EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 April 2023

IRIS guide to registration and RPIs

Preliminary requirements for all IRIS submissions, including substance and Research Product Identifier registration

Version 2.13

Revision History **3**
Table of abbreviations **3**
1. Purpose and context **4**
1.1 Registration steps for applicants of scientific procedures 4
1.1.1 EMA user account 4
1.1.2 Organisation registration in OMS 4
1.1.3 EMA customer account number 5
1.1.4 Research Product Identifier and substance registration 5
1.2 Registration steps for Parallel Distribution procedures 5
1.2.1 EMA user account 5
1.2.2 Organisation registration in OMS 5
1.2.3 EMA customer account number 6
2. Working out what steps are required for you **6**
3. EMA Account Management **7**
4. Organisation registration in OMS (SPOR) **7**
4.1 Look up your organisation in EMA Account Management Portal 7
4.2 Look up your organisation in IRIS (alternative) 7
4.3 Look up your organisation in OMS (alternative) 8
4.4 Request for an "Organisation" to be registered in OMS, or update data 10
4.4.1 Raise a change request in OMS to create a new organisation 10
4.4.2 Raise a change request in OMS to update organisation information 12
5. Access to IRIS **14**
5.1 Access roles and permissions: principles 14
5.2 Access roles: how to request IRIS user roles 16
5.3 Affiliation to more than one organisation 16
5.4 What can I see in IRIS, with my new role? 16
6. How to access IRIS after your role has been approved **17**
7. How to register a new active Substance in SMS **19**
7.1 Check if the substance(s) is already registered 19
7.2 Raise an EMA Service Desk request to register a "Substance" 19
8. Requests for a new Research Product Identifier **20**
8.1 "I am sure that an RPI already exists, but I cannot see it in my RPI list in IRIS" 20
8.2 How to request a new RPI 22
8.3 Transfer a Research Product Identifier (RPI) 23

Revision History

Date	Description
05/09/22	Section 5. Access to IRIS updated
18/11/22	"IRIS Industry User Admin" replaced with "IRIS – eAF Industry User Admin"
15/12/22	Minor changes to Section 7 and 8 for RPI and substance requests (see changes highlighted in yellow)
03/02/23	Minor change to Section 5. Access to IRIS (see change highlighted in yellow)
19/04/23	Link to EMA Substance names best practices added in 7.2 (see change highlighted in yellow)

Table of abbreviations

Abbreviation	Explanation
EC	European Commission
EMA	European Medicines Agency
EUTCT	European Union Telematics Controlled Terms
GMA	Global Marketing Authorisation
ITF	Innovation Task Force
OD	Orphan Designation
OMS	Organisation Management Service (part of SPOR)
PD	Parallel Distribution
RPI	Research Product Identifier
SMS	Substance Management System (part of SPOR)
SPOR	Management Services for Substances, Products, Organisations and Referentials

1. Purpose and context

This guide has been produced to help new users of IRIS to complete the prerequisite steps before accessing the platform. Most of these steps are independent from the IRIS platform and are similar to those to obtain registration to use other European Medicines Agency (EMA) systems, such as Management Services for Substances, Products, Organisation and Referentials (SPOR).

The instructions in this guide involve visiting different web portals, all of which appear, for data security reasons, outside the EMA website.

This document is primarily focused on industry and academic stakeholders but may also be of use to regulatory users.

1.1 Registration steps for applicants of scientific procedures

Currently these are: orphan designation procedures and Innovation Task Force (ITF) briefing meeting requests and shortly scientific advice procedures.

1.1.1 EMA user account

Applicants[1] including the Sponsor[2] of an Orphan Designation (OD) or persons acting on their behalf, must have an active **EMA user account** and must be subsequently registered with an IRIS user access role of **"IRIS Industry Manager"** (affiliated to one or more organisations, if submitting on behalf of an organisation), and/or **"IRIS Individual User"** (if submitting as an individual). (See sections 3. "EMA Account Management" and 5. "Access to IRIS" for further information).

Note: While approval of the "IRIS Industry Manager" is done by the "IRIS – eAF Industry User Admin" of your organisation, the approval of the first "IRIS – eAF Industry User Admin" is done by EMA and takes **two working days**.

1.1.2 Organisation registration in OMS

The **"Organisation"** for which the OD or ITF briefing meeting application is being submitted *must be* already listed in the EMA's **Organisation Management Service (OMS)** (see section Organisation registration in OMS (SPOR)) otherwise you will not be able to affiliate yourself to an organisation and request the appropriate IRIS user access role in the EMA Account Management Portal.

You can check whether your organisation is registered in the OMS during your IRIS user access request process in the EMA Account Management portal as well as search for it directly in the IRIS portal (see section Organisation registration in OMS (SPOR)).

Notes:

If your organisation is not already included in the OMS, the SPOR/OMS registration process takes **five to ten working days**.

Registration of an organisation in OMS is not required if a new application is being prepared by an individual, not affiliated to any organisation.

[1] "Applicant": The individual or organisation submitting the application to EMA.
[2] "Sponsor": The addressee of the European Commission decision granting orphan designation for the medicinal product.

1.1.3 EMA customer account number

Applicants *must have* a valid **EMA Customer Account Number**. This is a unique reference number for financial matters and is required to submit parallel distribution notifications. If you do not have one please follow the guidance on the "How to pay" webpage on EMA's corporate website.

1.1.4 Research Product Identifier and substance registration

Normally, each new application for a scientific procedure in IRIS must be associated with an existing Research Product Identifier (RPI), except when the submission makes reference to a previous submission/regulatory entitlement which already has an RPI or marketing status submission.

If an appropriate RPI does not exist yet, for a single medicinal product the RPI must be requested via IRIS (see section "Requests for a new Research Product Identifier).

For anything other than a new medicinal product, such as for procedures regarding a new technology, a group of products or other subjects (often the case in ITF procedures, and occasionally for Qualification procedures or Scientific Advice) you cannot use IRIS to request a new RPI. The RPI will need to be created for you by EMA. For assistance in obtaining an RPI in this case, please refer to Innovation in medicines (for ITF)) on EMA's corporate website, and for Scientific Advice, Protocol Assistance and Qualification Advice/Opinion, please contact the Scientific Advice office directly, at ScientificAdvice@ema.europa.eu.

To obtain a new RPI for a single medicinal product, the active **"Substance(s)"** in the product must be registered and appear as "authorised" on the official EMA list of all substances (SMS). You can check whether this is the case directly on the IRIS portal (see section "How to register a new active Substance)

Note: Approval of new substances in the Substance Management Service (SMS) may take **up to five working days**.

1.2 Registration steps for Parallel Distribution procedures

1.2.1 EMA user account

Applicants for notifications of Parallel Distribution (PD), must have **an active EMA user account** and *must be* registered with IRIS user access roles of "**IRIS Parallel Distribution Manager**" (see sections "EMA Account Management" and "Access to IRIS").

Note: While approval of the "IRIS Parallel Distribution Manager" is done by the "IRIS Parallel Distribution User Admin" of your organisation, the approval of the first "User Admin" is done by EMA and takes **two working days**.

1.2.2 Organisation registration in OMS

The **"Organisation"** for which the PD notification is being submitted *must be* registered in the EMA's **Organisation Management Service (OMS),** otherwise you will not be able to affiliate yourself to an organisation and request the appropriate IRIS user access role in the EMA Account Management Portal.

You can check whether your organisation is registered in the OMS during your IRIS user access request process via the EMA Account Management portal as well as search for it directly in the IRIS portal (see section 4"Organisation registration in OMS (SPOR))".

Note: New organisation registration takes **five to ten working days**.

1.2.3 EMA customer account number

Applicants *must have* a valid **EMA Customer Account Number.** This is a unique reference number for financial matters and is required to submit parallel distribution notifications. If you do not have one please follow the guidance on the "How to pay" webpage on EMA's corporate website.

2. Working out what steps are required for you

The following table of questions and answers will help you find out what steps you need to take.

Question	Answer	Action
Do I have an **active EMA user account**?	**Yes**	Log into the EMA Account Management Portal
	No	Self-register with EMA as a new "User" (see information on the EMA Account Management website)
	I don't know	Access here to find out you have an EMA account
Is an organisation on whose behalf I will be acting **listed in EMA's** OMS?	**Yes**	Proceed with your request for an appropriate IRIS user role via the EMA Account Management portal
	Yes, but data requires to be updated	Raise a request to have your organisation data updated (see section Raise a change request in OMS to update organisation information)
	I Don't know	Look up your organisation during the IRIS user access request process in the EMA Account Management portal or search for it in the IRIS homepage or EMA OMS) (see section Organisation registration in OMS (SPOR))
	No	Raise a change request to have your organisation registered (see section Raise a change request in OMS to update organisation information)
Is there at least one person with the **IRIS – eAF Industry User Admin / IRIS Parallel Distribution User Admin** roles in the organisation on whose behalf I will be acting?	**Yes**	Request the role you need in the EMA Account Management Portal, e.g. **IRIS Industry Manager** (for scientific procedures) or **IRIS Parallel Distribution Manager** (for PD procedures) (see section Access roles: how to request IRIS user roles)
	No	Before you request a role, ensure that at least two people from the organisation are set up as **IRIS – eAF Industry User Admin** (for scientific submissions) or **IRIS Parallel Distribution User Admin** (see section Access roles: how to request IRIS user roles). If no person with an Admin role has been set up, all role requests will be automatically rejected by the EMA Account Management Portal
(for scientific applications) Is	**Yes**	No action needed. The RPI will be visible at the appropriate time in the "submission form" in IRIS drop-down lists

Question	Answer	Action
there already an **RPI assigned** to my product?	**No**	First, go to the IRIS home page and look up each substance in your product, to check that it appears in the substance list (see sections How to register a new active Substance in SMS and Check if the substance(s) is already registered). Then, request a new RPI via IRIS
	I Don't know	Try to create the submission and see if your RPI appears in the submission form. All products that are authorised have an RPI

3. EMA Account Management

EMA Account Management is an online platform where you can request and manage access to EMA applications. Refer to this platform to seek guidance on how to:

- Find out if you have an EMA account
- Create an EMA Account
- Re-activate your account
- Recover your credentials
- Request a user access role
- Manage users' access for your organisation as an "User Admin"
- FAQ

4. Organisation registration in OMS (SPOR)

To request the necessary user access roles and submit applications/notifications via the IRIS platform, you will need to ensure that organisation on whose behalf you will be acting is listed in the EMA's Organisation Management Service (OMS).

There are a few ways for you to check this.

4.1 Look up your organisation in EMA Account Management Portal

You can check whether your organisation is registered in OMS during the IRIS user access request process in the EMA Account Management Portal (see section "Access roles: how to request IRIS user roles**"**).

If you cannot find your organisation or the organisation data require an update, follow the instructions in section "Request for an "Organisation" to be registered in OMS, or update data**"**.

4.2 Look up your organisation in IRIS (alternative)

Go to the Organisations and Locations List in the IRIS Home page (note: no login is required to search the list).

Type the name (or part of it, with an asterisk at the beginning) of the organisation you wish to find in the "**Organisation name**" box and hit "**Apply**". You can also add a country in the filters, if your company has multiple organisations with a similar name in different countries.

If the page displays all the locations (addresses) for the organisations found, this means that the organisation is already registered and will appear on the drop-down list when you are requesting your IRIS user access role (see section "Access to IRIS");

You may wish to take a note of your Organisation ID, which, in addition to the organisation name, can be used to search for an organisation you will need to affiliate with when you request your IRIS user access role in the EMA Account Management Portal;

If you cannot find your organisation or the organisation data require an update, follow the instructions in the section Request for an "Organisation" to be registered in OMS, or update data.

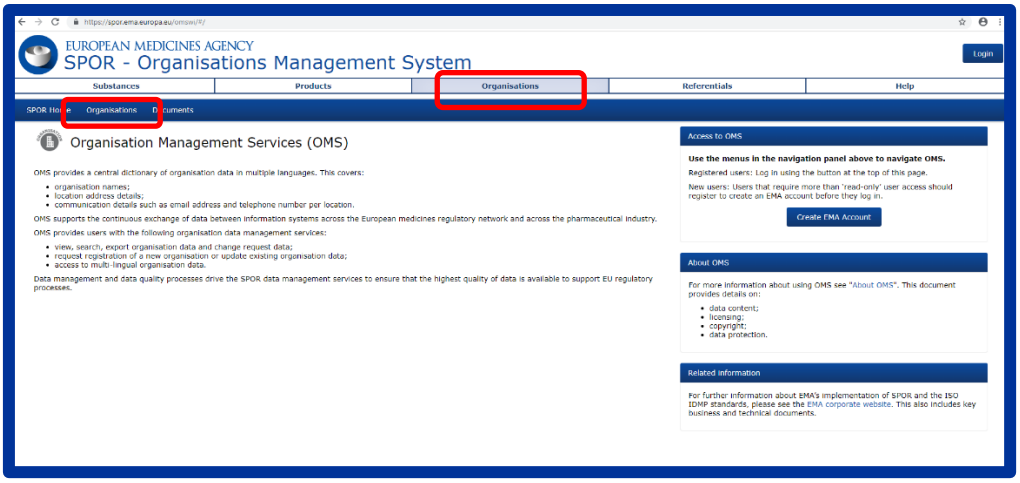
4.3 Look up your organisation in OMS (alternative)

Go to the SPOR portal;

Note: No login is required to look up your organisation ID;

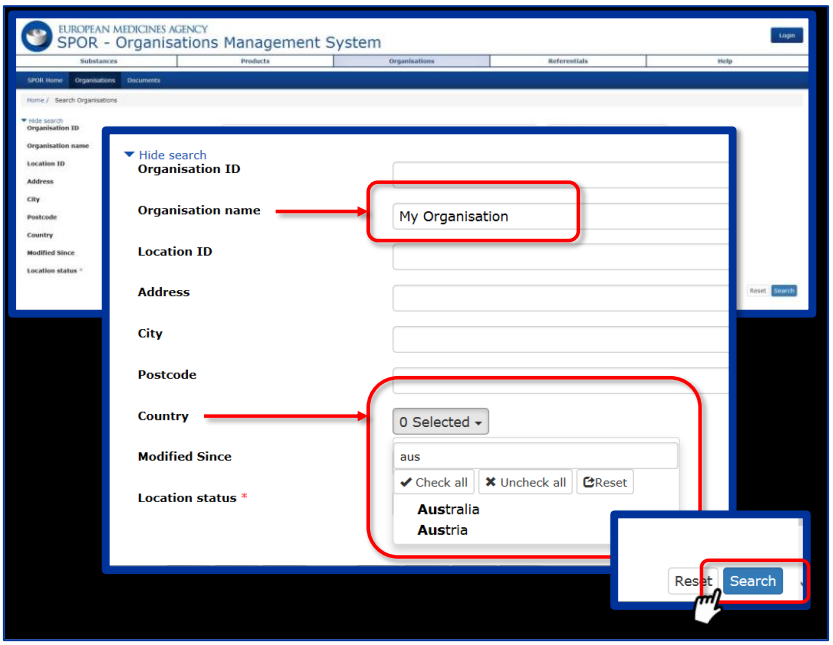
Click on "**Organisations**" in the top (white) menu bar (Figure 1);When the "**SPOR – Organisations Management Service**" web page opens, click on the "**Organisations**" button in the lower (dark blue) menu bar (Figure 1);

Figure 1



Type the name of the organisation you wish to find in the "**Organisation name**" box and hit "**Search**" (Figure 2);

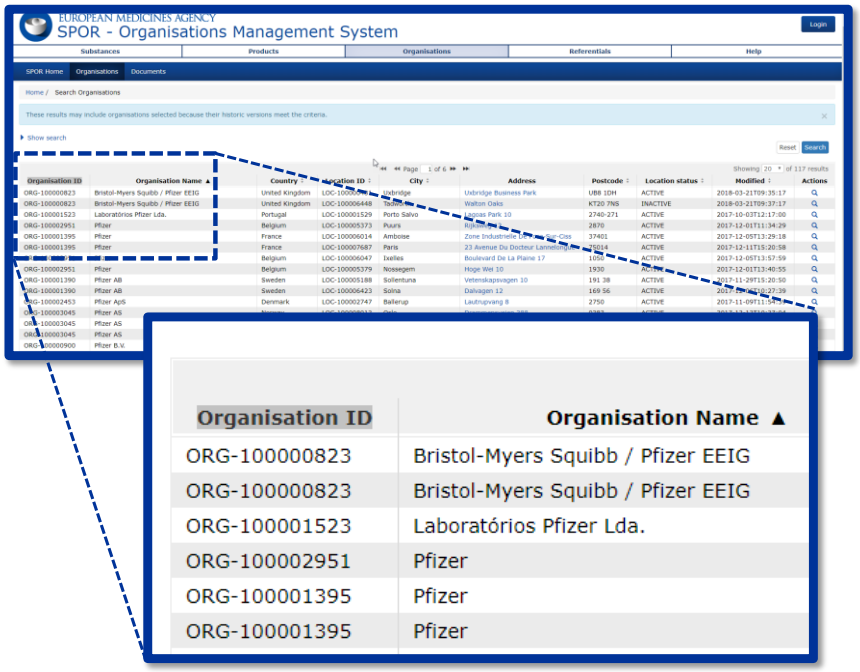
Figure 2



If the organisation does not appear in the list after hitting search, then follow the instructions in the next section (see section "Raise a change request in OMS to create a new organisation");

If the organisation appears in the list, this means that it is already registered and will appear on the drop-down list when you are requesting your IRIS user access role via the EMA Account Management portal (see section "Access to IRIS");

Figure 3



You may wish to take a note of your Organisation ID (left hand column, Figure 3) which, in addition to the organisation name, can be used to search for an organisation you will need to affiliate with when you request your IRIS user access role in the EMA Account Management Portal;

If the organisation data that appears require an update, follow the instructions in section "Raise a change request in OMS to update organisation information".

4.4 Request for an "Organisation" to be registered in OMS, or update data

It is the responsibility of all external organisations to ensure that any data held in SPOR about their organisation is accurate and up to date. Creation of a new organisation or changes needed to organisation data in OMS must be requested using the change request functionality in the OMS interface.

All change requests must be accompanied by relevant **supporting documents or information** as described in the **"Change requests validation in OMS"** guidance document available on the OMS documents page.

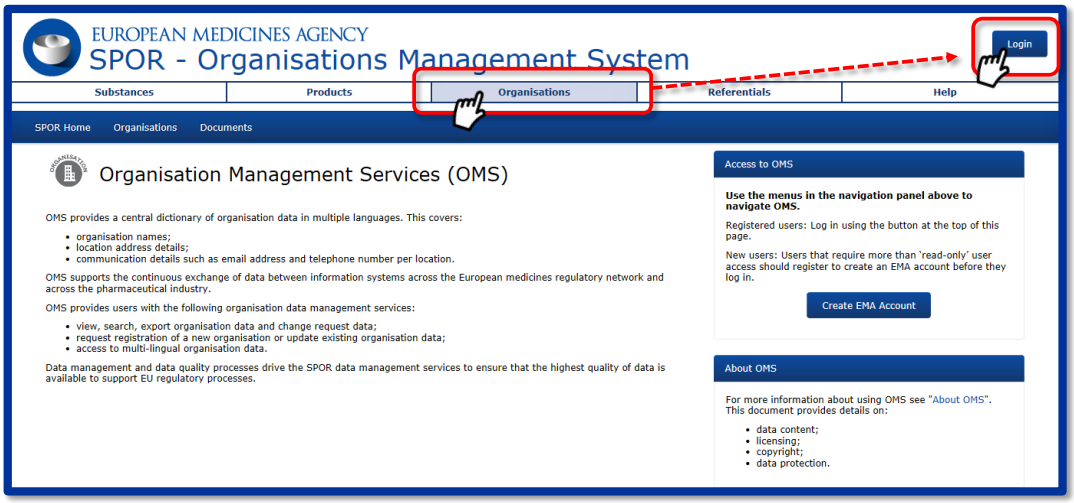
Further information on OMS can be found on EMA's corporate website.

4.4.1 Raise a change request in OMS to create a new organisation

During the self-registration process by the user, the **"SPOR unaffiliated user"** role is given by default so that they will be able to submit change requests for a new organisation, limited to one pending request at a time. Below steps describe this process in detail.

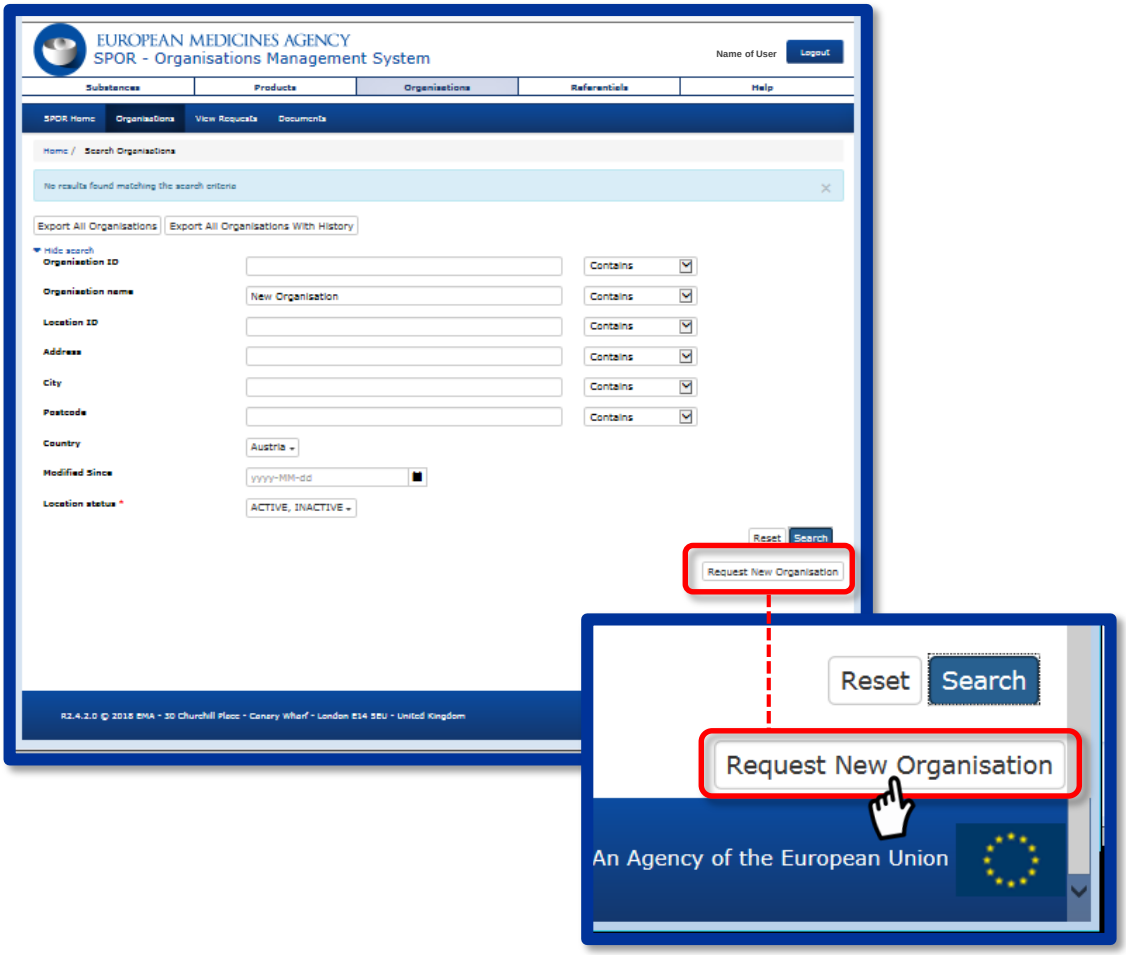
- Go to the SPOR portal;
- Click on the "**Organisations**" tab in the top menu (Figure 4);
- Click on the "**Login**" button (Figure 4);

Figure 4



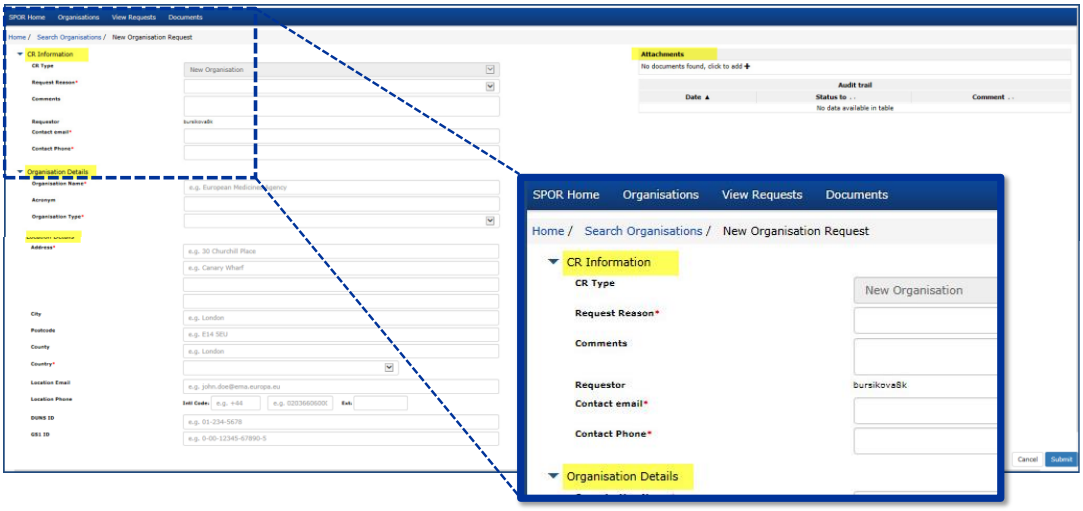
- Enter your EMA Account username and password;
- Once logged in, click on the "**Organisations**" button in the lower (dark blue) menu bar;
- Search for the new organisation (Figure 5);

Figure 5



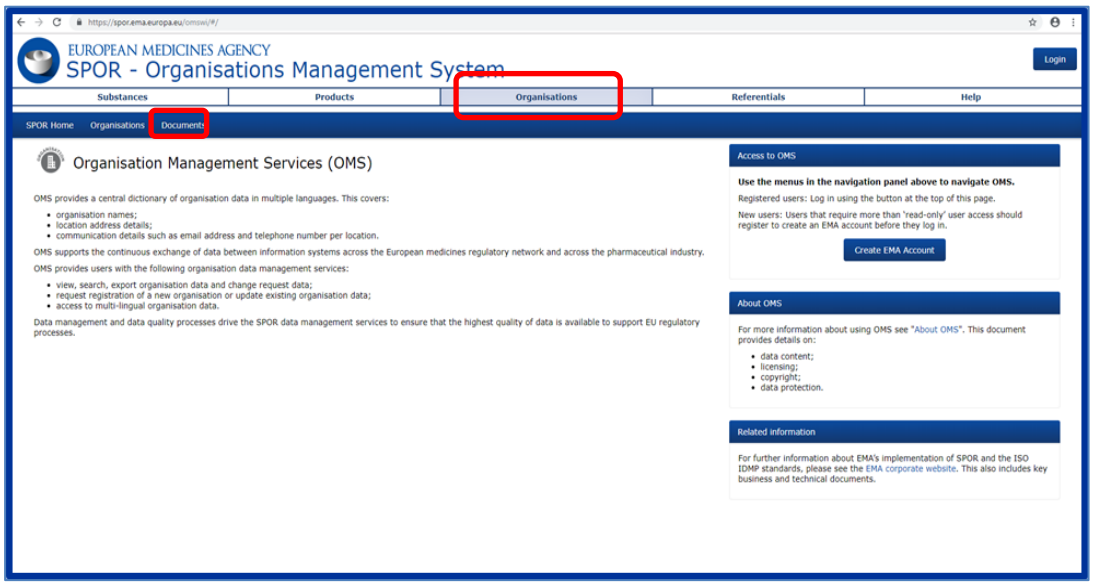
- When the "*No results found…*" message comes up, click on the "**Request New Organisation**" button that appears in the bottom right of the screen (Figure 5). The option to request a new organisation is only made available after a search is performed;
- Complete a change request form (Figure 6);

Figure 6



- Attach the mandatory documents and submit. For guidance on which documentation should be attached to the change request to create a new organisation, refer to the "**Change requests validation in OMS**" document on the OMS documents page (Figure 7).

Figure 7



When your organisation has been successfully registered, you will receive an email with an Organisation ID code, confirming the successful inclusion of your organisation in the OMS dictionary.

The standard change request to register a new organisation can take **five to ten working days** to be processed.

4.4.2 Raise a change request in OMS to update organisation information

Users can make changes to their organisation data in OMS using the already described **change request** functionality in the OMS interface (see section "Raise a change request in OMS to create a new organisation").

The first step is to search for and view the full details of an organisation and its locations in OMS. If the users:

- find the organisation but not its location, they can ask to add a new location to the organisation;
- find both the organisation and its location, but either of these are not up to date, they can ask to update the organisation and/or location data;
- find the organisation with an active status but the location with an inactive status, they can ask to update the organisation data or add new locations.

In order to perform these changes you need to have "**SPOR Industry User**" access to the SPOR portal. Prior to that, you need to make sure that the "**SPOR Industry Super User**" role which manages access requests for your organisation has already been set up. For detailed instructions on the SPOR user registration, refer to the "SPOR User Registration Manual" found on the OMS documents page.

Note: The first "**SPOR Super User"** for each organisation will be approved by EMA. Therefore, factor in time to submit the request with the required documentation and allow up to **two working days** for EMA to approve it.

Once your request for the **"SPOR Industry User"** role has been approved, follow the steps below to request an update to your organisation data. Steps 1-6 are identical as in section "Raise a change request in OMS to create a new organisation".

Go to the SPOR portal;

Click on the **"Organisations"** tab in the top menu;

Click on the **"Login"** button (top right of your screen);

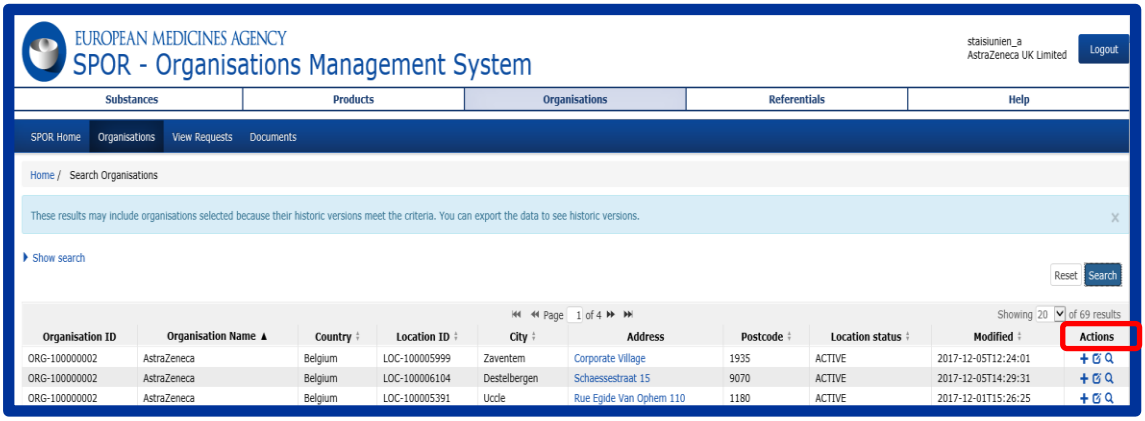
Enter your EMA Account username and password;

Once logged in, click on the blue **"Organisations**" button in the lower (dark blue) menu bar;

Search for your organisation;

When your organisation data appears, click on the appropriate symbol under the "**Actions**" button on the right side of the screen to request a change (Figure 8). The option to request a change is only made available after a search is performed;

Figure 8



Complete a change request form;

Attach the mandatory documents and click "**Submit**".

For guidance on which documentation should be attached to the change request to update organisation data, refer to the "Change requests validation in OMS" document on the OMS documents page.

For more detailed instructions on how to request a new organisation, new location, request a change in organisation or location including the use of the Change Request form, please refer to section 8. ("**Request new organisation, new location or request a change in organisation or location**") on pp. 26-39 of the "**OMS web user manual**". This can be found on the OMS documents page.

If you prefer instructions in video format, you can watch the "SPOR Learning Module: OMS03 - Working with OMS Change Requests" video on the EMA YouTube channel. The section on requesting a new organisation starts about 6 minutes into this 25-minute video (06:15 –> 09:30) and shows an on-screen run through of the process with voiceover commentary in English.

5. Access to IRIS

5.1 Access roles and permissions: principles

To use IRIS, you need to have been granted at least one of the following **affiliation roles** for the organisation on whose behalf you will be acting:

Scientific procedures (e.g. for Orphan Designation or Innovation Task Force briefing meetings)

Individual role:

- IRIS Individual User : only request this role if you intend to submit an IRIS application as an individual person, and not on behalf of an organisation.

Affiliated roles:

- **IRIS – eAF Industry User Admin**: can assign the other roles to those who request then for the organisation. Please note that an Industry User Admin cannot access IRIS, or create submission, unless the User also gives himself the role of Industry Manager (below).
- **IRIS Industry Manager**: can create new applications, and edit, submit and withdraw the created applications or any other where the user has been specifically added as Industry Manager.
- **IRIS Industry Contributor** (this role is automatically assigned also to IRIS Industry Managers): can edit submissions where he/she has been added as a Contributor by a Manager. An Industry Contributor cannot create, submit or withdraw a submission.
- **IRIS Industry Coordinator**: users with this role can access any submission/application made on behalf of an organisation, and not only those where the user is the creator or has been added as a manager/contributor, with the functions of IRIS Industry Manager. Please note that this role does NOT allow to create new submissions of any kind: for that, it is necessary to also have the role of Industry Manager, for the same organisation.

Parallel Distribution procedures

Affiliated roles:

- IRIS Parallel Distribution User Admin [(4)]
- IRIS Parallel Distribution Manager: can create, edit, submit and withdraw applications.
- IRIS Parallel Distribution Contributor: can edit applications (but not create, submit or withdraw them)

The access rights for each user type are tabled in the figure below:

Figure 9

IRIS user access roles

Activities	IRIS Industry/Parallel Distribution **User Admin**	IRIS Industry/ Parallel Distribution **Manager**	IRIS Industry/Parallel Distribution **Contributor**	IRIS **Individual** User
Approve IRIS Industry/Parallel Distribution Users in EMA Account Portal	✓			
Create/delete their own draft submissions in IRIS Portal		✓		✓
Edit/view their own submissions in IRIS Portal		✓		✓
Allocate contributors/managers to their own draft submissions in IRIS Portal		✓		
Edit/view specific submissions in IRIS Portal		✓	✓	
Submit submissions in IRIS Portal		✓		✓

Only the first request for a "User Admin" role (IRIS – eAF Industry User Admin or IRIS Parallel Distribution User Admin) is evaluated and granted by EMA.

All subsequent requests are "**Approved**" or "**Rejected**" by the first "User Admin" of the organisation, whether for one of the other roles listed above or for another "User Admin" role. If nobody has a User Admin role in your organisation, any requests for the other roles will be automatically forwarded to an "External Organisation Administrator", if any exists for your organisation; if no "External Organisation Administrator" exists, the request will be automatically rejected by the system.

For further information on the "External Organisation Administrator role, please see the the "User Administrator Guide" in the EMA Account Management System.

If you have requested an "**IRIS Industry Manager / IRIS Parallel Distribution Manager"** or "**IRIS Industry Contributor / IRIS Parallel Distribution Contributor"** or **"IRIS Industry Coordinator"** role/affiliation, the approver will be an "**IRIS – eAF Industry User Admin/Parallel Distribution User Admin"** from the organisation you selected in your request, not EMA.

EMA recommends having at least two users per organisation with the "User Admin" role, to ensure that user role requests are not delayed in the event of absences or staff mobility. EMA also recommends to have at least two users per organisation with the "Coordinator" role, to be able to reassign a submission and its portal contact to another user affiliated to the organisation, should the original user who created the submission become unavailable.

It is possible for one person to hold both "User Admin" and other roles, such as "Manager" or "Coordinator".

When a subsequent request is made for one of the user roles, the "IRIS – eAF Industry User Admin" or "IRIS Parallel Distribution User Admin" for the organisation to which you are requesting affiliation will be notified automatically by email and (one of them) will carry out the review and approval of your affiliation request. It is possible for a single user to be affiliated to multiple organisations, whether they are related or not.

5.2 Access roles: how to request IRIS user roles

As explained above, before you can request the necessary role/affiliation to perform submission activities via the IRIS platform, there are three pre-requisites[3]:

You need to have an "**EMA user account"** (see section EMA Account Management);

The organisation on whose behalf you will be carrying out activities in IRIS in this role must be registered in OMS (see section Organisation registration in OMS (SPOR)). For example, you could be employed by a consultancy but requesting access as an "IRIS Industry Manager" to create an OD submission on behalf of Pfizer Belgium. In this case, you would need to request affiliation to Pfizer Belgium.

At least one "**IRIS – eAF Industry User Admin/Parallel Distribution User Admin**" has been set up for this organisation (otherwise, your role request will be automatically rejected).

Note: Users applying as individuals do not require to affiliate to an organisation or to request a "User Admin" role.

Once the three prerequisites above are in place, you can request an IRIS user role by referring to the EMA Account Management for detailed information. Please note the following:

You do not need to know who the IRIS – eAF Industry User Admin[s] for your Organisation is/are: the EMA Account Management System will automatically forward your request to all users with that role, in your Organisation. Any of them can approve or refuse your request.

IRIS – eAF Industry User Admins are responsible for removing any user affiliated to their Organisation, when such need arises – for example, if the user leaves the Company. EMA is not responsible for maintaining the affiliation lists of Organisations. A guide on how to accept and remove affiliations for IRIS – eAF Industry User Admins is available here: User Administrator Guide · EMA Account Management (europa.eu).

5.3 Affiliation to more than one organisation

A single EMA user can request affiliation to more than one organisation. For example, a user who works for a consultancy may request to be affiliated with his/her own consultancy organisations, but also to one or more additional pharmaceutical companies.

This will allow the consultant to prepare and manage a submission on behalf of a pharmaceutical company. The regulatory entitlement issued (for example, an orphan designation) or the Research Product Identifier (RPI)created will still be in the name of the pharmaceutical company's location chosen in IRIS for the submission, and not the name of the consultant's direct employer.

However, IRIS – eAF Industry User Admin persons should be aware that **any user to which they grant affiliation to their pharmaceutical company/organisation will be able to see all Regulatory Entitlements and RPI's** "owned" by their pharma company/organisation, as this is necessary to create new submissions.

5.4 What can I see in IRIS, with my new role?

Every IRIS Industry Manager or Contributor affiliated to an Organisation can see all the Research Products associated to the Organisation, the Marketing Status of the Authorisation products as

[3] (if you are submitting your application as an individual user then only an "EMA user account" is needed)

communicated to EMA by the Organisation itself, and all Regulatory Entitlements associated to the Organisation (such as Orphan Designations and Scientific Advice outcome).

Regarding submissions, users with the IRIS Industry Manager or IRIS Industry contributor role can only see those submissions created by themselves, or where they have been explicitly added as additional Managers or Contributors by another IRIS user already associated with those submissions. Users with the IRIS Industry Manager or IRIS Industry contributor role therefore cannot see all previous, ongoing or draft submissions of their affiliated Organisation. However, users with the "IRIS Industry Coordinator" role can see and edit all submissions made on behalf of the organisation(s) to which they are affiliated with that role.

6. How to access IRIS after your role has been approved

Please note that after you have been notified that your IRIS user access role/affiliation has been granted, you will have to wait approximately half an hour before accessing IRIS. This is because the EMA Account Management system and the IRIS platform are synchronised about every 20 minutes.

To access the IRIS platform:

- After having been notified that your IRIS user access role has been approved, wait for half an hour to allow time for the synchronisation process mentioned above to be completed;
- Go to the IRIS platform;
- Click **"Sign In"** (top right of your screen) and then click on the blue **"EMA Account"** button (Figure 10);
- In the **"Pick an account"** window, EITHER:
  - ✓ Click on "**use another account**" and enter your **EMA username** in the first box **followed by "@id.ema.europa.eu"** – for example, if your EMA username is "surname_a", type in "**surname_a@id.ema.europa.eu**";

  OR

  - ✓ If this account name already appears in the "**Pick an account**" list, simply click on it;

Figure 10

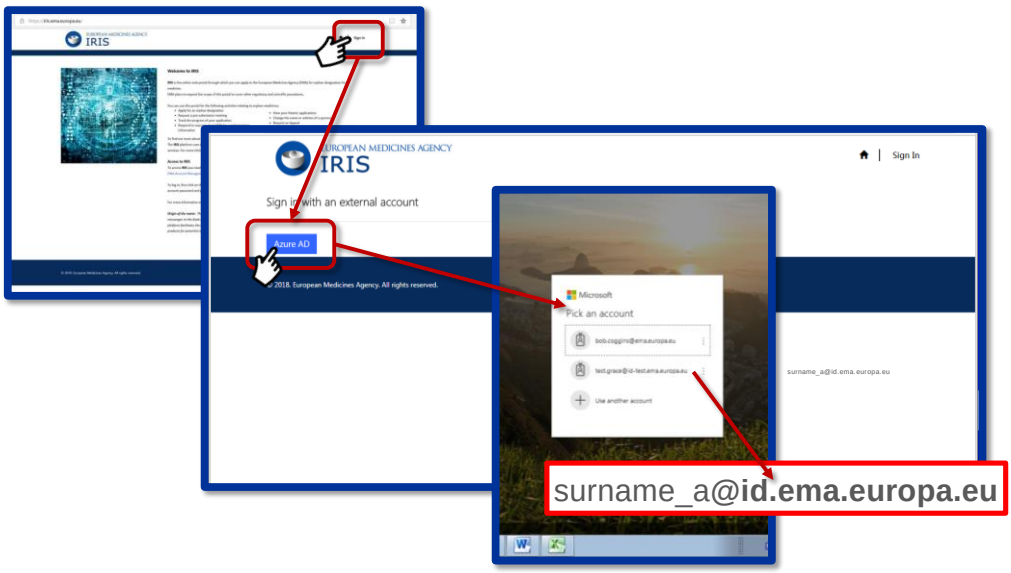
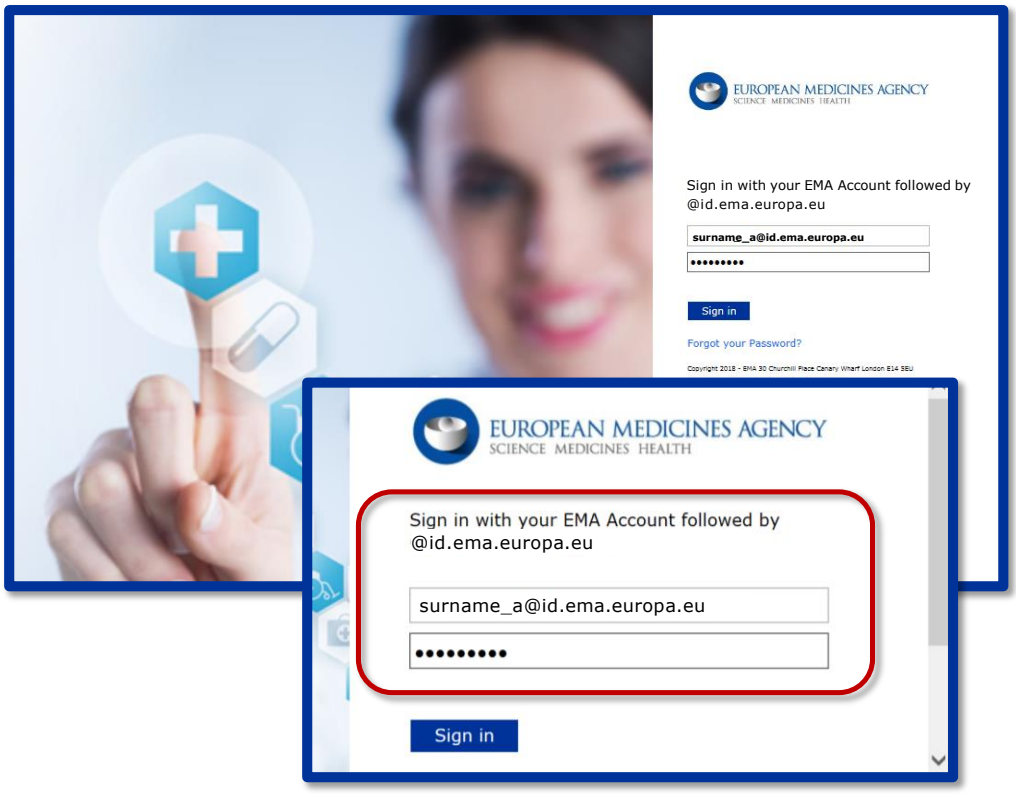


Figure 11



- Make sure that in the first of the sign-in boxes, your EMA Account username followed by the suffix "**@id.ema.europa.eu**" is shown, and then type your EMA Account password in the box below that (Figure 11);
- Click "**Sign In**" – this will take you to the IRIS home page, where you can start to use the platform.

After logging in once, the next time you log in you will only need to go as far as step 4 shown above.

7. How to register a new active Substance in SMS

For medicinal products in development, if they do not already have an RPI, you need to request one (authorised products already have an RPI). To do so in IRIS, the **active substance**(s) in the product must be already included as "authorised" and "current" in the EMA public list of all substances (SMS/SPOR).

7.1 Check if the substance(s) is already registered

Before beginning your application for a new RPI, you need to see whether the active substance is already included in the IRIS list (integrated from SMS).

1. Open the substance list available on IRIS (in the IRIS home page, no login is required to search for an active substance);
2. Type the name of the substance you wish to find (or part of it, preceded with an asterisk, e.g. *paracetamol) in the "**Name**" box and hit "**Apply**";

If the substance appears in the list, this means that it is already registered and is valid for inclusion in a submission for a new RPI;

If the substance does not appear in the list after hitting "Apply", then follow the instructions in the paragraph below (section 7.2).

Alternatively, when you start to create a submission for the request of a new RPI in IRIS you can simply see if your substance appears in the drop-down list. If the right substance appears you can select it and carry on with creating your RPI request in the platform.

7.2 Raise an EMA Service Desk request to register a "Substance"

To register a substance, there are three simple steps for you to carry out:

1. Read the EMA Substance names best practice guideline first.
2. Complete the Substance Request Form and save it.
3. Raise a request directly in the "Request SMS services" page of the EMA Service Desk for the substance(s) to be registered, attaching the substance request form and supporting documentation (e.g. Investigator's Brochure, Substance specifications, others…). Then follow the instructions in the system, and finally click on the "**Submit**" button.

Within five to ten days, you should receive a notification by e-mail that your substance has been registered. This assumes that all the information and documentation that you provide is accurate, complete and that the substance is valid for registration.

The substance will then appear in the drop-down list in IRIS, when you are creating your submission for an RPI request.

8. Requests for a new Research Product Identifier

Before you can proceed with a newly created submission for certain types of scientific procedures (e.g., Orphan designations, ITF, Scientific Advice, etc.[4]) you need a valid Research Product Identifier (RPI).

An RPI identifies a development concept, usually a potential new medicinal product or an already authorised one, being developed for one or more conditions, by a single company - or by multiple companies in parallel and under an agreement. RPIs can also be used, in special cases, to identify methodologies, technologies, or a pipeline of multiple medicinal products/substances of the same class.

Some **principles of the RPI concept** are:

- If a development product is transferred to another developer, or becomes co-developed in parallel, under an agreement, the RPI remains the same;
- A single RPI should cover authorised products considered to be under the notion of "Global Marketing Authorisation (GMA)" (European Commission (EC) Notice to applicants, sections 2.4 and 2.8);
- The same substance/product for the same developer/applicant must have different RPIs for human and veterinary development, if developed for both.
- A centrally authorised product is always associated to an RPI in IRIS; note that:
    - ✓ Generic, hybrid or biosimilar products from different applicants have different RPIs, as they constitute independent developments (without an agreement) and do not fall under the GMA concept;
    - ✓ An orphan and a non-orphan authorised product from the same applicant and containing the same substance(s) are associated to the same RPI.

If a valid RPI for your research product does not appear on the selection list when creating a draft submission for orphan designation, this may be for one of two reasons:

A. The RPI already exists but is not assigned to the organisation on behalf of which you have created the draft submission (or to you if creating an individual submission). It could be assigned to another legal entity of your Company, in the same or another country. See section "I am sure that an RPI already exists, but I cannot see it in my RPI list in IRIS below.

B. The RPI does not exist yet: see section 8.2 "How to request a new RPI" below.

RPIs are meant to link together all submissions and Regulatory Entitlements (e.g. orphan designations, scientific advice letters) pertaining to the same development entity/product, so please make sure to avoid requesting new RPIs if the product already has one. For example, all the products with an orphan designation and all centrally authorised products are already associated to an existing RPI.

8.1 "I am sure that an RPI already exists, but I cannot see it in my RPI list in IRIS"

You can visualise the RPIs assigned to the organisation(s) to which you are affiliated, in the Products tab of the IRIS portal. Once logged in, click on the "Products" tab, and then on "RPI – products". This

[4] Note that for submissions associated to an existing Regulatory Entitlement (such as Annual Reports on Orphan designations, Maintenance of the Designation Criteria, Amendments, Transfers, Change of Name and/or address, 5-year review, or Follow-up Scientific Advices) it is not necessary to specify an RPI in the draft submission, as this is imported automatically from the Regulatory Entitlement being referred to.

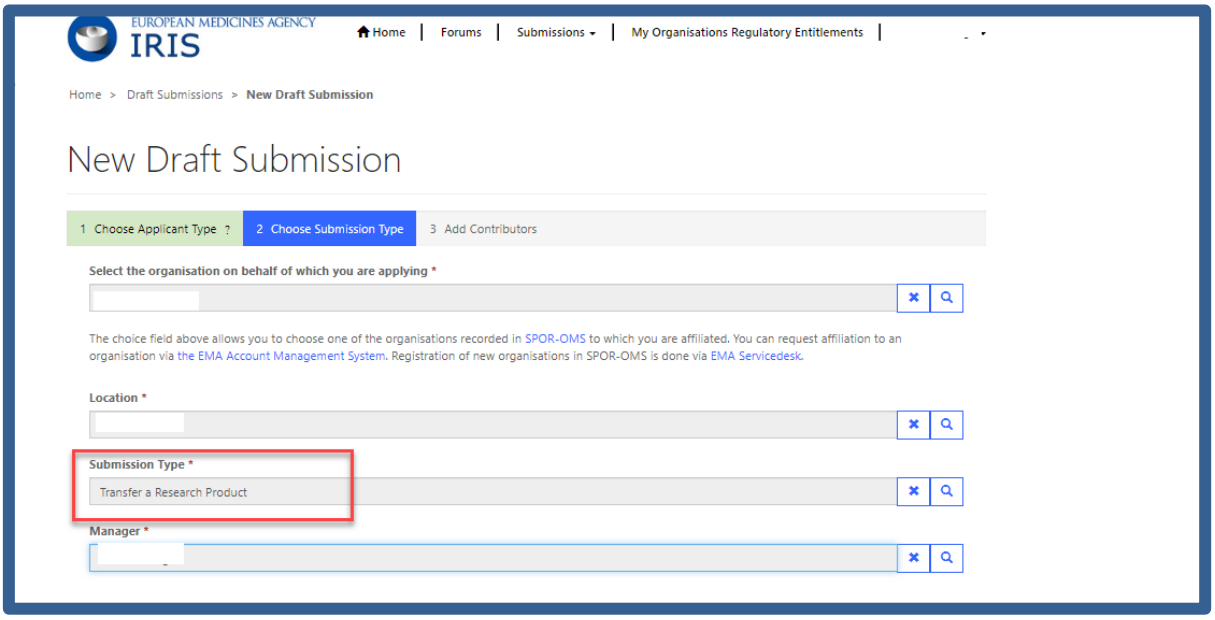
will show you the list of the RPIs 'owned' by you as an individual or by one of the organisations that you are affiliated to.

If you do not see the RPI you are looking for, please note that an RPI may be already existing but assigned to a different organisation (legal entity in a country). For example, it may be assigned to a different legal entity belonging to a same multinational organisation (e.g., ACME Italy vs. ACME Germany, or ACME Italy vs. ACME Registrations Italy). Or, it could be "owned" by a different organisation altogether, for example a regulatory consultant if the RPI was created by them. In such cases, you won't see the RPI, unless you are affiliated also to that organisation.

If the product and its development are the same, a new RPI should **not** be requested, as it would be refused by the EMA data stewards. There are two alternative possibilities:

A. **The existing (old) "owner" of the RPI transfers the RPI to the new organisation (location) beforehand**. A user with "Industry Manager" role, who is affiliated with the existing (old) sponsor, needs to request a "Transfer a research product" in IRIS (Figure 12) to the new RPI owner, either an organisation/location or an individual. The procedure is described in section 8.3below. In this case, the RPI will be transferred completely, and any new Regulatory Entitlement (such as Orphan Designation, Paediatric Decision, Scientific Advice letter) will be granted to the new RPI owner.

Figure 12



B. **The user can request to be affiliated to the organisation currently "owning" the RPI**, as IRIS Industry Manager, via the EMA Account Management Portal. This will allow the user to submit applications on behalf of the current owner of that RPI (and any other RPI owned by them). However, in this case any regulatory entitlement will be granted in the name of the current (old) owner of the RPI.

8.2 How to request a new RPI

If you believe that an RPI does not exist yet for your medicinal product, you need to request one by creating a "Request for Research Product" submission in the platform.

To register a new RPI, any substance(s) in the product must already be registered in the EMA SPOR/SMS database. Please see relevant instructions in section 7 You can check if your substance is already registered in SMS by opening the substance list available on IRIS (in the IRIS home page; no login is required to search for an active substance).

The steps set out below take you through a series of steps which are similar to those in other IRIS submissions.

1. Create a new submission in the Draft submissions page of the IRIS portal, selecting "**Request for Research Product**".
2. After clicking "**Create and Next**", you can add further managers and contributors to your submission (optional – not necessary for requests for RPI). Click on "**Continue to Submission form**" and compile the various sections of the form.
3. Note: you can only see and choose RPIs that are registered to an organisation to which you are affiliated as an Industry Manager. If you are applying on behalf of a different organisation, you should either request affiliation to the RPI "owner", or the RPI owner should transfer the RPI to your organisation (via a separate IRIS procedure).
4. You will need to specify if your RPI is for a product for "human use" or "veterinary use" (domain). If your product is intended for both, two separate RPIs should be created.
5. Add at least one substance to the list of the active substances. See the box for criteria to be used when selecting the substance[s]. Please do not add excipients, only **active** substances should be specified for RPIs.
6. For each substance, you also need to specify the "nature of the active substance, as thus is mandatory to save the data and progress with the application.
7. You now need to add all "enabling technologies" that apply to your product or its development (at least one), and all therapeutic areas in which your product might be developed, not limited to the current condition/indicaion (at least one).
8. Click "**Save and Return**" - and then complete the "**RPI Declaration**";
9. Click on the tick box and select if you have SME status at the time of submission;

Substance[s] to select for an RPI

Please consider the following principles when choosing the substance[s] to include in the RPI:

Human or Veterinary domain? If the RPI is to be used for human medicine[s], only substances in the human domain can be selected. For RPIs to be used for veterinary medicine, both 'human' and 'veterinary' domain substances can be selected; however, if the same substance is duplicated for both domains, please select the one in the 'human' domain.

Which duplicate should I choose? If there are duplicates, please select the substance with the largest number of synonyms.

Base substance or salt/hydrate? In early development, the salt/hydrate form may not be known yet. In these cases of uncertainty, it is in principle acceptable to select the base substance; this can subsequently be changed for the specific salt/hydrate once this is known (via a Servicedesk request).

10. Click on "**Submit application**" box - a pop-up window appears, giving you the last opportunity to go back and check that all the details you entered are correct ("Review Application"), or to continue and submit;

11. When you are satisfied with all the details entered, click on "**Submit**".

Back in the IRIS home page, you can look up the submission you have just made using the "My Submission" drop-down menu at the top of the page.

Note: The IRIS platform does not automatically approve your request for an RPI; it is reviewed by a scientific EMA team who then approve it or inform you if an RPI already exists for the product.

Note2: **if your RPI is not for a single medicinal product**, but for a group of products or technology or methodology (as is often the case for Innovation Task Force (ITF) briefing meeting, for example, or occasionally for Scientific Advice / Qualification procedures), the steps below do not apply as the RPI needs to be created by EMA. In such cases you need to seek assistance by referring to Innovation in medicines (for ITF), or by writing to the Scientific Advice office directly, at ScientificAdvice@ema.europa.eu. (for Scientific Advice, Protocol Assistance, or Qualification Advice/Opinion).

8.3 Transfer a Research Product Identifier (RPI)

This request can be made to EMA by industry users with **"Industry Manager"** role, to transfer an existing RPI from the current sponsor/owner to a new sponsor/owner. This process replaces the previous process of having to raise a request to the EMA Service Desk. The current sponsor of the RPI can submit this request by following the steps below:

1. From the IRIS home page, click on "**Draft submissions**" and then click "**New draft**".

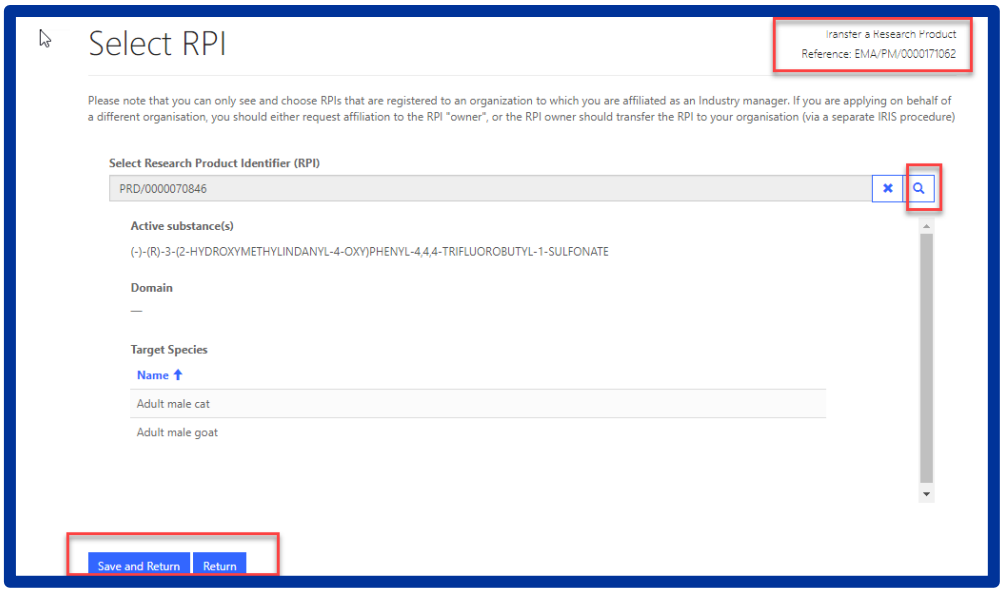
2. If applying on behalf of an organisation, a list will appear in the "**Organisation**" field, showing only the organisation(s) to which you are affiliated; once an organisation is selected you need to select also the relevant location (RPIs are assigned to a location).

3. Under "**Submission Type**" select "**Transfer a Research Product**" and confirm.

4. Click "**Create and Next**": you can now add further managers and contributors to your submission (not necessary for RPI transfers as they are automated). Click on "**Continue to Submission form**".

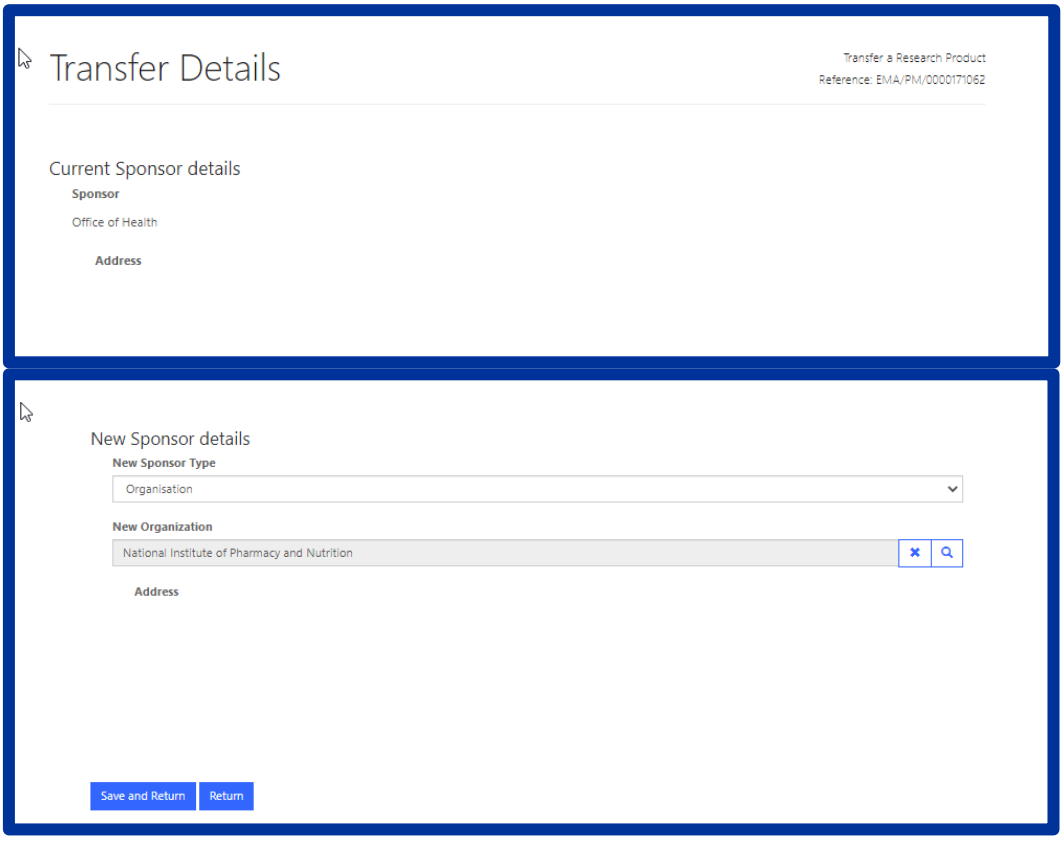
5. **Select the RPI to be transferred:** Click on the magnifier of this field, and a new screen will open. Please note that you will only see and be able to select RPIs that are registered to an organisation (location) to which you are affiliated as an Industry manager. Select the desired RPI to be transferred, using the search icon option if necessary, and click on "Save and Return" (Figure 13);

Figure 13



6. **Transfer Details**: Click on the tab, and a new screen will appear. Here you can add the "**New Sponsor Type**" as Organisation/Individual, then select the new Organisation and adding a correct address in the box provided. Once all details have been added, click on "**Save and Return**". Please note that you can only transfer an RPI to an organisation already existing in SPOR/OMS, or an individual who already has an account linked to IRIS (Figure 14).

Figure 14



7. **Declaration**: Click on this tab, new screen appears. Select the checkbox for the declaration and click on **"Save and Return"**;
8. **Submit Application**: once all above tabs has been filled and green tick shows against them, "**Submit Application"** button become enabled. Click on it, a new screen opens, select the checkbox asking for confirmation, click on **"Submit Button"** box - a pop-up window appears, giving you the last opportunity to go back and check that all the details you entered are correct ("Review Application"), or to continue and submit.

Once submitted, Submission will be shown in "**Outgoing**" tab and product will be updated with new sponsor type as mentioned while filling the form.

Consequences of transferring an RPI

Transferring an RPI does not transfer any submission or case/procedure, whether in draft, ongoing or completed status, to the new owner: all submissions already created will remain assigned to the existing applicant. The same applies for existing regulatory entitlements, such as orphan designations, Scientific advice entitlements, etc.: they remain assigned to the current holder/sponsor.

IRIS users affiliated to the new RPI owner will not be able to view and access previous submissions (or their documents) or regulatory entitlements associated to the previous different RPI owner(s).

Transferring an RPI will not prevent the current sponsor/holder of a regulatory entitlement from creating and submitting new applications that are based on an existing regulatory entitlement (even if the entitlement refers to that RPI), such as: annual reports on orphan designations, transfers of orphan designation, maintenance of orphan designation criteria, follow-up scientific advice / protocol assistance. All these submissions only require the IRIS user to specify the existing regulatory entitlement, not the RPI. However, those procedures that are based on the RPI, such as initial scientific advice or new orphan designations, can only be created by the current owner of the RPI.

Regarding the RPI itself, the new RPI sponsor will be able to see the following information from the RPI record, after the transfer:

- The substance(s) name and synonyms (from the European Union Telematics Controlled Terms (EUTCT)/SMS).
- Any 'enabling technologies' added by the previous sponsor(s) and by EMA.
- Any additional information on the product's mechanism of action that EMA collects from public sources such as ADIS Insight.

The new sponsor of the RPI will not be able to see any additional information on the product or its mechanism of action, added by previous sponsors, nor (as already mentioned) any submission or regulatory entitlement associated to the RPI by previous sponsors, such as scientific advice procedures or outcomes. Orphan designations and PIP/waiver decisions are of course public on the European Commission website and the EMA website respectively.