

Quick interactive guide to IRIS registration process

This presentation is interactive.

Please follow the instructions and click on the appropriate icon to be directed to the relevant section.

Click the button to start



How to register for access to IRIS



To access and use IRIS, the platform needs to know:


1. **Who** are you?
(do I have an EMA account?)
2. **What organisation** do you represent?
(is my organisation registered in OMS?)
3. **Which user access role(s)** do you have?
(what IRIS role do I need to request?)

This is managed in IAM – EMA Account Management Portal

To complete specific IRIS submissions, there can be additional pre-requisites:

- For **some*** scientific procedures in the orphan designation, ITF and scientific advice domain you also need a valid **Research Product Identifier (RPI)**.
- Procedures involving a **fee** require an **EMA customer account number** (SAP-FIN number).

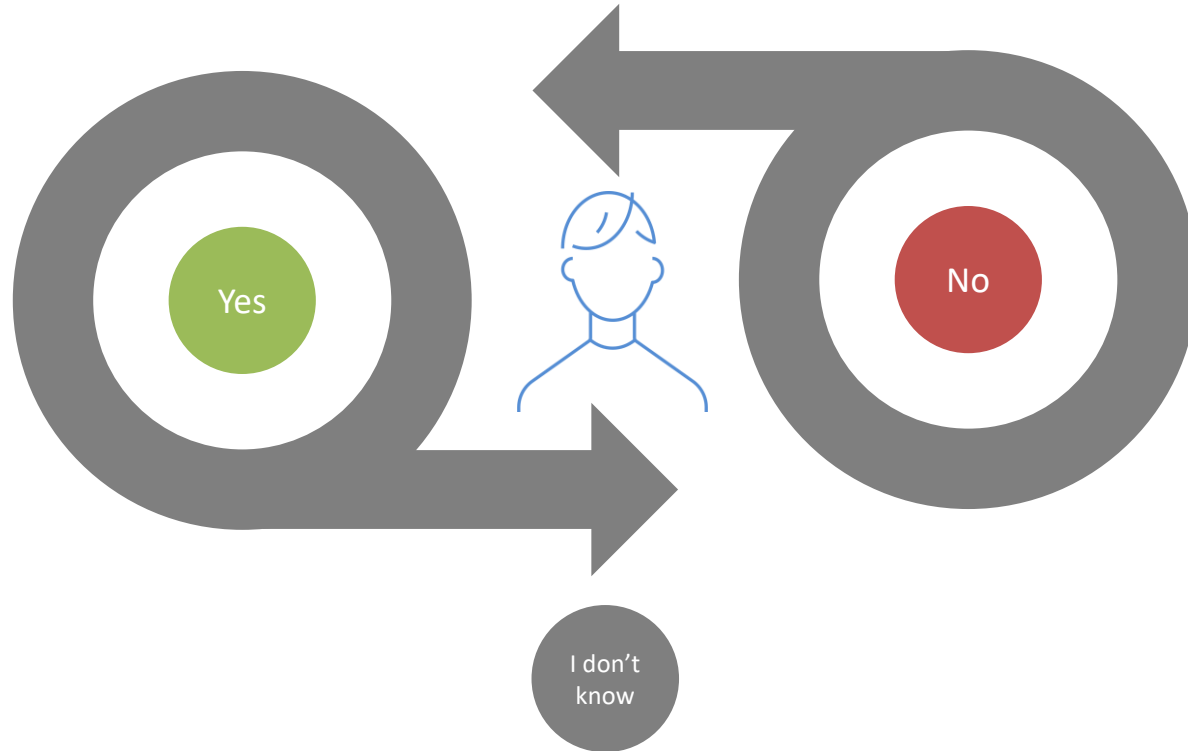
*for other procedures the RPI can be automatically identified by the platform

 : [IRIS guide to registration](#)

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the next step

Do I have an EMA account?

Please, click on the **appropriate** button



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User registration with EMA

1. Go to [EMA Account Management Portal](#) (IAM)
2. Create an account
3. Receive your self-registration confirmation



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[i EMA Account Management home page](#)

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To check if you have an EMA account



1. Go to [EMA Account Management Portal](#) (IAM)
2. Click on “Not sure if you have an EMA account”

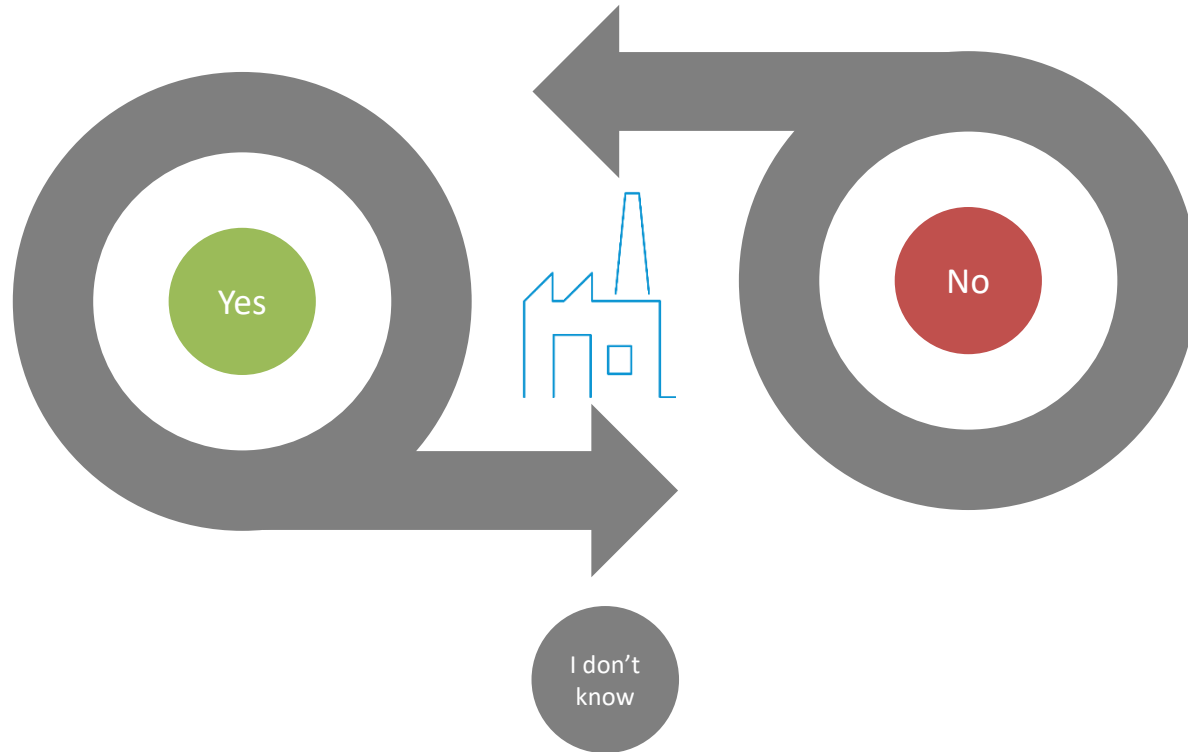
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 [EMA Account Management home page](#)

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the next step

Is my organisation registered with EMA?

Please, click on the **appropriate** button



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Organisation registration in OMS



1. If your look-up for an organisation in the [EMA Account Management Portal](#) (IAM), [IRIS website](#) or [SPOR Portal](#) (OMS) came back as negative:
 - **Login** to the OMS portal with your EMA account credentials and **create** a change request to register it. Registration of a new organisation takes from **5 to 10 working days**
2. If the organisation is found but data is incorrect, login to the OMS portal with your EMA account credentials and create a change request to update it (SPOR user role required)

*you can be affiliated to more than one organisation

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 : [IRIS guide to registration](#) Section 4 (Organisation registration in OMS (SPOR)) and [OMS documents page](#)

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the next step

Look up your organisation



Choose one of the following options:

1. [EMA Account Management Portal](#) (IAM)
Search for your organisation during your user access request process
2. [IRIS portal](#)
Search for your organisation on front-end to the list of organisations and their locations (same data as in OMS/SPOR)
3. [SPOR Portal](#) (OMS)
Search for your organisation in the OMS portal

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[!\[\]\(d66ff64371a51729ac8c1cdaa685ba6f_img.jpg\) : \[IRIS guide to registration\]\(#\) Section 4 \(Organisation registration in OMS \(SPOR\)\)](#)

[Click here to register/update organisation](#)

[Click here if your organisation is registered](#)

User access request to IRIS

1. Login to the [EMA Account Management Portal](#)


2. Request necessary role and affiliation

- As a first step ensure that at least one person in the organisation you are affiliating with already has an “**IRIS Industry User Admin**” role, as this person will approve your user access requests (not EMA)
- Only the **first request** for the ‘User Admin’ role is evaluated and granted by EMA. For this **create a Service Desk request** and attach the required documentation. Approval can take up to **2 working days**
- To create, submit, edit and withdraw an application, you need a “**Manager**” role. The “**Contributor**” role only allows editing an existing application
- One person can hold **both** “User Admin” and “Manager” roles
- “**IRIS Individual User**” role allows to create and submit applications as **an individual** (not on behalf of an organisation). The system approves this role automatically

3. Receive notification confirming role approval



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 : [IRIS guide to registration](#) Section 5 (Access to IRIS) and [EMA Account Management home page](#)


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Start using IRIS

1. After notification that your IRIS user access role has been approved, wait for **30 min** to allow time for the synchronisation process
2. Go to [IRIS website](#) and click 'Sign In' and then blue '**EMA Account**' button
3. In the Microsoft sign-in window enter your EMA username followed by “**@id.ema.europa.eu**” (e.g. [jones_a@id.ema.europa.eu](#))
3. In next window make sure that your EMA Account username is followed by the suffix '**@id.ema.europa.eu**' and then enter your EMA account password.
4. You are now ready to use the platform!

If your submission requires a **new RPI** or **EMA customer account number** click on **appropriate buttons** for guidance.

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 : [IRIS guide to registration](#) Section 6
(How to access IRIS after your role has been approved)

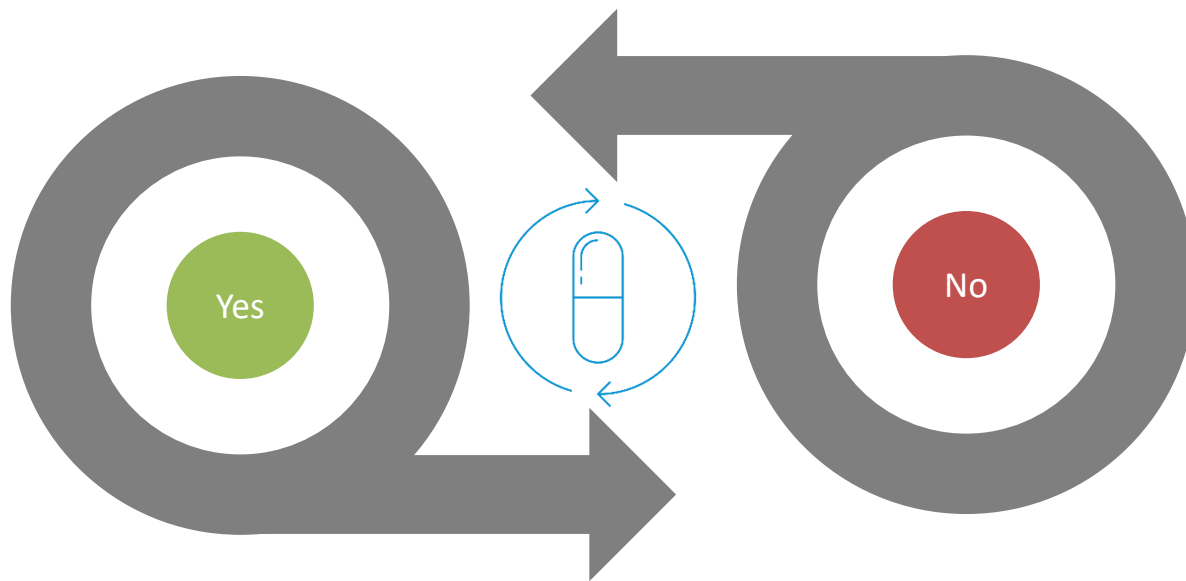
Click here for
RPI

Click here for
EMA customer
account #

Click here to
start over

Does my RPI appear in the IRIS selection list when creating a submission?*

Please, click on the **appropriate** button



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*Applicable to OD, ITF and SA procedures only

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Request an RPI



1. **Create** a submission for ‘Request for Research Product’ in the [IRIS website](#)
 - IRIS does not automatically approve your request for an RPI; it is reviewed and approved by the EMA
2. To do so, the **active substance(s)** in the product must be already **registered** in the [EMA public list of all substances](#)
3. In case your “active substance” is **not registered** you will need to raise an EMA Service Desk request and attach a completed form to register a new “Substance”
 - Active substance registration may take up to 5 working days

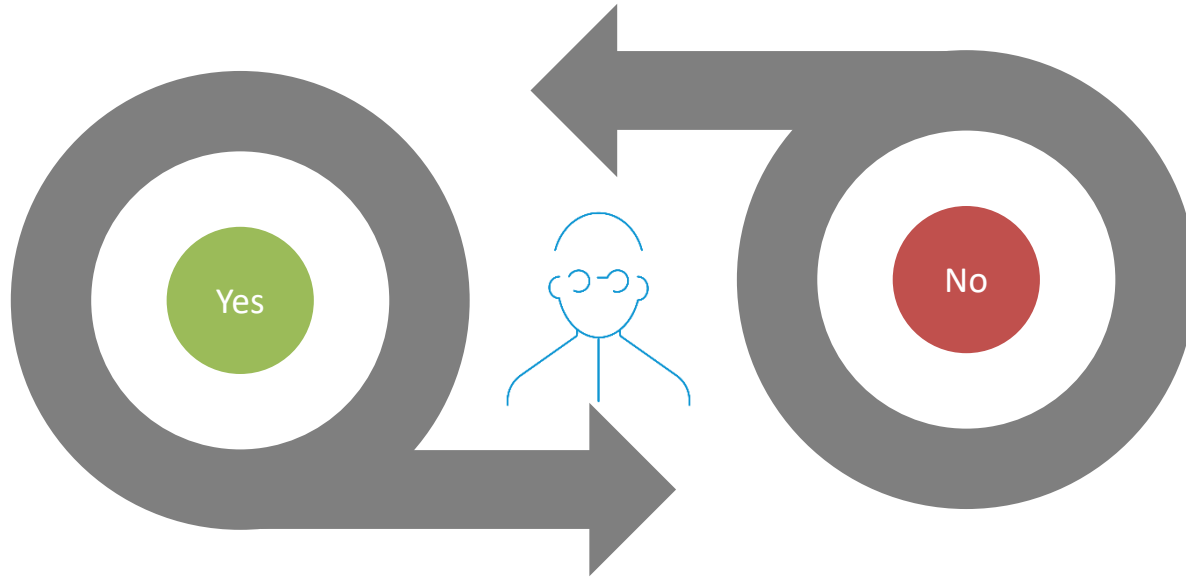
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① : [IRIS guide to registration](#) Section 7 (How to register a new active “Substance” in SMS), Section 8 (How to create a request for a “Research Product Identifier”)

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Do I have an EMA customer account number?

Please, click on the **appropriate** button



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*Applicable for procedures where fee is involved

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Request a customer account number

(a unique reference number with the Agency for financial matters)



1. Go to the [EMA Invoicing Portal](#)
2. Click on “Register Now”

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 : [How to pay](#) page on EMA website

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the next step

Proceed with submission



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Support for IRIS registration queries:
[EMA Service Desk](#)

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