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

FAQs/Lines to Take

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 Procedures
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
UAT	User Acceptance Testing

Questions

Regulatory Procedures' transition to IRIS

1. Which procedures is IRIS covering after the 1st roll-out?

After the 1st roll-out on 23 January 2024 IRIS is set to handle Variations, Art. 61.3 notifications, and Marketing Authorisation Transfers procedures for a subset of human and veterinary medicinal products for which the relevant MAHs have been informed.

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

The transition to IRIS exclusively impacts CAPs. IRIS is designed for managing regulatory procedures with EMA, and thus, there are no current plans to extend its coverage to NAPs.

However, there is a small subset of NAPs, MRPs and DCPs that are included in procedures overseen by EMA. Examples of these include variations worksharings with both NAPs, MRPs, DCPs and CAPs, single assessments of PSURs (which may exclusively pertain to NAPs), as well as some referrals and PASSes. It follows that, for these specific cases, NAPs will also be affected by IRIS in future.

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

3. Will mutual recognition procedures and decentralised procedures transition to IRIS? If yes, when?

With the exception of the procedures mentioned in 2. , MRP and DCP procedures will not be handled through IRIS.

4. When will the use of IRIS be mandatory for CAPs?

The use of IRIS is mandatory for products selected for the first roll-out (on 23 January 2024). Consequently, MAHs overseeing these products will not have an alternative method for conducting regulatory procedures after the roll-out.

The transition to IRIS for the remaining CAPs will occur once all procedures have been transitioned to IRIS, enabling a comprehensive lifecycle management even for the most intricate products.

Nonetheless, the objective is to effectuate a transition that is expeditious while maintaining compliance with regulatory standards.

5. How are group variations and transfers selected for transition to IRIS?

Group variations and transfers are selected based on specific criteria, including whether products can be fully managed together in either IRIS or SIAMED. Worksharing procedures are managed accordingly.

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

The linguistic review process itself stays outside IRIS. However, MAHs have a translation timetable available in the IRIS portal and documents with translations are submitted directly through the Portal (no need of EudraLink).

Please note the linguistic review process will be adapted to IRIS, at the moment, only for the products in scope of the 1st roll-out (i.e. 67 Human and 44 Veterinary products). Procedures for other products will carry the linguistic review as per current process (including Eudralink).

7. 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 and Other Portals

8. 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.

9. 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.

10. 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 2. . 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.

11. 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

12. How are notifications managed in IRIS?

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 email notification. This notification serves as a general alert indicating the presence of new documents or information that require their attention. In cases of more complex variations, a notification is dispatched once the validation outcome is available.

13. 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".

Documents in IRIS

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

15. Can document be submitted after a closed case via IRIS?

Documents cannot be submitted after the case is closed.

16. How long do 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.

1st roll-out preparatory activities

17. Will there be a User Acceptance Testing (UAT) for IRIS?

Yes, a UAT was performed with Industry and Network Subject Matter Experts (SMEs) in November 2023 to ensure the system's functionality and usability.

18. Will there be training for IRIS?

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

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

General Information

19. 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.

20. 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.

21. Will the IRIS platform eventually replace the current repository?

At present, the current repository will remain unchanged and separate. Future integration or changes will be evaluated as the transition progresses.