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IRIS quick guide to the portal for Orphan Industry users

Version 1.7

| | |
|---|-----------|
| 1. Purpose and context..... | 2 |
| 1.1. Purpose of this Quick Guide | 2 |
| 1.2. Context and pre-requisite steps for new draft OD applications..... | 2 |
| 2. How to log into the IRIS portal..... | 3 |
| 3. Prior to final submission of an application..... | 4 |
| 3.1. How to create a 'Request for Research Product' | 4 |
| 3.2. How to create an application for orphan designation (OD) | 6 |
| 3.3. How to add contributors to a draft OD application..... | 8 |
| 3.4. How to delete a draft application | 9 |
| 3.5. How to submit a request for a Pre-Submission Meeting | 9 |
| 3.6. How to display and sort submissions..... | 10 |
| 3.7. How to search for submissions | 10 |
| 4. After final submission of an application..... | 11 |
| 4.1. How to respond to a notification email from EMA requesting VSI | 11 |
| 4.2. How to respond to a List of Questions (LoQ) request..... | 12 |
| 5. After a COMP opinion has been adopted | 13 |
| 5.1. How to create a request for an Appeal | 13 |
| 5.2. How to submit an Annual Report for an orphan designation | 14 |



1. Purpose and context

1.1. Purpose of this Quick Guide

This 'Quick Guide' has been produced to help people using the IRIS | Regulatory & Scientific Information Management platform know how to use the portal to submit an orphan designation (OD) application and to carry out several related activities. This guide will be updated in the weeks following the launch of the portal, with the addition of further sub-sections screenshots to illustrate some of the steps.

This document is intended for **Orphan Industry users** who have already been granted Orphan Industry user access roles for the IRIS portal.

If you have not yet requested a user access role or have not carried out the pre-requisite steps listed below (in Section 1.2 'Context') please refer to the '**IRIS Quick Guide to Registration**' which can be found under 'Guidance and forms' in the orphan designation section of the [EMA corporate website](#).

1.2. Context and pre-requisite steps for new draft OD applications

From **19 June 2018 onwards**, organisations seeking to apply to the EMA for a product to be considered for orphan designation will be able to follow a new process.

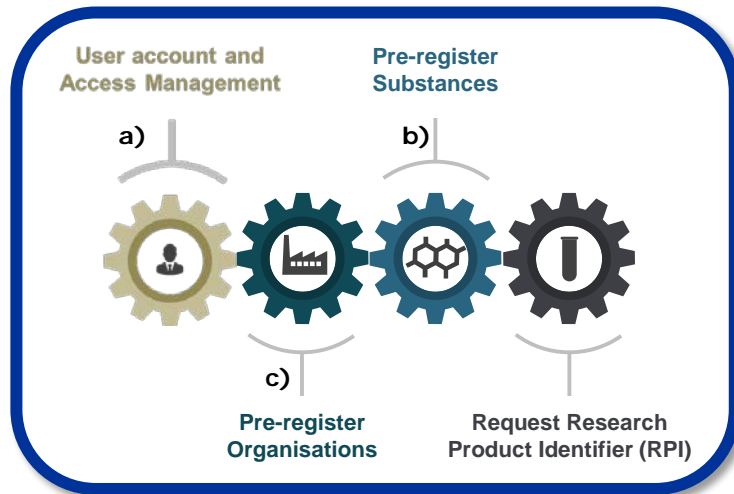
This new process, which became **mandatory after 19 September 2018** for orphan designation, requires the following steps to be completed before any activity relating to an orphan designation procedure can be carried out using the IRIS Portal:

- a) Both the Applicant¹ and Sponsor² of an orphan designation, or persons acting on their behalf, *must have an active EMA user account* and *must be registered with IRIS user access roles* of either '**Orphan Industry Manager**' or '**Orphan Industry Contributor**';

- b) The '**Organisation**' for which the OD application is being submitted *must be registered* in the EMA's **Organisation Management System (OMS)**;

- c) You will need to ensure that the '**Substance(s)**' for which the application is being submitted have been registered and appear as '**Current**' on the official EMA list of all substances, the **European Union Telematics Controlled Terms (EUTCT)** database;

- d) A validated **Research Product Identifier (RPI)** must already be listed in IRIS. If the **RPI** is not listed, then a '**Request for Research Product**' needs to be submitted through the portal (For instructions on how to do this see **Section 3.1** of this Quick Guide). The request will be validated by EMA staff and it may take a day or two for the validated **RPI** to appear in the portal for you to use when creating your draft OD submission. So it is a good idea to do this in advance.



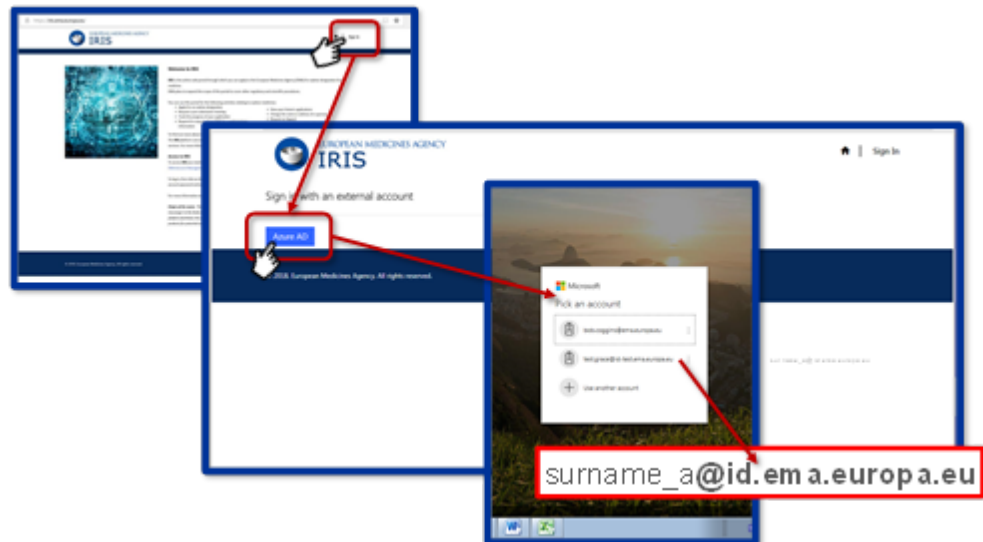
¹ 'Applicant': The individual or organisation submitting the application to EMA.

² 'Sponsor': The addressee of the European Commission decision granting orphan designation for the medicinal product.

2. How to log into the IRIS portal

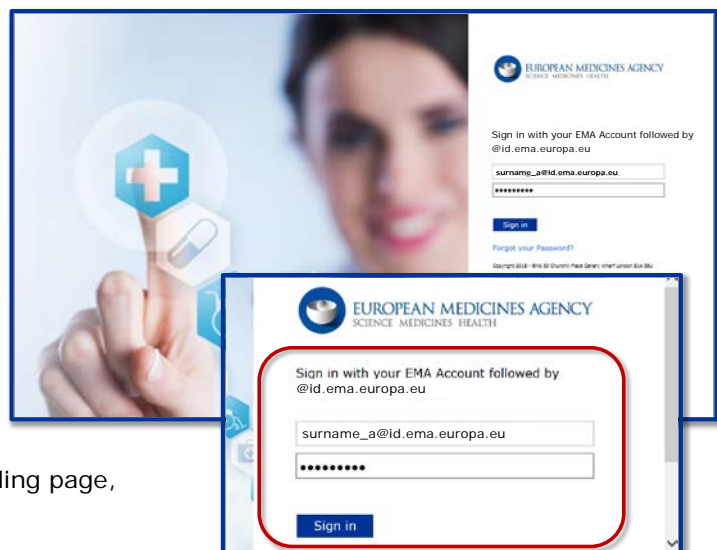
To access IRIS you need an active EMA user account and an 'Orphan Industry' user access role. To log in, carry out the following steps:

1. Click on the following link to the [IRIS portal](https://iris.ema.europa.eu) or type "<https://iris.ema.europa.eu>" in your web browser;



2. Click on '**Sign In**' at the top right of your screen;
3. In the next window that opens, click on the blue '**Azure AD**' button – this will take you to the Azure AD (Active Directory) screen;
4. In the '**Pick an account**' window, EITHER:
 - a. click on '**use another account**' 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
 - b. if this account name appears in in the '**Pick an account**' list window, simply click on it;

5. In the first box of the 'Sign in' screen that appears, type the same account name (as described in step 4 above - i.e. **your EMA username** followed by "**@id.ema.europa.eu**");
6. In the box below that, enter your **EMA user account password**;
7. Click on the blue "**Sign in**" button.



You will be returned to the IRIS portal landing page, ready to access the portal.

3. Prior to final submission of an application

3.1. How to create a 'Request for Research Product'

Before you can create a new submission for orphan designation you need a valid Research Product Identifier (RPI).

If a valid RPI for your research product does not appear on the list when creating a draft submission for orphan designation, you must request one by creating a 'Request for Research Product' submission in the portal.

The steps set out below take you through a series of stages which are similar to the stages you go through in many of the activities carried out in the portal.

1. From the IRIS portal home page, click on **"My submissions"**;
2. Click on **"Draft submissions"** - the "Draft Submissions" screen opens up with a blue "New Draft" button on the right;
3. Click **"New draft"**- a screen with the heading "Portal – New Submissions" opens up showing 4 stages. The first stage "1. Choose Sponsor Type" is highlighted in blue;
4. Click the drop-down arrow at the right hand end of the box entitled "Is the sponsor an organisation or individual?";
5. Select **"Organisation"** from the drop-down list;
6. Click the **"Next"** button - a blue box saying "Processing..." appears. The screen is refreshed with "Choose Sponsor Type" now coloured green and with a tick next to it to indicate that step is completed;
7. The next stage, "2. Choose Submission Type", is now coloured blue and 2 mandatory fields (marked with a red asterisk **"*"**) appear, labelled "Organisation" and "Submission Type" with a magnifying glass symbol on the right of each box to signify that you can "search" a list to populate this field;
8. Type in your **Organisation ID** in the "Organisation" box and click on the magnifying glass search symbol;
9. Click on the right organisation from the list;
10. Click "Select" - a **"Lookup records"** window pops up and, after the system has finished loading the records, a list appears showing the organisation(s) that are affiliated to the portal user role that you logged into the portal with. If, when you requested your Orphan Industry role, you only selected a single organisation to be affiliated to, only that one organisation will appear in this list;
11. After you **select an organisation** and click **"Next"**, you are returned to the "Portal - New Submission" screen where the "Organisation" field has been populated with the organisation you selected;
12. Click on the **magnifying glass** search symbol for the **"Submission Type"** box; Scroll down the list and click on **"Request for Research Product"**;
13. Click **"Select"** - you are returned to the "Portal – New Submission" screen where the "Submission Type" field has been populated with the type you selected;

14. Click **"Create and Next"** - another "Lookup records" window appears and after the system has finished loading the records an alphabetical list of submission types comes up. If the list is longer than one page, the numbers of pages available are shown at the bottom of the pop-up window. You can navigate between the pages by clicking the "<" or ">" symbols or clicking on a particular page number;
15. After clicking "Create and Next", a box saying "Processing..." appears and you are then taken to the "3. Location" stage. The "Choose Submission Type" stage is now coloured green with a tick next to it. By clicking on "Previous" you can look back at the stage you have just completed;
16. Click on the **magnifying glass** search symbol for the **"Location"** box;
17. Select an **organisation location** from the list and click **"Select"** –again, a "Lookup records" window appears and after the system has finished loading the records, a table of organisation names and their geographical locations appears;
18. Choose the location and click **"Select"** - you are returned to the "Portal - New Submission" screen where the "Location" field has been populated with the location you selected, but only the Organisation name will be shown;
19. Click **"Next"**- a box saying "Processing..." appears and you are then taken to the "4. Add Contributors" stage. The "3. Location" stage is now coloured green with a tick next to it. If there are no other people who have Orphan Industry roles affiliated to the organisation you have selected, the list will contain the message "no records to display";
20. Click **"Continue to Submission Form"** - a new screen entitled "Submission Form" appears with the "Research Product Details" coloured in blue with a green tick next to it;
21. Double click on the word **"Research Product Details"**;
22. In the **"Request for Research Product"** screen that appears, click on the **"Add"** button to the right of the heading "Substance" - a pop-up window showing a list of substances appears. This list is populated from the EUTCT list of validated substances and includes those substances with the status "Current" in EUTCT;
23. In the pop-up window that appears search for the substance(s) that your research product contains;
24. **Click on each substance** that your research product contains;
25. Click **"Add"** - a "Request for Research Product" screen appears showing a "First Developer" box pre-populated with the organisation you selected earlier and a box labelled "Name";
26. **Select the substance(s)** contained in your medicinal product and click **"Add"** - you are returned to the "Request for Research Product" screen, where you can see the selected substance(s) listed both in the name field and, below that, under the heading "Name";
27. Click on the **"Add"** button to the right of the heading **"Enabling Technologies"** - a pop-up window showing a list of enabling technologies appears;
28. **Select the enabling technologies** that should be included and click **"Add"** - you are returned to the "Request for Research Product" screen, where you can see the selection you made listed under the heading "Enabling Technologies";

29. Click "**Save and Return**" - there will be a pause of a few seconds, while the system records what you have entered, before the next screen appears. You are then returned to the "Submission Form" screen and invited to make the "RPI Declaration";
30. Double click on the word "**RPI Declaration**" that is shown in blue;
31. Click on the tick box to the left of the declaration statement (that begins with the words: "I confirm...");
32. Click on the "**Declaration and submission**" box - a pop-up window appears, allowing you a chance to go back and check that all the details you entered are correct ("Review Application"), or to continue and submit;
33. When you are happy with all the details entered click on "**Submit**".

Back in the portal 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 system does not automatically approve your request for an RPI, it is reviewed by the EMA team who then approve it. A standard lead time is being agreed for how quickly the team will respond to RPI requests and will be communicated before the end of the pilot transition period.

3.2. How to create an application for orphan designation (OD)

In order to create an application for orphan designation in the IRIS portal, you must have already registered for, and been granted an '**Orphan Industry Manager**' role through the [EMA Account Management portal](#).

If you have only been granted an '**Orphan Industry Contributor**' role, you will **NOT** be able to create an application for orphan designation.

To request an 'Orphan Industry Manager' access role, please refer to the '**IRIS Quick Guide to Registration**' which can be found under 'Applying for an orphan designation' on the [EMA corporate website](#).

Creating a new submission for orphan designation is the most involved process that you will carry out using the IRIS portal but, if you have already been through the 'Request for Research Product' process using IRIS, some of the steps are the same and the general flow will feel familiar to you.

1. From the IRIS portal home page, click on "**My submissions**";
2. Click on "**Draft submissions**";
3. Click "**New draft**" [a screen with the heading "Portal – New Submissions" opens up showing 4 stages. The first stage "**1. Choose Sponsor Type**" is highlighted in blue];
4. From the drop-down arrow on the box below "**Is the sponsor an organisation or individual?***" select "**Organisation**" and click "**Next**";
5. "**2. Choose Submission Type**" is now coloured blue and 3 mandatory fields (marked with a red asterisk *****) appear labelled "**Organisation**" "**Location**" and "**Submission Type**";

6. Use the magnifying glass search symbol to look up the organisations available for you to select (N.B. only the organisation(s) affiliated to the portal user role that you logged into the portal as will be displayed here);
7. Pick the right organisation and (there may only be one) and click **"Select"**;
8. Use the search symbol to look up the locations available for you to select, pick the right one and click **"Select"**;
9. Use the search symbol to look up the submission types available, click on "Application for Orphan Designation" and **"Select"**;
10. Click **"Create and Next"**;
11. Click **"Add"** to bring up a list of people to select as contributors (N.B. The list will only include those people who have been granted an Orphan Industry access role that is affiliated to the specific organisation (Company + Country) you selected in the previous screen. If no-one has done this, the list will be empty);
12. If there are names on the list, select one or more contributors and their names will appear on the main "Portal – New Submission" screen (N.B. You are not required to add any contributors at all. You can also add and remove contributors later on.);
13. Click **"Continue to submission form"** and a reference number (e.g. EMA/OD/0000001234) for your draft submission is displayed on the upper right hand side of the "Portal – New Submission" screen (N.B. It is a good idea to take note of the reference number created) There is also now a list of seven steps starting with **"Select RPI"** and ending with **"Declaration"**) relating to the OD Application displayed on the left hand side of your screen;
14. Click on **"Select RPI"** to bring up "Research Product Identifier (RPI)" screen;
15. Click the **magnifying glass** search symbol to bring up a list of RPI names;
16. In the pop-up window, pick an RPI name from the list and click **"Select"**;
17. Back in the "Research Product Identifier (RPI)" screen, click **"Save and Return"** and you are returned to the "Submission Form" screen;
18. Click on **"General Information"** complete (at least) the mandatory fields marked with a red asterisk **"*"** and click **"Save and Return"** (N.B. if you miss out mandatory field it will not let you move on until you have done so);
19. Click on **"Scientific Information"** and complete (at least) the mandatory fields marked with a red asterisk **"*"** and click **"Save and Return"** (N.B. in the prevalence box, enter the number of incidences out of 10,000 as a single number and NOT in the form of a ratio);
20. Back in the main **"Submission Form"** Screen, click on **"Documents from industry"**;
21. In the next screen that appears, you can directly upload documents and create subfolders in your submission. You can update multiple files by holding the 'Ctrl' key while selecting them; while there is no maximum number of files or global size, there is a size limit of 50 Mb per file. It is suggested that for references, a subfolder is created to contain individual files for each reference;
22. Click **"Save and Return"** when you have finished uploading documents;

23. You have now successfully created a draft submission which will now appear in your "**Draft Submissions**" list and can open it up again to add more information when you are ready to do so;
24. When you want to add more information, click on "**My submissions**"; then "**Draft submissions**" find the draft submission you want to edit;
25. Click on the downward arrow on the right hand side and select "**Edit Draft**" from the drop-down list that appears;
26. Make your changes or additions and, if you are still not ready to submit the final application, click "**Return**" to save your draft application;
27. Repeat steps "26." to "28." until you are ready for final submission;
28. When you are ready to submit your final application, click on "**Declaration**";
29. **Click on the tick box** to the left of the declaration statement (that begins with the words: "I confirm...") to formally declare that you are authorised to submit the application;
30. Click on the "**Declaration and submission**" button;
31. If you are unsure or think of any part of the application you want to revise, click "**Review Application**" and this will return you to the draft submission;
32. If you are sure you want to submit the application, click "**Submit**".

Your application has now been submitted and is locked for edit/upload unless EMA open it up again for you to add or amend any information.

You are returned to the portal homepage and you can now look up the submission you have just submitted using the "My Submission" drop-down menu at the top of the page and selecting either "Draft Submissions" or "Ongoing Submissions".

3.3. How to add contributors to a draft OD application

You can only do this for the draft applications that you yourself have created as an "Orphan Industry Manger".

From the IRIS portal home page, carry out the following steps:

1. Click on "**My submissions**" then "**Draft submissions**";
2. Scroll down and find the application you want from the list of your drafts;
3. On the right hand side, click on the drop-down arrow and select "**Manage Contributors**";
4. Click "**Add**";
5. In the pop-up window, click the **magnifying glass search symbol** to bring up a list (of people eligible to be contributors) search by name and find the name you want to add as a contributor;
6. Click "**Continue to submission form**";
7. To add more contributors to the same application, repeat steps 4. to 6. above.

3.4. How to delete a draft application

You can only do this for the draft applications that you yourself have created as an "Orphan Industry Manger" role.

1. Click on "**My submissions**" then "**Draft submissions**";
2. Scroll down and find the application you want from the list of your drafts;
3. On the right hand side, click on the drop-down arrow and select "**Delete Draft**" and a confirmation message will open up in a new window;
4. Click on the "**Delete**" button to confirm that you definitely want to delete your draft – you cannot undo this afterwards;
5. The draft has now been deleted from the portal.

3.5. How to submit a request for a Pre-Submission Meeting

The way you do this in IRIS is by following a reasonably simple 'generic submission' process whose first two stages (covered in steps '1.' to '8.' below) are identical to those you follow when creating an application for orphan designation.

1. **IMPORTANT:** before creating a request for a **presubmission meeting**, please create the draft request for orphan designations (to be left as a draft, without submitting it for the moment); any documents should be uploaded within the draft request for orphan designations, not in the presubmission meeting request. The number of the draft request for orphan designation should be referenced in the presubmission meeting request;
2. From the IRIS portal home page, click on "**My submissions**";
3. Click on "**Draft submissions**";
4. Click "**New draft**" [a screen with the heading "Portal – New Submissions" opens up showing 4 stages. The first stage "**1. Choose Sponsor Type**" is highlighted in blue];
5. From the drop-down arrow on the box below "**Is the sponsor an organisation or individual?***" select "**Organisation**" and click "**Next**";
6. "**2. Choose Submission Type**" is now coloured blue and 3 mandatory fields (marked with a red asterisk "*****") appear labelled "**Organisation**" "**Location**" and "**Submission Type**";
7. Use the magnifying glass search symbol to look up the organisations available for you to select (N.B. only the organisation(s) affiliated to the portal user role that you logged into the portal as will be displayed here);
8. **Click on the right organisation** and (there may only be one) and then click "**Select**";
9. Use the search symbol to look up the locations available for you to select, **click on the right location** and then click "**Select**";
10. Use the search symbol to look up the submission types available, click on "**Request for Pre-Submission Meeting**" and then click "**Select**";
11. Click "**Create and Next**";

12. Click "**Continue to submission form**" and a number (e.g. EMA/OD/0000001234) for your draft submission is displayed on the upper right-hand side of the "Portal – New Submission" screen (N.B. It is a good idea to take note of the reference number created);
13. Back in the Submission Form screen, click on "**Submission Details**", enter the information that you want the EMA Orphan Medicines team to know and click "**Save and Return**";
14. Back in the Submission Form screen, click on "**Documents from Industry**", where you will be able to upload documents;
15. Click on "**Save and Return**";
16. **Click on the tick box** to the left of the declaration statement (that begins with the words: "I confirm...") to formally declare that you are authorised to submit this request;
17. Click on the "**Declaration and submission**" button;
18. If you are unsure or can think of any part of the request or documents uploaded that you want to revise, click "**Back To List**" and this will return you to the draft submission;
19. If you are sure you want to submit the application, click "**Submit**", then "Ok" and then "**Submit**";
20. Your request for a Pre-Submission Meeting has now been submitted and will appear in your "**Draft Submissions**" list. To view it, go to the IRIS portal home page, click on "**My submissions**"; and then click "**Draft submissions**" – your Request for Pre-Submission Meeting will appear at the top of the list.

3.6. How to display and sort submissions

1. From the IRIS portal home page, click on "**My submissions**";
2. Click on any of the options where you expect to find more than one submission listed: "**Draft Submissions**", "**Ongoing Submissions**" or "**Completed Submissions**";
3. If you have a Manager role, you will see all the submissions you have created and all the submissions you have been assigned to as a contributor. If you have a Contributor role, you will see all the Submissions to which you have been assigned. If you have both roles, you will see all submissions of your own and those for which you have been added as a Contributor;
4. Click on any of the column headings that appear in **blue** font and the rows listed in the table will be sorted either in ascending or descending order – the sorting will be either alphabetical or numerical, depending on the contents of the column.

3.7. How to search for submissions

1. From the IRIS portal home page, click on "**My submissions**";
2. Click on any of the options where you expect to find more than one submission listed: "**Draft Submissions**", "**Ongoing Submissions**" or "**Completed Submissions**";
3. If you have a Manager role, you will see all the submissions you have created and all the submissions you have been assigned to as a contributor. If you have a Contributor role, you

will see all the Submissions to which you have been assigned. If you have both roles, you will see all submissions of your own and those for which you have been added as a Contributor;

4. In the search bar, you can enter any combination of letters and or numbers that will identify the submission you are looking for and might be contained in the columns that are displayed on screen (e.g. "Submission ID", "Organisation", "Submission Type");
5. If you don't know the exact wording of the submission you are searching for but you know part of it, you can use the asterisk symbol "*" as a 'wild card' to enlarge your search;
6. Click on the magnifying glass search symbol or press "Enter" on your keyboard to launch the search;
7. A list of the relevant results that match the search criterion you typed in the search bar will be displayed. If the list contains multiple records, it can be sorted by clicking on the blue column headers, as described in the previous section.

4. After final submission of an application

4.1. How to respond to a notification email from EMA requesting VSI

On receipt of a notification email from EMA stating that "Validation Supplementary Information (VSI)" relating to one of your Ongoing Submissions is required, log into the IRIS portal and carry out the following steps:

1. From the IRIS portal home page, click on **"My submissions"**;
2. Click on **"Ongoing submissions"**;
3. Locate the submission mentioned in the e-mail by using the sort or search features described in Sections 3.6 and 3.7 earlier in this Quick Guide, or by just scrolling down the list until you find it;
4. At the end of the row in the list where your submission appears, click on the drop-down arrow and select **"View/edit"**;
5. In the **"Submission Form"** page that appears click on the sections that you need to update as stated in the notification you received from EMA (e.g.: General Information, Scientific information, etc.);
6. The selected sections will open in edit mode - make the requested modifications and click on **"Save and Return"** - all modifications will have been saved and you will return to the **"Submission Form"** page;
7. If you need to upload documents, click on **"Documents from Industry"**; **please upload revised versions of files using the same file name and extension**, to avoid separate files for revised documents. Click on **"Save and Return"** when you are done;
8. **Click on the tick box** to the left of the declaration statement (that begins with the words: "I confirm...") to formally declare that you are authorised to submit this request;

9. Click on the **"Declaration and submission"** button;
10. If you are unsure or can think of any part of the request or documents uploaded that you want to revise, click **"Back To List"** and this will return you to the draft submission;
11. If you are sure you want to submit the application, click **"Submit"**, then "Ok" and then **"Submit"**;
12. Your updated application has now been submitted and will now appear in your "Draft Submissions" list.

4.2. How to respond to a List of Questions (LoQ) request

On receipt of a notification email from EMA regarding a "List of Questions (LoQ)" relating to one of your Ongoing Submissions, log into the IRIS portal and carry out the following steps:

1. From the IRIS portal home page, click on **"My submissions"**;
2. Click on **"Ongoing submissions"**;
3. Locate the submission mentioned in the e-mail, using the sort or search features described in Sections 3.6 and 3.7 earlier on in this Quick Guide, or by just scrolling down the list until you find it;
4. At the end of the row in the list where your submission appears, click on the drop-down arrow and select **"View/edit"** – Note: In the LoQ process, most of the submission form is locked in 'Read Only' mode and so the only action that can be performed is to upload new documents;
5. If you need to upload documents, click on **"Documents from Industry"**; **please upload revised versions of files using the same file name and extension**, to avoid separate files for revised documents. Click on **"Save and Return"** when you are done;
6. **Click on the tick box** to the left of the declaration statement (that begins with the words: "I confirm...") to formally declare that you are authorised to submit this request;
7. Click on the **"Declaration and submission"** button;
8. If you are unsure or can think of any part of the request or documents uploaded that you want to revise, click **"Back To List"** and this will return you to the draft submission;
9. If you are sure you want to submit the application, click **"Submit"**, then "Ok" and then **"Submit"**.

Your updated application has now been submitted and will appear in your "Draft Submissions" list and you will receive an e-mail notification to confirm that you have re-submitted the application as requested by EMA.

5. After a COMP opinion has been adopted

5.1. How to create a request for an Appeal

You can only create a request for an Appeal if you hold the role of "Orphan Industry Manger" and you can only do this for those applications that you have created yourself in that role.

1. From the IRIS portal home page, click on **"My submissions"**;
2. Click on **"Ongoing submissions"**;
3. Click **"New draft"** [a screen with the heading "Portal – New Submissions" opens up showing 4 stages. The first stage **"1. Choose Sponsor Type"** is highlighted in blue];
4. From the drop-down arrow on the box below **"Is the sponsor an organisation or individual?*"** select **"Organisation"** and click **"Next"** ;
5. **"2. Choose Submission Type"** is now coloured blue and 3 mandatory fields (marked with a red asterisk **"*"**) appear labelled **"Organisation"** **"Location"** and **"Submission Type"**;
6. Use the magnifying glass search symbol to look up the organisations available for you to select (N.B. only the organisation(s) affiliated to the portal user role that you logged into the portal as will be displayed here);
7. **Click on the right organisation** and (there may only be one) and then click **"Select"**;
8. Use the search symbol to look up the locations available for you to select, **click on the right location** and then click **"Select"**;
9. Use the search symbol to look up the submission types available, click on **"Appeal"** and then click **"Select"**;
10. Click **"Create and Next"** – you will see the message "processing..." for a short while;
11. Click **"Continue to submission form"** and a reference number (e.g. EMA/OD/0000001234) for your draft submission is displayed below the word "Appeal" on the upper right hand side of the **"Submission Form"** screen (N.B. It is a good idea to take note of the reference number created);
12. Click on **"Start Appeal"** and the "View Start Appeal Form" screen appears;
13. Click on the magnifying glass to select the procedure to be appealed - Procedures which have been submitted and are currently in "On-going Submissions" should be displayed;
14. Click on one of the procedures listed then click **"Select"** and **"Submit"**;
15. From the **"Submission Form"** screen, click on the **"Ground of appeal"** Section;
16. Fill in the relevant information in the mandatory **"Applicant's grounds for appeal *"** box and click **"Save and Return"**;
17. If you need to upload documents, click on **"Documents from Industry"**; **please upload revised versions of files using the same file name and extension**, to avoid separate files for revised documents. Click on **"Save and Return"** when you are done;
18. Click **"Save and Return"**;

19. Click on **"Declaration"**, then click on **the tick box** to the left of the declaration statement (that begins with the words: "I confirm...") to formally declare that you are authorised to submit this request;
20. Click on the **"Declaration and submission"** button;
21. If you are unsure or can think of any part of the request or documents uploaded that you want to revise, click **"Back To List"** and this will return you to the draft submission;
22. If you are sure you want to submit the application, click **"Submit"**, then **"Ok"** and then **"Submit"**.

Your updated request has now been submitted and will appear in your "Draft Submissions" list and you will receive an e-mail notification to confirm that you have re-submitted a request for an Appeal.

5.2. How to submit an Annual Report for an orphan designation

The way you do this in IRIS is by following a simple process whose first two stages (covered in steps '1.' to '8.' below) are identical to those you follow when creating an application for orphan designation.

The process for submitting Annual Reports has now been simplified. Applicants are not requested to compile and submit the previous PDF form, which has been removed from the website. It is now only necessary to complete the information in a few specific data fields in IRIS. Uploading additional supporting documents is still possible but not mandatory.

1. From the IRIS portal home page, click on **"My submissions"**;
2. Click on **"Draft submissions"**;
3. Click **"New draft"** [a screen with the heading "Portal – New Submissions" opens up showing 4 stages. The first stage **"1. Choose Sponsor Type"** is highlighted in blue];
4. From the drop-down arrow on the box below **"Is the sponsor an organisation or individual?*"** select **"Organisation"** and click **"Next"** ;
5. **"2. Choose Submission Type"** is now coloured blue and 3 mandatory fields (marked with a red asterisk **"*"**) appear labelled **"Organisation"** **"Location"** and **"Submission Type"**;
6. Use the magnifying glass search symbol to look up the organisations available for you to select (N.B. only the organisation(s) affiliated to the portal user role that you logged into the portal as will be displayed here);
7. **Click on the right organisation** and (there may only be one) and then click **"Select"**;
8. Use the search symbol to look up the locations available for you to select, **click on the right location** and then click **"Select"**;
9. Use the search symbol to look up the submission types available, click on **"Annual Report"** and then click **"Select"**;
10. Click **"Create and Next"**;

11. Click "**Continue to submission form**" and a reference number (e.g. EMA/OD/0000001234) for your draft submission is displayed on the upper right-hand side of the "Portal – New Submission" screen (N.B. It is a good idea to take note of the reference number created);
12. Click on "**Regulatory Entitlement**" (a generic term for a right granted to a sponsor such as an orphan designation or a transfer of orphan designation);
13. In the "Regulatory Entitlement" window, **click on the magnifying glass symbol** to search through the existing orphan designations for your organisation;
14. Select the orphan designation for which you are submitting the Annual Report and click "**Save and Return**". If you cannot find your orphan designation, please contact the Orphan medicines office;
15. Click on "**Scientific content**" and complete the information in the data fields, amending the prefilled fields where appropriate. All fields with an asterisk are mandatory. Click on "**Save and Return**";
16. Back in the Submission Form screen, Click on "**Submission Notes**", enter any additional free-text information that you want the EMA Orphan Medicines team to know and click "**Save and Return**";
17. Back in the Submission Form screen, if you need to upload documents, click on "**Documents from Industry**". You can update multiple files by holding the 'Ctrl' key while selecting them; while there is no maximum number of files or global size, there is a size limit of 50 Mb per file. It is suggested that for references, a subfolder is created to contain individual files for each reference.
18. Click on "**Save and Return**" when you are done, and then click on "**Declaration**";
19. **Click on the tick box** to the left of the declaration statement (that begins with the words: "I confirm...") to formally declare that you are authorised to submit this request;
20. If you are unsure or can think of any part of the request or documents uploaded that you want to revise, click "**Back To List**" and this will return you to the draft submission;
21. If you are sure you want to submit the application, click on the "**Declaration and submission**" button, then "**Ok**" and then to confirm there is nothing left you want to edit or add, click "**Submit**";
22. Your **Annual Report** has now been submitted and will appear in your "**Ongoing Submissions**" after a couple of minutes;
23. To view it, from the **IRIS portal home page**, click on "**My submissions**"; and then click "**Ongoing submissions**" – your **Annual Report** submission will appear at the top of the list, which is in chronological order.