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*

*Click here for the next step*

ℹ️: [IRIS guide to registration](#)
Do I have an EMA account?

Please, click on the appropriate button

Yes

No

I don't know

Click here for the next step

Click here to go back
User registration with EMA

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

Click here for the next step
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”
Is my organisation registered with EMA?

Please, click on the **appropriate** button

Yes

No

I don’t know

Click here to go back

Click here for the next step
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

[Click here for the next step](#)

[Click here to go back](#)

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

Click here to go back

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

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

4. 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.
Does my RPI appear in the IRIS selection list when creating a submission?*

Please, click on the **appropriate** button

*Applicable to OD, ITF and SA procedures only
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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Click here to go back

Click here for the next step
Do I have an EMA customer account number?

Please, click on the *appropriate* button

*Applicable for procedures where fee is involved*
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”
Proceed with submission

Support for IRIS registration queries:
EMA Service Desk