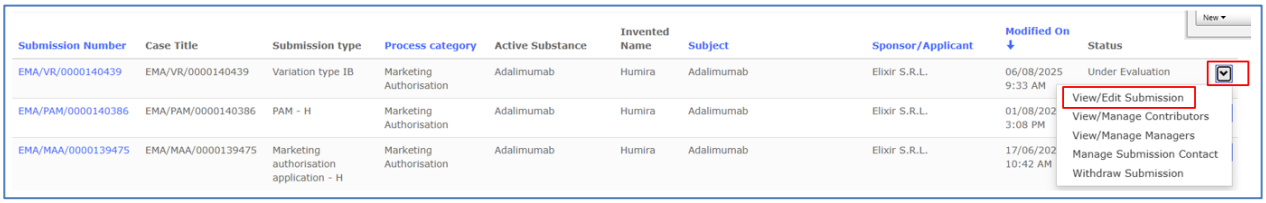

Figure 2

~~35.~~ 37. 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

~~36.~~ 38. How has the procedure number format changed in IRIS?

Human and Veterinary domains

The procedure number format in IRIS has changed and now referred to as a "case number~~/~~" or "submission number". The case and submission 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 requiring assessment: EMA/VRA/0000066521

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

The submission number is the same as a case number for the PLM procedures with only one MAH involved in the procedure.

The submission number is different to the case number (the last 10 digits) for the PLM procedures with potentially more than one MAH involved in the procedure (e.g. PSURs, referrals). It allows each and

individual MAH to manage individual submissions via IRIS Industry Portal independently for the same procedure.

~~37.~~ 39. What is PRD number in IRIS?

Human and Veterinary domains

The PRD is a unique identifier generated by the IRIS when a new product is created and 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.
While PRD is not an acronym, it is the internal label used by IRIS to indicate the system-generated product identifier.

The PRD remains essential for IRIS procedure management, as it supports internal processes and product types not managed under the ISO framework. It is used within the IRIS platform and other connected portals as a product reference.

Although Marketing Authorisation Holders (MAHs) are not required to track the PRD number outside IRIS, it remains a useful reference for internal tracking and communication purposes when interacting with the platform.

Guidance & training

~~38.~~ 40. Where can I find training & guidance resources?

Human and Veterinary domains

All guidance and training material on IRIS for the MAHs are available under Home - news · IRIS.

Any other regular updates or information for the MAHs are published on What's New in IRIS · IRIS page.

A **comprehensive training session** for MAHs took place on 12 November 2024 (presentation & recording available on event page) and a refresh webinar will take place on 30 September 2025 (registration link available here).

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

41. How to submit questions related to IRIS procedures?

- **For procedural questions** use the form Send a question to the European Medicines Agency;
- **Questions on specific procedures in IRIS** should be raised to EMA procedure team replying to email received from EMA/IRIS on the specific procedure.
- For **technical support** with IRIS use the EMA Service Desk (ServiceNow)

General information

~~40.~~ 42. How many days after submission via EMA Gateway will procedures be showing up on IRIS?

Human and Veterinary domains

The notification on success/failure of the submission continues to be issued by eSubmission portal after the submission is performed.

Within 72 hours (considering working days) after the successful submission for any PLM procedure except PSUR, Submission contact/Portal contact will receive an email on case creation and will be able to access the procedure via IRIS portal.

For PSURs the procedures are made accessible and email to Submission contact/Portal contact is sent just before the planned start date of the PSUR procedure.

~~41.~~ 43. Are IRIS submissions created per MAH or per registration/country?

Human and Veterinary domains

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 (e.g., PSURs, referrals) IRIS Industry submissions are created per product.

~~42.~~ 44. How does 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.

~~43.~~ 45. 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.