28 March 2025

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IRIS guide to registration and RPIs

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

Version 2.17



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Revision History

Date	Description
28/03/25	Section 5. Access to IRIS updated and Section 6. How to access IRIS after your role has been approved
09/01/24	Minor changes to Section 8. Requests for a new Research Product Identifier
17/05/23	Removal of outdated content
11/05/23	Minor changes to section 8. Requests for a new Research Product Identifier (see changes highlighted in yellow)
19/04/23	Link to <u>EMA Substance names best practices</u> added in 7.2 (see change highlighted in yellow)
03/02/23	Minor change to Section 5. Access to IRIS (see change highlighted in yellow)
15/12/22	Minor changes to Section 7 and 8 for RPI and substance requests (see changes highlighted in yellow)
18/11/22	"IRIS Industry User Admin" replaced with "IRIS – eAF Industry User Admin"
05/09/22	Section 5. Access to IRIS updated

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

1.1.1 EMA user account

Applicants¹ including the Sponsor² 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.



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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.

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 <u>IRIS</u> <u>portal</u> (see section



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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.

1.1.3 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 "<u>How to pay</u>" 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 <u>IRIS portal</u> (see section "How to register a new active substance)

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



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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").

<u>Note:</u> 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 <u>IRIS</u> portal (see section \Box ^{*}



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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 "<u>How to pay</u>" webpage on EMA's corporate website.



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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.

Table 1.

Question	Answer	Action
De L bave an active	Yes	Log into the EMA Account Management Portal
EMA user account?	Νο	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
	Yes	Proceed with your request for an appropriate IRIS user role via the EMA Account Management portal
Is an organisation	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)
on whose behalf I will be acting listed in EMA's OMS?	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 <u>IRIS homepage</u> or EMA <u>OMS</u> (see section 4. Organisation registration in OMS)
	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	Yes	Request the role you need in the <u>EMA Account</u> <u>Management Portal</u> , 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)
Admin/IRISParallelDistributionUserAdminrolesinAdminrolesinorganisationonwhosebehalfIbeacting?	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 <u>EMA</u> <u>Account Management Portal</u>

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Question	Answer	Action
	Yes	No action needed. The RPI will be visible at the appropriate time in the "submission form" in IRIS drop-down lists
(for scientific applications) Is 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

<u>EMA Account Management</u> 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
- <u>Create an EMA Account</u>
- <u>Re-activate your account</u>
- <u>Recover your credentials</u>
- <u>Request a user access role</u>
- <u>Manage users' access for your organisation as an "User Admin"</u>
- <u>FAQ</u>



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 <u>Organisation Management Service (OMS)</u>, whose data are also integrated in IRIS and in IAM.

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 <u>Organisations and Locations List</u> 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;

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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.

← → C								☆ \varTheta :
SPOR - Organisa	ENCY tions Management S	yst	em					Login
Substances	Products		Organisations			Referentials	Help	
SPOR Home Organisations Documents								
Organisation Managem	ent Services (OMS)					Access to OMS Use the menus in the naviga	ation panel above to navigate OMS.	
OMS provides a central dictionary of organisation d organisation names; location address details; communication details such as email address	lata in multiple languages. This covers: and telephone number per location.					Registered users: Log in using New users: Users that require register to create an EMA accor	the button at the top of this page. more than 'read-only' user access should unt before they log in.	
OMS supports the continuous exchange of data bet	tween information systems across the European med	dicines re	egulatory network and across t	e pharmaceu	tical industry.	c	reate EMA Account	
OMS provides users with the following organisation	data management services:							
 view, search, export organisation data and cr request registration of a new organisation or access to multi-lingual organisation data. 	nange request data; update existing organisation data;					About OMS		
Data management and data quality processes drive processes.	e the SPOR data management services to ensure tha	at the hig	phest quality of data is available	to support E	U regulatory	For more information about usi provides details on:	Ing OMS see "About OMS". This documen	t
						 data content; licensing; copyright; data protection. 		
						Related information		
						For further information about E IDMP standards, please see the business and technical docume	EMA's implementation of SPOR and the IS E EMA corporate website. This also includ ints.	0 es key

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



Figure 2.

EUROPEAN SPOR -	MEDICINES AGENCY Organisations Management Sys	tem	1		Login
Substand	Products	Organisations	Referentials	Help	
SPOR Home Organisatio Home / Search Organisatio	ns Documents				
Organisation name Location ID Address	 Hide search Organisation ID 				
City Postcode Country	Organisation name	My Organisat	ion		
Modified Since	Location ID				
	Address				Reset Search
	City				
	Postcode				
	Country	0 Selected -			
	Location status *	✓ Check all Australia	★ Uncheck all		
		Austria			
				Reset S	Search

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.

St	ubstances		Products		Organisations	F	eferentials		Help	
POR Home Org	anisations Docume	nts								
ome / Search Org	ganisations									
nese results may in	include organisations se	elected because their histor	ric versions meet the crite	eria.						×
how search										
			-	N					Rese	Search
				lec.	44 44 Page 1 of 6 ₩	**			Showing 20 * of	117 results
rganisation ID	Organ	isation Name 🔺	Country 👘	Location ID ‡	City 0	Address	Postcode ‡	Location status \$	Modified 0	Actions
G-100000823	Bristol-Myers Squibb	/ Pfizer EEIG	United Kingdom	LOC-10000043	Uxbridge	Uxbridge Business Park	UB8 1DH	ACTIVE	2018-03-21109:35:17	Q
G-100001523	Laboratórios Pfizer L	da.	Portugal	LOC-100001529	Porto Salvo	Lagoas Park 10	2740-271	ACTIVE	2010-03-21109:37:17	q
G-100002951	Pfizer		Belgium	LOC-100005373	Puurs	Rijksweig 12	2870	ACTIVE	2017-12-01T11:34:29	à
G-100001395	Pfizer		France	LOC-100006014	Amboise	Zone Industrielle De Lore-Sur-Ciss	37401	ACTIVE	2017-12-05T13:29:18	Q
G-100001395	Pfizer		France	LOC-100007687	Paris	23 Avenue Du Docteur Lannelongu	75014	ACTIVE	2017-12-11T15:20:58	Q
1100000951		/	Belgium	LOC-100006047	Ixelles	Boulevard De La Plaine 17	1050	ACTIVE	2017-12-05T13:57:59	Q
G-100002951	Pfizer		Belgium	LOC-100005379	Nossegem	Hoge Wei 10	1930	ACTIVE	2017-12-01T13:40:55	۹
G-100001390	Pfizer AB		Sweden	LOC-100005188	Sollentuna	Vetenskapsvagen 10	191 38	ACTIVE	2017-11-29T15:20:50	Q
G-100001390	Pfizer AB		Sweden	LOC-100006423	Solna	Dalvagen 12	169 56	ACTIVE	2017-12-06710:27:39	Q
0.40000450			Denmark	LOC-100002/4/	Ballerup	Lautrupvang a	2750	ACTIVE	2017-11-09111:54:55	- u
G-100002453	Pfizer Aps		Norway	100-100008013	Oclo	Drammancusian 200	0292	ACTIVE	2017 12 12 12 10 27:04	
G-100002453 G-100003045	Pfizer AS Pfizer AS		Norway	100-100008012	Oclo	Drammensvoien 388	0383	ACTIVE	2017-12-12710-27-04	
G-100002453 G-100003045 -100003045 G100003045	Pfizer AS Pfizer AS Pfizer AS		Norway	10C-100008012	Oslo	Drammensvelen 288	0283	ACTIVE	2017-12-1210-27-04	
G-100002453 G-100003045 G-100003045 G-100003045 G-100003045	Pfizer AS Pfizer AS Pfizer AS Pfizer B.V.		Nonway	LOC-100008012	Oslo	Prammencueien 388	0383	ACTIVE	2017-12-12710-27-04	
G-100002453 G-100003045 G-100003045 G-100003045 G-00000900	Pfizer Aps Pfizer AS Pfizer AS Pfizer B.V.		Nonway	LOC-100008012	Oclo	Drammensuelan 388	0383	ACTIVE	2017.12.12710.27.04	1
G-100002453 G-100003045 G-100003045 G-100003045 G-00000900	Pfizer AS Pfizer AS Pfizer AS Pfizer AS Pfizer B.V.		Norway	LOC-100008012	Osla	Drammearuelen 388	0283	ACTIVE	2017-12-12710-27-04	1
RG-100002453 G-100003045 RG-100003045 RG-100003045 RG-00000900	Pfizer AS Pfizer AS Pfizer AS Pfizer B.V.		Norway	LOC-100008012	Odo	Drammasoulan 288	0283	ACTIVE	2017 12 12710-27-04	1
G-10002453 G-100003045 G-100003045 G-100003045 G-100003045 G-100000900	Prizer AS Prizer AS Prizer AS Prizer AS Prizer B.V.		Матизи	100-100008012	Oda	Drammaseusian 288	0283	ACTIVE	2017.12.12110:37:04	}
G-100002453 G-100003045 -100003045 G-100003045 G-00000900	Prizer ADS Prizer AS Prizer AS Prizer AS Prizer B.V.	Ora	anisatio	on ID	Oda	Or	aanis	ation N	ame A	\mathbf{r}
G-10002453 G-100003045 G-100003045 G-100003045 G-00000900	Prizer ADS Prizer AS Prizer AS Prizer AS Prizer B.V.	Org	anisatio	on ID	Odlo	Or	ganis	ation N	ame 🛦	\mathbf{F}
G-10003045 G-10003045 G-10003045 G-10003045 G-10003045 G-100003045 G-10000900	Prizer AS Prizer AS Prizer AS Prizer B.V.	Org ORG-	anisatio	on ID 823	Brist	Or ol-Myers Sq	ganis Juibb /	ation N Pfizer E	l ame ▲ EEIG	
KG-100002453 KG-100003045 KG-100003045 KG-100003045 KG-100003045	Prizer AS Prizer AS Prizer AS Prizer B.V.	Org ORG-	anisatio	on ID 823	Brist	Or ol-Myers Sq	ganis Juibb /	ation N Pfizer E	ame ▲	
G-10003045 6-100003045 -100003045 -100003045 G-100003045 G-100003045 G-100003045 G-100003045	Prizer AS Prizer AS Prizer AS Prizer AS Prizer B.V.	Org ORG- ORG-	anisatio 100000	on ID 823 823	Brist	Or ol-Myers Sq ol-Myers Sq	ganis Juibb / Juibb /	ation N Pfizer E Pfizer E	ame ▲ EIG EIG	Ì
G-10002453	Prizer AS Prizer AS Prizer AS Prizer AS Prizer B.V.	Org ORG- ORG- ORG-	anisatio	on ID 823 823 523	Brist Brist Labo	Or ol-Myers Sq ol-Myers Sq pratórios Pfiz	ganis Juibb / Juibb /	ation N Pfizer E Pfizer E	l ame ▲ EEIG EEIG	
G-10002453 (510003045) (10003045) (G-00000045) (G-0000000)	Prizer AS Prizer AS Prizer AS Prizer B.V.	Org ORG- ORG- ORG- ORG-	anisatio	on ID 823 823 523 951	Brist Brist Labo	Or col-Myers Sq col-Myers Sq pratórios Pfiz r	ganis Juibb / Juibb / zer Lda	ation N Pfizer E Pfizer E a.	l ame ▲ EEIG EEIG	
G-10002453	Prizer AS Prizer AS Prizer AS Prizer B.V.	Org ORG- ORG- ORG- ORG-	anisatio	on ID 823 823 523 951 395	Brist Brist Labo Pfize	Or ol-Myers Sq ol-Myers Sq oratórios Pfiz r	ganis Juibb / Juibb / Zer Lda	ation N Pfizer E Pfizer E A.	l ame ▲ EEIG EEIG	
G-10002453 (c.10003045) (c.1000	Prizer AS Prizer AS Prizer AS Prizer AS Prizer B.V.	Org ORG- ORG- ORG- ORG-	anisatio	on ID 823 823 523 951 395	Brist Brist Labo Pfize	Or ol-Myers Sq ol-Myers Sq oratórios Pfiz r	ganis Juibb / Juibb / zer Lda	ation N Pfizer E Pfizer E a.	ame ▲ EIG EIG	

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. If you do not find your organisation when requesting an affiliation in the EMA Account Management System, you can create it directly in the Account Management system, which will then update OMS automatically.

Creation of a new organisation can also be requested using the change request functionality in the OMS interface, which is, importantly, the only approach to be used if changes to an existing organisation are needed.



4.4.1 Add a new organisation directly in the EMA account management system

You can add a new organization directly in the EMA Account management system (but not change the details of an existing one: see 4.4.3). It is sufficient to follow the instructions in the portal of the EMA Account management system.

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

It is also possible to request registration of a new organisation in the OMS system, via a "change request".

All change requests in OMS must be accompanied by relevant supporting documents or information as described in the "E - Change requests" guidance document available on the <u>OMS documents page</u>.

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

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 <u>SPOR portal;</u>
- Click on the "Organisations" tab in the top menu (Figure 4);
- Click on the "Login" button (Figure 4);

Figure 4.

EUROPEAN MED SPOR - Or	DICINES AGENCY Ganisations N	anagement Sy	stem	
Substances	Products	Organisations	Referentials	Help
SPOR Home Organisations Docum	ients			
	Management Servi		Access to OMS	
OMS provides a central dictionary of org organisation names; location address details; communication details such as er OMS supports the continuous exchange across the pharmaceutical industry. OMS provides users with the following of view, search, export organisation request registration of a new org access to multi-lingual organisation	nail address and telephone number pe of data between information systems rganisation data management service: data and change request data; anisation or update existing organisatio o data.	This covers: r location. across the European medicines regulatory net s: on data;	Use the menus in the navigate OMS. Registered users: Log page. New users: Users the access should register log in.	te navigation panel above to in using the button at the top of this t require more than 'read-only' user to create an EMA account before they Create EMA Account
Data management and data quality pro available to support EU regulatory proc	cesses drive the SPOR data manageme sses.	nt services to ensure that the highest quality	of data is About OMS For more information This document provid • data content; • licensing; • copyright; • data protection	about using OMS see "About OMS". es details on:

- 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.

EUROPEAN I	MEDICINES AGENCY				
SPOR - Orga	nisations Managemen	t System		Name of User	
Substances	Products	Organisations	Referentiels	Help	
SPOR Home Organizations	View Requests Documents				
Home / Search Organisations					
No results found matching the sear	rch critoria			×	
Export All Organisations Expo	ort All Organisations With History				
Organization ID			Contains		
Organization name	New Organisation		Contains		
Location ID			Contains		
Address			Contains		
City			Contains		
Postcode			Contains		
Country	Austria				
Modified Since	Austria +	-			
	YYYY-MM-dd				
Location status -	ACTIVE, INACTIVE +				
				Reset Search	
				Request New Organisation	
				Re	set Sear
R2.4.2.0 () 2018 EMA - 30 Chu	urchill Place - Canary Wharf - London E1	4 SEU - United Kingdom			
				Request Ne	w Organisa
					rd b
			An Agen	cy of the Europea	nUnion 🛛 🦸

- 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.

SPOR Home Organisations View Requests Do	pouments		
Home / Search Organisations / New Organisation Re	iquest		
CR Information CR Type Request Research Comments Requestor	New Organisation	Attachments Ne documents found, click to add 4 Date A St N	Audit trail attus to - Comment data available in table
Contact email*			
Criganisation Details Criganisation Name* Acronym	e.g. European Medionalijamoy	SPOR Home Organisations View Requests	Documents
Organisation Type*			
		Home / Search Organisations / New Organisation	Request
	e.g. 30 Churchill Face e.g. Canary Wharf	CR Information CR Type	New Organisation
City	e.g. London	Request Reason*	
Caunty Cauntry*	e.g. El4 SEU e.g. Landon	Comments	
Location Email	e.g. john.doe@ema.europa.eu	Requestor	bursikova8k
Location Phone	Intl Code: e.g. +44 e.g. 02036606000 Ext:	Contact email*	
DUNS ID	e.g. 01-234-5678		
651 10	e.g. 0-00-12345-67890-5	Contact Phone* Organisation Details	Cancel Submit

 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 "<u>Change requests</u> <u>validation in OMS</u>" document on the <u>OMS documents page</u> (Figure 7).

Figure 7.

Substances	Products	Organisation	15	Referentials	Help	
Home Organisations Documents						
Organisation Manage	ment Services (OMS)			Access to OMS		
g organisation nanage				Use the menus in the navigation	on panel above to navigate OMS.	
5 provides a central dictionary of organisatio	n data in multiple languages. This covers:			Registered users: Log in using the	button at the top of this page.	
 organisation names; location address details; communication details such as email addr 	ess and telephone number per location.			New users: Users that require mo register to create an EMA account	New users: Users that require more than 'read-only' user access should register to create an EMA account before they log in.	
S supports the continuous exchange of data	between information systems across the European	medicines regulatory network and a	cross the pharmaceutical industry.	Crea	te EMA Account	
5 provides users with the following organisat	tion data management services:					
 view, search, export organisation data and request registration of a new organisation access to multi-lingual organisation data. 	I change request data; or update existing organisation data;			About OMS		
a management and data quality processes d cesses.	rive the SPOR data management services to ensure	e that the highest quality of data is a	vailable to support EU regulatory	For more information about using provides details on:	OMS see "About OMS". This document	
				 data content; licensing; copyright; data protection. 		
				Related information		
				For further information about EMA IDMP standards, please see the El business and technical documents	's implementation of SPOR and the ISO MA corporate website. This also includes	

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.

4.4.3 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 <u>OMS documents page</u>.

<u>Note</u>: 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 <u>SPOR portal;</u>

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.

SPOR - Organisations Management System						staisiunien_a AstraZeneca UK Limiti	ed Logout		
Substances Products Organisations Referentials Help									
SPOR Home Organis	SPOR Home Organisations View Requests Documents								
Home / Search Organi	ations								
These results may inclu	These results may include organisations selected because their historic versions meet the criteria. You can export the data to see historic versions.						×		
Show search	• Show search Reset Search						Reset Search		
	₩ 🐳 Page 1 of 4 🕨 ₩ Showing 20 💙 of 69 results							✓ of 69 results	
Organisation ID	Organisation ID Organisation Name 🛦 Country 🗧 Location ID 🗧 City 🗧 🛛 Address Postcode 🗧 Location status 🕴 Modified 🕴 Action							Actions	
ORG-100000002	AstraZeneca	Belgium	LOC-100005999	Zaventem	Corporate Village	1935	ACTIVE	2017-12-05T12:24:01	+ 16 Q
ORG-10000002	AstraZeneca	Belgium	LOC-100006104	Destelbergen	Schaessestraat 15	9070	ACTIVE	2017-12-05T14:29:31	+ 0° Q
ORG-100000002	AstraZeneca	Belgium	LOC-100005391	Uccle	Rue Egide Van Ophem 110	1180	ACTIVE	2017-12-01T15:26:25	+ [©] Q

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 <u>OMS documents page</u>.

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 <u>OMS documents page</u>.

If you prefer instructions in video format, you can watch the "<u>SPOR Learning Module: OMS03 -</u> <u>Working with OMS Change Requests</u>" 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 onscreen 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:

All scientific procedures (e.g. for Orphan Designation, Innovation Task Force briefing meetings, PLM, etc.)

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. Cannot access IRIS, or create/manage submission, unless the User also gives himself the role of Industry Manager (below).
- **IRIS Industry Manager**: can create new applications, edit, submit and withdraw the created applications or any other where the user has been specifically added as Industry Manager. Assigns other managers / contributors, reassigns submission/portal contact only to these submissions.

This role is also acting as a **Submission/Portal Contact**. There can be multiple managers assigned to the submission/case, but only one of them can be set as a submission/portal contact for communication.

- **IRIS Industry Contributor** (this role is automatically assigned also to IRIS Industry Manager): 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**: can access any submission/application made on behalf of an organisation, assign submissions to managers and contributors, reassign submission/portal contact to the submissions.

•

Parallel Distribution procedures

Affiliated roles:

- IRIS Parallel Distribution User Admin⁽⁴⁾
- IRIS Parallel Distribution Manager: can create, edit, submit and withdraw applications.



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• 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 role	es				
Activities	User Admin	Manager (who is also a Submission/Por tal contact)	Contributor	Coordinator	IRIS Individual user
Approve IRIS Industry/Parallel Distribution Users in EMA Account Portal	V	_			
Create/delete/submit their own draft submissions in IRIS Portal		V			V
Edit/view/withdraw their own submissions in IRIS Portal		V			V
Edit/view specific submission in IRIS Portal		V	V		
Allocate managers/contributors to their own and specific submissions in IRIS Portal		V			
Reassign submission/portal contact to their own and specific submissions in IRIS Portal.		V			
Edit/view all submissions in IRIS Portal made on behalf of an organisation				V	
Allocate managers/contributors to all submissions made on behalf of an organisation				V	
Reassign submission/portal contact to all submissions made on behalf of an organisation				V	

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 "<u>User</u> <u>Administrator Guide</u>" 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-requisites³:

You need to have an "EMA user account" (see section

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

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

Official addressDomenico Scarlattilaan 6 • 1083 HS Amsterdam • The NetherlandsAddress for visits and deliveriesRefer to www.ema.europa.eu/how-to-find-usSend us a questionGo to www.ema.europa.eu/contactTelephone +31 (0)88 781 6000



 Question
 Go to www.ema.europa.eu/contact
 Telephone +31 (0)88 781 6000
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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).

<u>Note</u>: 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 <u>EMA Account Management</u> 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: <u>User Administrator Guide · EMA Account Management (europa.eu)</u>.

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



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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 <u>IRIS platform</u>;
- Click "Sign In" (top right of your screen) and then click on the blue "EMA Account" button;
- On the Sign in window (see Figure 10), check your email address is correct, and click Next button.

Depending on the user domain, you will either be redirected to your organisation authentication page or will receive an email with an authentication code as showed in the Figure 10 below.

C Sign in	The user insert the email address instead of	Pedicines john.smith@company.co Enter password Password Pergotten your password? Other ways to sign in	Federation: the user is redirected to its own organisation authentication page	Microsoft John smith@company.co Review permissions	The user accept the EMA Terms and Condition and can see the information collected
john smith@company.co Cant access your account? Back EMA users: sign in with your ema	Next il address		Sign in OTP: A numeric	European Medicines Agency even This resource is not shared by M The organisation European Medic would like to: Sign you in Sign you in You Bood only accept if you hast Europe	nanponnicrosoft. Nicrosoft. ines Agency ss and photo an Medicines Agency.
Other users: sign in with your use @id-test.ema.europa.eu Follow this guidance to recover y password. Sign-in options	rname followed by	← johnsmith@company.co Enter code We just sent a code to johnsmith@co Enter code	code is sent to the email address	by accepting, yoak for this arguments of according to the police. However, the privacy statement, European Medicine Ap, information act your access. You can e photos with your access with you can be https://myaps.microsoft.com/euromanp.com	o accesso process percy may log merry may log wmicrosoft.com Accept
			Sign in		

Figure 10.

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

 Official address
 Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

 Address for visits and deliveries
 Refer to www.ema.europa.eu/how-to-find-us

 Send us a question
 Go to www.ema.europa.eu/contact

 Telephone +31 (0)88 781 6000
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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 <u>substance list available on IRIS</u> (in the IRIS home page, no login is required to search for an active substance);
- 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 in SMS

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

- 1. Read the <u>EMA Substance names best practice</u> guideline first.
- 2. Complete the <u>Substance Request Form</u> and save it.
- 3. Raise a request directly in the "<u>Request SMS services</u>" 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.



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

IMPORTANT: please note that for many procedures at EMA and in IRIS, e.g. for marketing authorisation, orphan designation or paediatric investigation plan and waivers, a company code is not acceptable as preferred term for the active substance(s) involved.

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.
- An RPI can be "owned" by only one organisation (location) at a time. If multiple organisations are creating separate submissions for the same product, they will have to transfer the RPI to one another (see Transfer a Research Product Identifier (RPI)).
- A single RPI should cover authorised products considered to be under the notion of "Global Marketing Authorisation (GMA)" (<u>European Commission (EC) Notice to applicants</u>, sections 2.4 and 2.8); if there are doubts as to whether a requested RPI relates to a product for which an RPI has already been granted, EMA may further investigate the matter to clarify the situation.
- 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:

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.



- The RPI already exists but it 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.
- 2. 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 <u>Products</u> <u>tab</u> of the IRIS portal. Once logged in, click on the <u>"Products" tab</u>, and then on "RPI – products". This 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 an RPI you are looking for, there are several possibilities:

- 1. This is a **completely new substance**, not yet registered with EMA. Please follow the instructions in "How to register a new active substance in SMS" to request registration of the substance(s) in SMS, then request a new RPI based on the substance(s) (see 8.2).
- 2. The **substance(s)** is **present** in **IRIS**, and is visible in IRIS in the <u>List of SMS approved</u> <u>substances</u>, but **there is no RPI yet**, as this is a new development for that substance. Please proceed directly to request a new RPI in IRIS (see 8.2), based on the substance(s).
- 3. 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 the 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 <u>not</u> be requested, as it will be refused by the EMA data stewards. There are two alternative possibilities:
 - 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 10) to the new RPI owner, either an organisation/location or an individual. The procedure is described in section 8.3 below. In this case, the RPI will be transferred to the new owner, and any new Regulatory Entitlement (such as Orphan Designation, Paediatric Decision, Scientific Advice letter) will be granted to the new RPI owner.



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, or the one in lowercase letters.

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). **Please do not add both a base substance and one of its salt/hydrates.**

Figure 10.

IRIS	AGENCY ♠ Home Forums Submissions - My Organisations Regulatory Entitlements	
ome > Draft Submissions > N	w Draft Submission	
New Draft Su	Ibmission	
1 Choose Applicant Type ?	Choose Submission Type 3 Add Contributors	
Select the organisation on be	alf of which you are applying *	
	х Q	
The choice field above allows yo organisation via the EMA Account	u to choose one of the organisations recorded in SPOR-OMS to which you are affiliated. You can request affiliation to an nt Management System. Registration of new organisations in SPOR-OMS is done via EMA Servicedesk.	
The choice field above allows y organisation via the EMA Account Location *	u to choose one of the organisations recorded in SPOR-OMS to which you are affiliated. You can request affiliation to an nt Management System. Registration of new organisations in SPOR-OMS is done via EMA Servicedesk.	
The choice field above allows yo organisation via the EMA Accou Location *	u to choose one of the organisations recorded in SPOR-OMS to which you are affiliated. You can request affiliation to an nt Management System. Registration of new organisations in SPOR-OMS is done via EMA Servicedesk.	
The choice field above allows y organisation via the EMA Accou Location *	u to choose one of the organisations recorded in SPOR-OMS to which you are affiliated. You can request affiliation to an nt Management System. Registration of new organisations in SPOR-OMS is done via EMA Servicedesk. X Q	
The choice field above allows y organisation via the EMA Accou Location * Submission Type * Transfer a Research Product	x Q u to choose one of the organisations recorded in SPOR-OMS to which you are affiliated. You can request affiliation to an nt Management System. Registration of new organisations in SPOR-OMS is done via EMA Servicedesk. x Q x Q	
The choice field above allows y organisation via the EMA Accou Location * Submission Type * Transfer a Research Product Manager *	x Q u to choose one of the organisations recorded in SPOR-OMS to which you are affiliated. You can request affiliation to an nt Management System. Registration of new organisations in SPOR-OMS is done via EMA Servicedesk. x Q x Q	

• The user can request to be affiliated to the organisation currently "owning" the RPI, as IRIS Industry Manager, via the EMA <u>Account Management Portal</u>. 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 <u>substance list available on IRIS</u> (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 like those in other IRIS submissions.

- 1. Create a new submission in the <u>Draft submissions page</u> of the IRIS portal, selecting "**Request** for Research Product".
- 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. <u>Note:</u> 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. IMPORTANT: for many procedures at EMA and in IRIS, e.g. for marketing authorization, orphan designation or paediatric investigation plan and waivers, a company code is not acceptable as preferred term for the active substance(s) involved. If any of active substances in your proposed RPI has a company code as preferred term, and you plan to request e.g. a paediatric investigation plan, you will need to change the preferred term (name) of the substance record in SMS first (see 7 above7 above).
- 6. For each substance, you also need to specify the "nature of the active substance", as this 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/indication (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.
- 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.

- <u>Note 1:</u> 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.
- <u>Note 2:</u> 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 <u>Innovation in medicines</u> (for ITF), or by writing to the Scientific Advice office directly, at <u>ScientificAdvice@ema.europa.eu</u> (for human Scientific Advice, Protocol Assistance, or Qualification Advice/Opinion) or <u>VetScientificAdvice@ema.europa.eu</u> (for veterinary scientific advice procedures). You will be sent a specific form to request one of these "special" RPIs.

8.3 Transfer a Research Product Identifier (RPI)

This automated procedure can be managed directly in IRIS by industry users with **"Industry Manager"** role, to transfer an existing RPI from the current sponsor/owner to a new sponsor/owner, or to transfer a RPI to a different location of the same sponsor/owner.

Please transfer an RPI only after any draft submission that directly references that RPI has been completed and submitted (thus becoming "ongoing"). Transferring an RPI before completing a submission that uses it can block that submission. On the other hand, transferring an RPI has no interdependence with other EMA systems, different from IRIS.

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.
- 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 11);



Figure 11.

ß	Select RPI	Iranster a Research Product Reference: EMA/PM/0000171062
	Please note that you can only see and choose RPIs that are registered to an organization to which you are affiliated as an Industry manag a different organisation, you should either request affiliation to the RPI "owner", or the RPI owner should transfer the RPI to your organis	ger. If you are applying on behalf of ation (via a separate IRIS procedure)
	Select Research Product Identifier (RPI)	_
	PRD/0000070846	× Q
	Active substance(s)	
	(-)-(R)-3-(2-HYDROXYMETHYLINDANYL-4-OXY)PHENYL-4,4,4-TRIFLUOROBUTYL-1-SULFONATE	
	Domain	
	_	
	Target Species	
	Name 🕇	
	Adult male cat	
	Adult male goat	
		*
	Save and Return Return	

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 search the new Organisation Location (you can search by organisation name, LOC ID code from OMS, or also address/postcode) and add the correct address. 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 12). It is advisable to transfer the RPI to the location (address) corresponding to the legal seat of the organisation.



Figure 12.

\$	Transfer Details	Transfer a Research Product Reference: EMA/PM/0000171062
	Current Sponsor details Sponsor Office of Health	
	Address	
6	New Sponsor details	
	Organisation	~
	New Organization	
	National Institute of Pharmacy and Nutrition	× Q
	Address	
	Save and Return Return	

- 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.

8.4 Consequences of transferring an RPI

1. **Transferring an RPI does not transfer any associated submission or case/procedure**, whether in draft, ongoing or completed status, to the new RPI "owner": all submissions already created will remain assigned to the existing applicant (submissions in "draft"status may be prevented from progressing, as mentioned above). The same applies for any existing regulatory entitlements, such as orphan designations, Scientific advice entitlements, etc.: they remain assigned to the current holder/sponsor.



- 2. IRIS users affiliated to the new RPI owner (organisation) will not be able to view and access previous submissions (or their documents) or regulatory entitlements associated to the previous RPI owner(s).
- 3. 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, etc.. 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 <u>ADIS Insight</u>.

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 <u>European</u> <u>Commission website</u> and the <u>EMA website</u> respectively.