

Training webinar on post-authorisation procedure management in IRIS for Marketing Authorisation Holders

12 November 2024, 10:00 – 11:30 Central European Time (CET) Webex Webinar





Please note that:

- You can access the **live broadcast for this session** on the **event web page** on EMA Corporate website
- This session is **being recorded** and **will be made available** through **EMA Corporate Website and YouTube channel.**



At certain points throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.

Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the <u>EMA Data</u> <u>Privacy Statement for Slido</u>.

Agenda









1. Join via the QR code or link



- 2. Send or upvote the questions you want to hear answered
- 3. Questions will be shown on the screen and managed live in the Q&A session





Procedures already available in IRIS:

- General procedures (requests for RPIs for new products, change of name and address of applicant)
- Inspections (GMP, GVP, GCP)
- Marketing status reporting
- Orphan designations
- Paediatrics procedures
- Veterinary signal management
- Scientific advice

- Parallel distribution regulatory procedures
- PRIME eligibility
- Product lifecycle procedures *
 - Variations
 - Marketing Authorisation
 Transfers
 - $\circ~$ Art 61.3 notifications

New procedures on IRIS from end of Dec 2024 (date TBC)**:

- Post-authorisation measures (PAM)
- Annual reassessment
- Referrals
- Post-authorisation safety study (PASS)/ Post-marketing surveillance studies (PMSS)
- Periodic safety update reports (PSUR)
- Line extensions
- Renewals

*For a subset of Human and Veterinary Centrally Authorised Products (CAPs)

**eCTD/VNeeS submissions will be registered in SIAMED until then



NOTE: Submission of all regulatory procedures of the product lifecycle will still be performed via the current systems (i.e. Gateway and PSUR repository)

4 For questions: www.slido.com Code: #MAHRPM



After today's training session, you will:

- Have a clear idea of the key actions for MAH users before the transition at the end of the year
- Know how to access EMA IAM, IRIS
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Key actions for MAHs before the transition



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| | | Procedure Management Platform | | | | | | | |
|--------------|------------------------------------|--|---|--|--|--|--|--|--|
| | | SIAMED | IRIS | | | | | | |
| Product type | All CAPs* and involved non-CAPs | Procedures submitted until end of December 2024 (exact date TBC**) | Procedures submitted from end of December 2024 (exact date TBC**) | | | | | | |

*Except H&V CAPs already transitioned to IRIS this year

** Please note a communication on cut-off date for specific procedures will be issued soon



NOTE: Submission of all regulatory procedures of the product lifecycle will still be performed via the current systems (i.e. Gateway and PSUR repository)





ALL Marketing Authorisation Holders (MAHs) to be registered in OMS

Check section 4 of **IRIS guide to registration and RPIs** for more information

Centrally authorised products (CAPs) contact person & non-CAP MAHs contact person for post-authorisation procedures has **EMA account** and relevant **IRIS Industry role**

How to request access? Via the **EMA Account Management System** for all IRIS Industry affiliated roles.

Instructions are available in the **IRIS guide to registration and RPIs**. It is crucial that all new submissions in IRIS created from CRM for PLM procedures reaches the correct portal contacts.



CAP MAHs update product contact information (see next slide)



NOTE: after raising request on Service Desk, please allow some time for updates to be approved, as there is a high volume of requests.



MAHs for **centrally authorised products** (CAPs) may need to **perform specific actions concerning product contacts** detailed below according to the situation:

Scenario 1 The product contact person remains unchanged, but linked to a generic mailbox

Update products currently list generic mailboxes **with personal email addresses** associated with responsible contact person.

How to change product contact email? Raise a ticket:

- a. In sub-section 'Service', select 'Identity and access management'
- b. In sub-section 'Service offering', select 'Eudra Common Directory ECD'

Scenario 2 The product contact person changes

Submit the updated form using this template: template_letter-change_contact_person_en.doc (live.com).

Instructions to submit the form:

- Human-use products: <u>Contacting EMA: post-authorisation | European Medicines Agency (europa.eu)</u>.
- Veterinary-use products: Notifying EMA of changes to contact persons (veterinary medicines) | European Medicines Agency (europa.eu)

CAP MAH product contact role

MAHs have the obligation to indicate a **product contact (eAF 2.4.3)** for communication between EMA and the MAH

- The product contact person will be used for as **default contact communication** regarding the IRIS case.
- At their end, the contact person for the MAH will **receive a notification** and will be able to **view the case data** and **collaborate with EMA** for documents exchange.
- The contact can also **add other users to view/collaborate** and can **change the contact person in the portal**, for a specific case.

The contact person must have **IRIS account** to **access** the case (via IRIS portal) and the **case documents** (e.g. preliminary and final assessment reports, Outcome, PRAC Recommendation)



EMA-led procedures managed in IRIS will include **non-Centrally Authorised Products** (NAP/MRP/DCP) for PSUR, PASS and Referrals.

MAHs of these products will have a **contact person for these procedures:**

- 1. When an EMA led procedure containing non-CAPs (e.g. PSUSA) is submitted, the MAH will **indicate a contact person at submission**.
- 2. In other cases, (e.g. referrals) EMA may use the QPPV (recorded in XEVMPD) as a main contact.

The contact person must have **IRIS account** to **access** the case (via IRIS portal) and the **case documents** (e.g. preliminary and final assessment reports, Outcome, PRAC Recommendation)

MAH contact person role

- The contact person will be used for **communication regarding the IRIS case**.
- At their end, the contact person for the MAH will **receive a notification** and will be able to **view the case data** and **collaborate with EMA** for documents exchange.
- The contact can also add other users to view/collaborate and can change the contact person in the portal, for a specific case.











- Answer to a quick quiz via Slido
- Ask any questions on what we just explained!



IRIS Access for MAHs



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Request Access to EMA account management & IRIS



| | h your organisation | Manage My Access > | Request Access for Organizations |
|--|----------------------------|---|----------------------------------|
| Search Criteria 02 Search Organisation | s 03 Sele | ct Roles 04 Additional Inf | o 05 Request Submitte |
| arch Criteria vide the search criteria to look for the desired anisations: ect one or more country by typing in the Country if eacherd countries will angear under the field | Country Italy x | ed + | |
| vide one of the other search criteria like the anisation name | | Other Criteria | |
| By default searches are performed in English (EN) Need more help? Have a look at the step by step documentation. | Organisation ID | Organisation Name Location ID Italian Medicines Age | City |
| | Postal code | Address | Language Required |
| | | | Reset Next |
| Search Criteria (02) Select Organ | isations 03 Sele | ct Roles 04 Additional Info | 05 Request Submittee |
| | | | |
| Organisations 1 results | Search | 1 | 0 |
| Organisations 1 results Id Name | Search Country Location | City Postal Address | Historical Records Acronym |

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Request Access (for CAP & non-CAP MAHs)

- Go to EMA account management portal: <u>https://register.ema.europa.eu</u>
- 1. Select **Single sign on** or **create an account** following the information on <u>this page</u>
- 2. Click on "Request Access for Organisations" and **look for** the MAH Organisation ID.
- **3. Select** one of the records representing the **Organisation.**



The system displays all available locations, but access is granted at Organisation level.

4. Request relevant IRIS Industry role(s)

- Pre-requisites for request:
- a. EMA account is active
- b. MAH registered in OMS
- c. Existing Industry user admin for the MAH

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| Role | Permissions |
|-----------------------------------|--|
| IRIS Industry Manager | Create new applications, edit, submit and withdraw the created applications or any other where the user has been specifically added as Industry Manager. Assign other managers / contributors to submissions to which the user has already access (that were created by the user or to which the user was added) Automatically assigned IRIS Industry Contributor role |
| IRIS Industry Contributor | Edit submissions where he/she has been added as a Contributor by a Manager - cannot create, submit or withdraw a submission. |
| IRIS Industry Coordinator | Access ALL submissions made on behalf of an organisation Assign submissions to managers and contributors |
| IRIS – eAF Industry User Admin | Assign the other IRIS Industry roles on EMA Account Management System to those who request then for the organisation. Cannot access IRIS, or create submission, unless the User also gives himself the role of Industry Manager |





Type "iris.ema.europa.eu" in your browser and add it as a favourite



Click on either "Sign In" (Fig. 1)



Step 4

Click on "EMA Account" (Fig. 2)

Enter **username** and password

- ✓ follow instructions to setup MFA (MultiFactor Authentication)
- ✓ it is suggested to download the Microsoft Authenticator app on your phone, for MFA (also works if there is only WiFi, unlike SMS)







First time you log in you are asked to set up your **Multi Factor Authentication**.

We advise to use a **mobile authenticator application** as more secure method.

In addition to MFA, we use also the **authentication context** (i.e. the device and the location from where you are authenticating) and **behaviour** (i.e. the time of the day or the frequency of your authentication) to determine risk factors.



Further guidance are available here



Something you **know**

- A password
- A pin

NOTE: a code on email falls in "Something you know" as to access an email you are probably using a password



Something you are



- Your fingerprint
- Your face
- Your eye
- Your voice

- A mobile phone
- An office phone
- A security Key
- A code generator



Perform procedure management in IRIS



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IRIS | Regulatory & Scientific Information Management Platform

| EUROPEAN MEDICINES AGENCY IRIS | New Submission Platform (Industry Portal) | Accessed by industry stakeholders | | Online web form replaces PDF Application form (for selected processes) |
|-----------------------------------|--|--|---|--|
| | | | • | View of submitted applications |
| | | | • | Pre-populated admin data |
| | New Evaluation/ | Accessed by EMA | • | Case Management |
| | (Dynamics 365 - CRM) | staff | | Manage Interactions |
| | New collaboration tool | Accessed by | • | CXMP + NCA Assessors + EC |
| | (Network Portal) | regulatory network | • | All cases (procedures) visible to everyone \rightarrow access to documents |
| | New Document | Accessed by EMA | • | Document sharing (viewing + editing) |
| | Repository (SharePoint CRM site) | staff and regulatory network | • | All users edit files here (no document attachments via emails/Eudralink!) |

What stays the same

- MAH's submission and responses to RSI via eCTD/VNeeS submissions
- **Timelines** and **active email notifications** on the main milestones of the submission (e.g. start of the procedure, requests for supplementary information (RsI), outcomes etc.
- Requests for withdrawal of single scopes in grouped variations (via email)
- Receipt of European Commission decision (via Eudralink)
- **Content** of the documentation
- Guarantee of confidentiality

Procedure Process flow for MAHs

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Different process types will have different data in their submission summary forms

| Submission summary for VRA-S | | | | | | | | | | |
|--|---|----------------------|-----------------------|------------|---|--------------------------------------|----------------------|-----------------------|---|---------------|
| Submission Summary | | | | | | | | | | |
| Applicant * | Timelines | | | | | | | | | |
| Virbac | Name (Timeline configuration) | TT trigger date ↓ | Evaluation outcome | Comment | | | | | | |
| EMA/VRA/0000133703 | Linguistic Review (H&V) | 05/12/2024 | | | ~ | | | | | |
| Process Category Marketing Authorisation | VRA-S - Phase 1 - 2024-2026 03/09/2024 Opinion This timeline has been created automatically using default Time table related to procestype. | | | | ~ | | | | | |
| Process Type VRA-S | Submissior | <mark>ı sum</mark> | mar | y for PSUR | | | | | | 0010 |
| Start date | Submission details | | | | | | | | Reference: EMA/PS | UR/0000126102 |
| 08/10/2024 Precise scope (case) To update to QRD template v.9. | Submission Summary Case Title | | | | | Timelines | | | | |
| | EMA/PSUR/0000126101 | | | | | Name (Timeline configuration) | TT trigger date ↓ | Evaluation outcome | Comment | |
| | Process Category Marketing Authorisation | | | | | PSUR_2024_2026_PRAC | 08/04/2024 | | This timeline has been created automatically using default Time table related to procestype: PSUR | ~ |
| | Process Type PSUR | | | | | | | | | |
| | Start date | | | | | | | | | |
| | 09/05/2024 | | | | | | | | | |
| Withdrawal reasons | | | | | | | | | | |
| | | | | | | | | | | |
| | EURD list | | | | | | | | | |
| | EURD list number PSUSA/00000010/202212 | | | | | Submission deadline 30/03/2023 | | | | |
| | Active substance(s) abacavir | | | | | PSUR submission frequency 3 years | | | | |
| | DLP 31/12/2022 | | | | | | | | | |

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- Variation Type II case
- PSUR case





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Next steps







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Q&A Session

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Closing



Further information

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EMA's approach to transferring procedures to IRIS



Stage 1 (2018-2021)

- Learning to use IRIS (Microsoft dynamics)
- Transfer relatively standalone procedures

Stage 2 (2022-2025)

 Move post-authorisation procedures to IRIS in a controlled manner to have a system ready for new fee regulation in 2025

Variations, Art 61.3, Transfers, PSURs, PAMs, Line extensions, Renewals, Annual Reassessments, PASS, Referrals*

Stage 3 (2025 onwards)

- Move marketing autorisation application procedure to IRIS
- Integrate necessary changes: improvements, create new opportunities for efficiency
- Integrate regulation & improve

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A controlled transition

Procedures will be developed and transitioned in phases in a lean and simple way and in the shortest possible time. This will:

- Enable a gradual learning curve & evolve with users' feedback
- Enable incremental migration of procedural data starting from products with lower regulatory complexity
- Allow to meet new fee regulation implementation deadline (Jan 2025)

*note: Development started with the lifecycle procedures to enable processing of high number submissions such as variations

Roadmap for 2024-2025



| | 20 | 24 | | | | 2025 | | |
|--|---|--|---------------|---|-------------------------------------|-----------------------|--|--|
| Q1 | Q2 | Q3 | | Q4 | Q1 | | Q2 | |
| 1 st roll-out* 23 Jan 2024 | | | | Ready for 2 nd roll-out 2 nd ro Q4 2024 Jar | oll-out** 1 2025 | | | |
| EPIC 1 UAT Fixes | Variat | ions, MA transfers, art. 61.3 | 3 selected pr | oducts - Maintenance based on busine | ss prioritisation *** | | | |
| EPIC 2 Development for remaining extensions, Renev | post-authorisation processes for all vals, Annual Reassessments, PASS, | (PSURs, PAMs, Line Referrals) | Testing | Pre-roll out | Maintenai | nce based on business | prioritisation | |
| What we are currently | working on | | EPIC | 3 Analysis & preparat (with migration of remaining proces | ory work dural data from SIAMED) | Ma | rketing Authorisation Application, etc. | |
| of products (67 H & 45 V products) from SIAMED | 2 (f | nd migration of products ≈50 H & ≈20 V products) om SJAMED | | 3 rd migration of products (all CAPs) from SIAMED | | | | |

*for variations, MA transfers and Art 61.3 for subset of products (CAPs)

**with Post-authorisation processes in IRIS for all CAPs (and involved NAPs) -> all EMA-led post-authorisation processes will be managed in IRIS in 2025

***Please note the ongoing development of RPM will happen epic by epic, with incremental improvements across the entire regulatory procedure management landscape.

| | Acronyms | | | Legend | | |
|-------------------------------------|---------------------------------------|--|-------------|----------------|------------------------|-------------------------|
| AVS: Assisted Validation System | NAPs: Nationally Authorised Products | PSURs: Periodic Safety Update Reports | | Milestone | Development activities | Migration activities |
| CAPs: Centrally Authorised Products | PAMs: Post-Authorisation Measures | UAT: User Acceptance Testing | | | Analysis & preparatory | A New Fee |
| MA: 46 rketing Authorisation | PASS: Post-Authorisation Safety Study | | | UAT activities | activities | Regulation |
| | | Classified as public by the European M | odicinos Aq | ODCV | | |

Key changes for Industry users

Case number use

#

Format: {agency ID}/{process group type (case form)}/{unique case number (10digits)} Examples: Human: EMA/VR/0000076556 Veterinary: EMA/VRA/0000076559

While the current format contains detailed information within the procedure numbers, IRIS offers this **visibility through dashboards and views** within the system

EMA communication format

- Emails sent from EMA to the Industry portal contact contain basic administrative information on the submissions and the link to the IRIS industry portal (no Eudralinks or attachment in the emails).
- Emails from EMA IRIS will always come from <u>EMA-IRIS@id.ema.europa.eu</u> and contain a routing ID.
- During the procedure, the document exchange (outside eCTD/ VNeeS) takes place via IRIS Industry portal, relevant for CAP and NAP MAHs (in case of EMA led procedures, e.g. PSUSA NAP)

MAH Contact person

 The MAH contact person for CAPs - <u>user</u> stated in MAA eAF section 2.4.3 - for the product, by default becomes portal contact and submission manager in IRIS for the procedure

Lead product for Worksharing procedures

- For WorkSharing procedures 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
 - ✓ set up a lead MAH for payment-related activities

Procedure withdrawal

Procedure withdrawal (whole procedure) to be requested via Industry Portal

Key changes for PSURs



| # | Process step | Scope | Change |
|---|------------------------|----------|--|
| 1 | (pre)Submission | NAP | Submission of PSUR via the Submission Gateway/PSUR repository remains unchanged. IRIS will be the case management system. Both CAP and NAP submissions are recorded in IRIS for PSUR procedures handled by the EMA. There is a need that all NAP products are registered in PMS as IRIS sources NAP product data from PMS. |
| 2 | (pre)Submission | CAP, NAP | A EURD entity is linked to the case which includes relevant details of the EURD list |
| 3 | (pre)Submission | CAP, NAP | Pharmacovigilance fee system will source procedure start date from IRIS instead of SIAMED and PSUR Filemaker. |
| 4 | Evaluation/ Outcome | CAP, NAP | Any document related to the PSUR (e.g. preliminary AR, outcome documents) is shared with MAH via IRIS Industry Portal (rather than Eudralink) |
| 5 | Outcome | CAP, NAP | The final version of the AR is uploaded in the PSUR repository for record keeping. |