EMA
EUROPEAN MEDICINES AGENCY

# Refresher training webinar on post-authorisation procedure management in IRIS for MAHs

30 September 2025, 10:00 – 12:00 (CEST)

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1. **Join at slido.com** with the code #IRIS-MAH or by scanning the QR code below.

2. Send your **feedback** on the session

Thank you!

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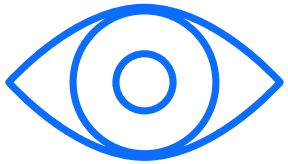
# Agenda

| | | | |
|---|---|---|---|
| 1 | **Welcome** | *10 min* | **Madalina Duta-Mare**, RPM for PLM Product Owner, EMA |
| 2 | **Context, roadmap overview and key changes recap** | *25 min (incl. Q&A)* | **Madalina Duta-Mare**, RPM for PLM SME, EMA |
| 3 | **Industry IRIS account management & roles recap** | *25 min (incl. Q&A)* | **Simona Griniene**, RPM for PLM SME, EMA |
| 4 | **IRIS current functionalities & demo** | *20 min* | **Madalina Duta-Mare**, RPM for PLM Product Owner, EMA |
| 8 | **Next steps** | *5 min* | **Madalina Duta-Mare**, RPM for PLM Product Owner, EMA |
| 6 | **Q&A session** | *30 min* | **Moderator: Irene Mumeni Urbani,** RPM for PLM Change Management Team |
| 7 | **Closing** | *5 min* | **Madalina Duta-Mare**, RPM for PLM Product Owner, EMA |

# Roadmap overview & key changes

# The vision behind the IRIS transition



IRIS as a **one-stop platform** that empowers stakeholders achieving **regulatory excellence** by managing EMA scientific and regulatory procedures

# Procedures currently managed in IRIS

## Already in IRIS

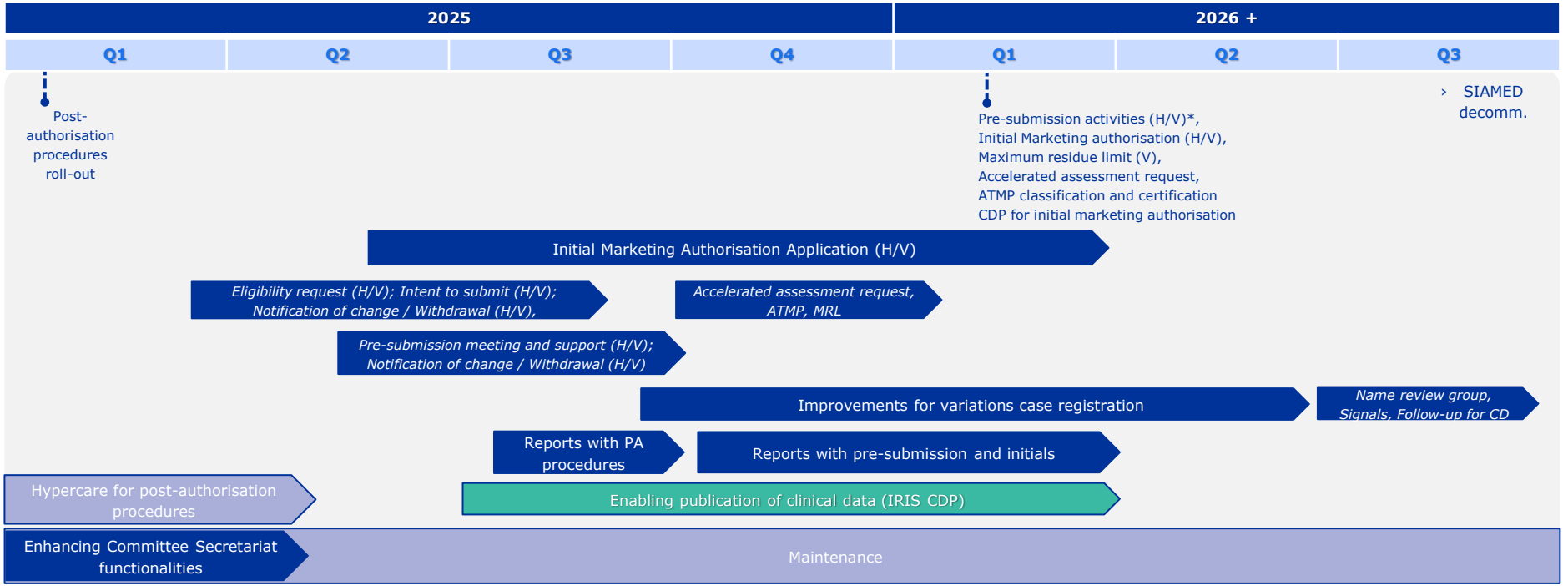
- General procedures (requests for RPIs for new products, change of name and address of applicant);
- Inspections (GMP, GVP, GCP);
- Marketing status reporting;
- Orphan designations;
- Paediatrics procedures;
- Veterinary signal management;
- Scientific advice;
- Parallel distribution regulatory procedures;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

- Variations;
- Marketing Authorisation Transfers;
- Art 61.3 notifications;
- 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

## Coming up in 2026

- Initial Marketing Authorisation Application (H/V); Pre-submission activities (H/V);
- Maximum residue limit (V);
- Accelerated assessment request (H/V);
- ATMP classification and certification (H);

# Regulatory Procedure Management in IRIS roadmap




*Please note the ongoing development of Regulatory Procedure Management in IRIS will happen in stages, with incremental improvements across the entire regulatory procedure management landscape.*

**Eligibility request (H/V); Intent to submit (H/V); Pre-submission meeting and support (H/V); Notification of change / Withdrawal (H/V)*

**Legend**

Milestone/ go-live | Development | Maintenance/ Hypercare | Enabler

**Acronyms**

- **CDP:** Clinical data publication
- **PA**: Post-Authorisation
- **MRL:** Maximum Residue Limit
- **CD**: Companion Diagnostic
- **ATMP:** Advanced Therapy Medicinal Products
- **H/V:** Human/Veterinary domains

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# Recap of key changes for MAHs working with IRIS

## Case number use

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

*Example:* EMA/**VR**/0000076556

While the former procedure number format contained detailed information, IRIS offers this **visibility through dashboards and views** within the system

## Communication format & procedural documents

- **Emails sent from EMA IRIS** to the Industry 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 EMA-IRIS@id.ema.europa.eu and contain a routing ID.
- During the procedure, the **document exchange** (outside eCTD/ VNeeS) takes place via **IRIS Industry portal**
- **No special characters in the name of the file to be uploaded in IRIS (except space, hyphen and full stop)**

## Primary MAH Contact person

**For CAPs**- user stated in MAA eAF section 2.4.3

**For NAPs** – depends on the type of the procedure (see slide 19)

IRIS user registered in IAM with individual email address (no functional emails)

## Lead product for Worksharing procedures

Based on the **indicated "Lead MAH"** in the electronic Application form, one of the products of that MAH is set up as a "**Lead Product**" in order to:

- ✓ assign the correct MAH Industry portal contact;
- ✓ set up a lead MAH for payment-related activities;

## Procedure withdrawal

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

# What stayed the same for impacted MAHs working with RPM in IRIS

**What stayed 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**

# Industry IRIS account management recap

# General access to EMA account management & IRIS

**Step 1** Go to **EMA account management portal**: https://register.ema.europa.eu

**Step 2** Select **Single sign on** or **create an account** following the information on this page

**Step 3** Click on “Request Access for Organisations” and **look for** the MAH Organisation ID.

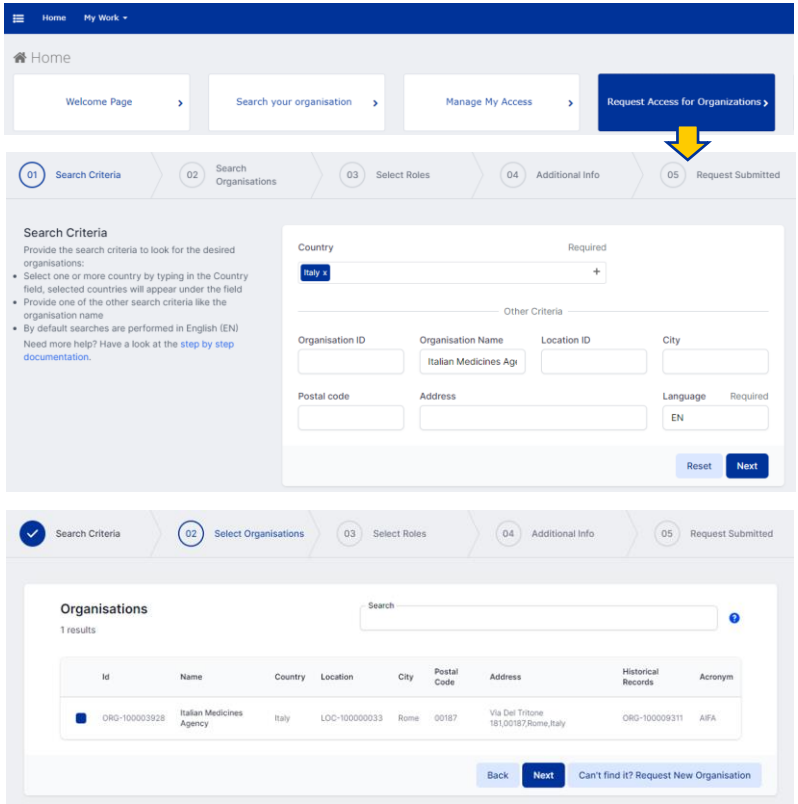
**Step 4** **Select** one of the records representing the **Organisation.**

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

**Step 5** **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*



# IRIS roles - automatic procedure access

| User Role (General level access) | Procedure role (Procedure level access) | Permissions |
|---|---|---|
| ***IRIS – eAF Industry User Admin*** | N/A | • **Assign the other IRIS Industry roles** on EMA Account Management System to those who request then for the organisation.<br>• Cannot access IRIS, or create submissions, unless the User also gives himself the role of Industry Manager. |
| **IRIS Industry Coordinator** | N/A | • **Access ALL submissions** made on behalf of an organisation.<br>• **Re-assign submissions** to managers and contributors (in case of absences, leaves).<br>**Tip:** Recommended to have **more than one** Coordinator. |

# IRIS roles - assigned procedure access

| User Role (General level access) | Procedure role (Procedure level access*) | Permissions |
|---|---|---|
| **IRIS Industry Manager** | IRIS Procedure Manager | • **Create new** applications, edit, submit and withdraw the created applications.<br>• Can **be assigned** as **Primary IRIS Procedure Manager** and **IRIS Procedure Portal contact** to the PLM procedure when case is created.<br>• *Automatically assigned IRIS Industry Contributor role* |
| | IRIS Procedure Portal contact | • **Receives all IRIS communication and notifications via email.** |
| **IRIS Industry Contributor** | IRIS Procedure Contributor | • **Edit submissions** where he/she has been added as a Contributor by a Manager or Coordinator - cannot create, submit or withdraw a submission. |

# How MAHs IRIS users are assigned to the procedures?

## 1 Pre-requisite

Have a **general level access user role for the MAH of the product** *(IRIS Industry Manager, IRIS Industry contributor)* granted after raising a **request on EMA account management portal** *(as explained in slide 14)*

## 2 Obtaining access to the specific procedure

- **For new procedures:** when a case is created by EMA, the MAH contact is automatically assigned by EMA based on the product type and procedure *(as explained in the next two slides)*.
- **For all ongoing procedures:** the MAH can update or add contacts via the IRIS Industry portal *(as explained in the next two slides)*.

# Procedure level access for CAP MAH contact

## Who is the primary MAH Contact person in IRIS for CAP MAHs?

The person authorised for communication with the Agency (as in section 2.4.3 of the application form) and with **IRIS Industry Manager user access** for the MAH of the product **(Product ORG ID = IRIS access ORG ID)**

## How to change the CAP contact?

### Scenario 1

The **product contact remains the same**, but is now linked to a functional mailbox → need to **link a personal email** to this contact.

**How to change the product contact email?**

**Raise a ticket**:

1. In sub-section 'Service', select 'Identity and access management'
2. In sub-section 'Service offering', select 'Eudra Common Directory – ECD'

### Scenario 2

**The product contact person changes** - Submit the updated form using this template

**How to submit the form?**

- Human-use products instructions.
- Veterinary-use products instructions

# Procedure level access for non-CAP MAH contact

## Who is the primary MAH Contact person in IRIS for non-CAP MAHs?

- For PSURs, contact person indicated in the PSUR form (Human 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)

## How to change the non-CAP contact?

- Register as a QPPV and regulatory contact point for a MAH, following the process described in the section **Registering individual users of the** EudraVigilance: how to register webpage
- Create a link between the authorised medicinal product (AMP) and the QPPV in the Art57 database,by referencing the QPPV Code assigned to the QPPV in the AMP. Instructions are in section **1.2.5.** of Chapter 3.II: XEVPRM user guidance for MAHs
- Update QPPV information reference in an AMP entry in the Art57 database following instructions in section **2.1.** of Chapter 3.II: XEVPRM user guidance for MAHs
- Liaise with NCA to update the MAH contact person at NCA level

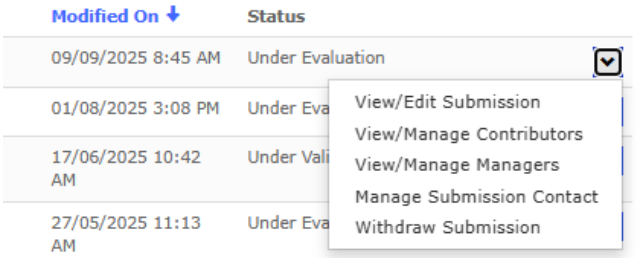
# How to change the MAH procedure contact for ongoing procedures

## Who can change/add the contact?

- MAH Industry Coordinator;
- IRIS Procedure Manager of that specific case;

## How to change the contact via IRIS portal?

- Select the case you want to change the contact for;
- On the right side of the screen click on the arrow and select which contact you want to change;
- Click on “Add” button and select the new contact name from the list of IRIS users approved by the MAH of the product;



# How to access the IRIS Portal for the first time

**Step 1** Type "iris.ema.europa.eu" in your browser and add it as a favourite

**Step 2** Click on either "Sign In" (Fig. 1)

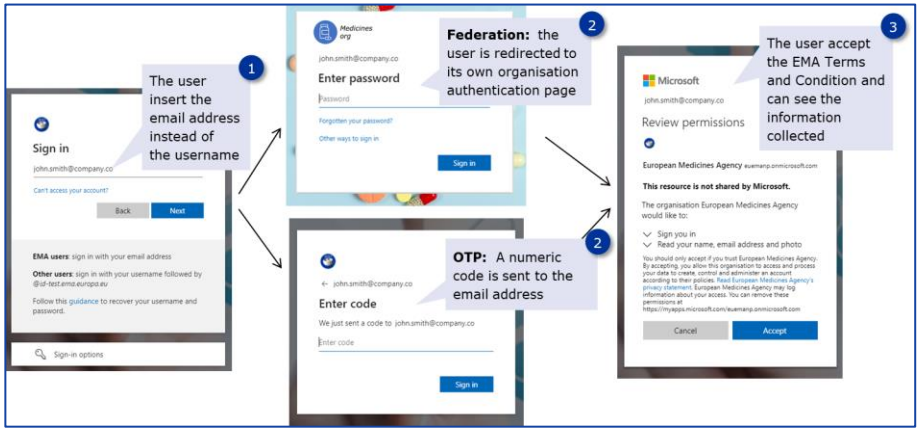
**Step 3** Click on "EMA Account" (Fig. 2)

**Step 4** Enter credentials (Fig. 3)

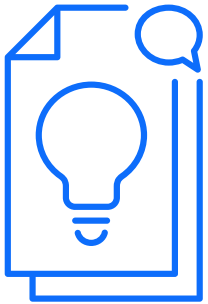
***Figure 1***


***Figure 2***


***Figure 3***



# Tips for MAHs to work with IRIS



- Before submitting the procedures **ensure that primary MAH contact has IRIS access** for the MAH of the product (ORG ID);
- **Assign more than one IRIS Industry Coordinator** to manage access to the cases and documents in IRIS during IRIS procedure manager's and portal contact's absences;
- **Change/ add** procedure contacts directly **via IRIS portal**;
- Note that PSUR procedures are made available in within a 2–4 day window around the start date of the procedure.

# IRIS current functionalities & demo

# Demo time

- Recap overview of key IRIS functionalities for procedure management in IRIS
- Assign managers to ongoing and closed cases *(not yet in production)*

# Next steps

# How to stay informed on IRIS developments

## IRIS Forum

Check:

- News
- Events announcements
- Downtime comms

Check regularly

## PLM Newsletter

- See planned IRIS activities for upcoming quarter
- **Subscribe** here

Receive via email quarterly after subscription

## Quarterly System Demos

- See the latest developments
- Give your feedback on features and priorities
- **Next system demo:** Dec 2025

Announced via EMA's Website Events Pages - broadcast live

Click here to see the recording from the September System Demo

# Subscribe to quarterly PLM Insights newsletter for updated news on IRIS

Scan the QR code or click on this **link**

**Next issue**: Mid-October 2025

# Upcoming events and engagement for IRIS Industry users

**Oct-Nov 2025**

Communications on confirmation of go-live date in 2026 and training activities planned

**Dec 2025**

Public system demo

**Feb 2026**

Training session on pre-submission activities and iMAAs

**Feb-Mar 2026**

Public Q&A Clinics for MAHs

**Mar 2026**

Public system demo

# Recap of guidance and training materials

In the IRIS Forum, find the updated support document for MAHs, a comprehensive repository of actions, training materials and Service desk triage guidelines

## Key guidance & training documents

Industry **training** on post-authorisation procedures in IRIS (12 Nov 2024): presentation & recording available on event web page

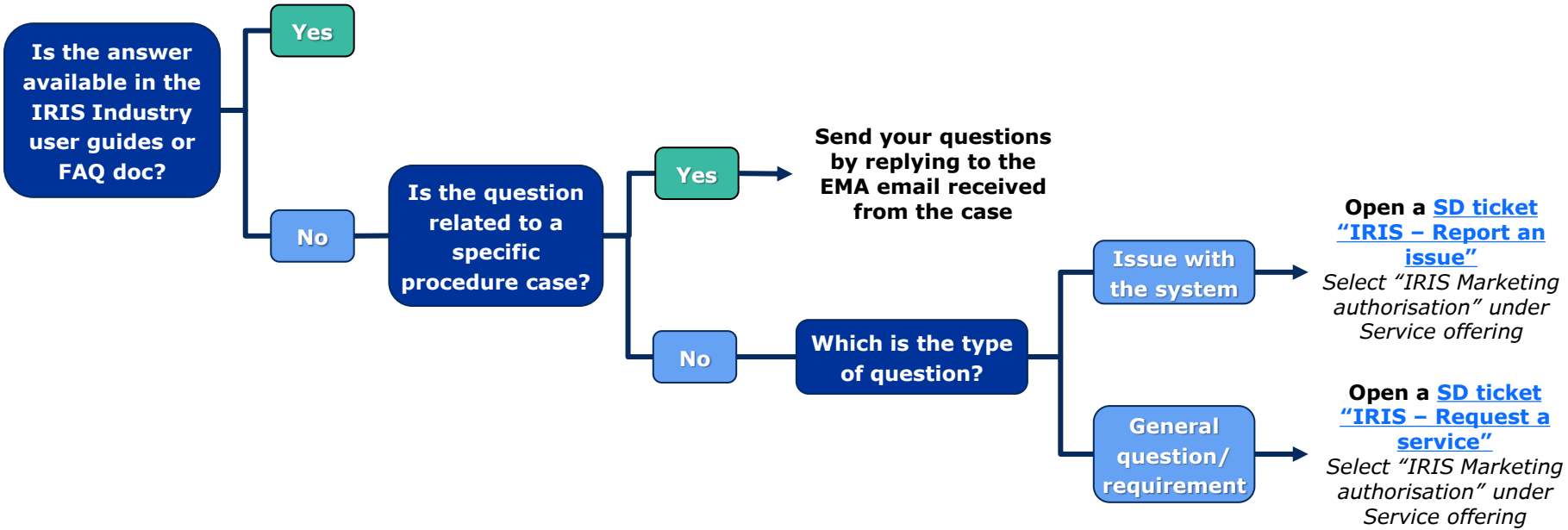
Industry **FAQ document** (updated): most frequently asked questions from MAHs on post-authorisation procedures management in IRIS

**User guide for applicants** (updated)

**IRIS Guide for registration** (updated)

Click here for the list and contacts of Industry SMEs

# Recap of available support for MAHs



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# Thank you

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