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Information Management Division

IRIS guide for applicants

(how to create and submit scientific applications, for industry and individual applicants)

Version 1.8

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1. Purpose and context

1.1. Purpose of this guide

This guide has been produced to show applicants how to use the [IRIS](#) platform to prepare and submit an application for a scientific procedure (e.g. orphan designation application or ITF briefing meeting request) and related activities.

1.2. Preliminary requirement

EMA Account and appropriate role: for any type of submission in IRIS, you need an EMA account and an appropriate role in IRIS to login into IRIS. Registration needs to be done only once and will allow you to submit other types of scientific applications in future. For information on how to request an EMA account and an appropriate IRIS role (these are two separate actions), please consult the separate [IRIS guide to registration](#) in the [IRIS home page](#).

2. Orphan submissions

2.1. How to create a submission for an application for orphan designation

1. From the IRIS home page, click on **"My submissions"**, then on **"Draft submissions"**;
2. Click **"Create new submission"** [a screen with the heading "Portal – New Submissions" opens up showing 4 stages. The first stage **"1. Choose Sponsor Type"** is highlighted in blue];
3. From the drop-down arrow on the box below **"Are you applying as an individual or on behalf of an organisation?"** select the appropriate answer and click **"Next"**;
4. Only if you are applying on behalf of an organisation:
 - a. 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);
 - b. Pick the right organisation and (there may only be one) and click **"Select"**;
 - c. Use the search symbol to look up the locations available for you to select, pick the right one and click **"Select"**; please note that the Regulatory entitlement (Orphan Designation) will be granted to the address of this location and the relevant organisation.
5. **"Choose Submission Type"** is now coloured blue and 3 mandatory fields (marked with a red asterisk **"*"**) appear labelled **"Organisation"** **"Location"** and **"Submission Type"** (the first two only if you are applying on behalf of an organisation). Use the search symbol to look up the submission types available, click on "Application for Orphan Designation" and **"Select"**.
6. Add at least one Manager in the specific field (when applying on behalf of an organisation, the popup list will only include those people who have been granted an IRIS Industry Manager 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).
7. Click **"Create and Next"** or **"Submit"**. A new screen appears with a reference number (e.g. EMA/OD/0000001234) for your draft submission 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.

8. Click on **"Select RPI"** to bring up "Research Product Identifier (RPI)" screen:
 - a. Click the **magnifying glass** search symbol to bring up a list of RPI names;
 - b. In the pop-up window, pick an RPI name from the list and click **"Select"**;
 - c. Back in the "Research Product Identifier (RPI)" screen, click **"Save and Return"** and you are returned to the "Submission Form" screen;

If you do not see the RPI for your product in the list:

- Make sure you read the instruction in the RPI selection page. The RPI may already exist, but "owned" by another sister company in the same or a different country, a different company or a consultant. In such cases, it won't appear in the selection list, and you need either to request affiliation to the RPI "owner", or the "owner" should transfer¹ the RPI to your company, depending on which company should be the sponsor of the orphan designation.
- If you are sure that no RPI exists for the medicinal product yet, please request one via IRIS following [the IRIS guide to registration](#) section: '8. How to create a 'Request for a 'Research Product Identifier'. This is a separate submission. After receiving communication from EMA that your RPI has been created, you can **go back to your draft submission and** proceed to the steps below.

9. Click on "Additional product information/update":
 - a. Make sure that the list of innovation/enabling technologies includes at least one term; if not, choose at least one with the "Add" button;
 - b. Click **"Save and return"**.
10. Click on **"General Information"** complete (at least) the mandatory fields marked with a red asterisk **"*"** and click **"Save and Return"** (N.B. you cannot save your changes until you have completed all mandatory fields in a single section);
11. 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 prevalence per 10,000 persons in the EU population, as a single number (normally, from 0 to 5.0) and NOT in the form of a ratio);
12. Back in the main **"Submission Form"** Screen, click on **"Documents from industry"**:
 - a. In the next screen that appears, you can directly upload documents and create subfolders in your submission. While there is no maximum number of files or global size, there is a size limit of 50 Mb per file. ; please upload individual files for each document, rather than a single Zip file (or similar) for the set of all documents. A Zip file is acceptable as the container for the literature references.
 - b. Click **"Save and Return"** when you have finished uploading documents;

¹ Currently done via an EMA ServiceDesk request. An IRIS procedure is being developed to facilitate and accelerate the transfers.

13. At any stage during the procedure above, clicking "Return" on the Submission form page saves the draft submission (which will now appear in your "**Draft Submissions**" list). You can open it again at a later time to edit/add more information;
14. When you are ready to submit your final application, click on "**Declaration and re(submission)**":
 - a. **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;
 - b. Click on the "**Declaration and submission**" button;
 - c. 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;
 - d. 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 opens it up again for you to add or amend any information or documents.

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".

2.2. How to submit a request for a Pre-Submission Meeting (for OD)

1. **IMPORTANT:** before creating a request for a **pre-submission meeting**, please create the draft submission for the orphan designations as described above. This must be left as a draft, without submitting it for the moment. Any documents should be uploaded within the draft submission for orphan designations, not in the pre-submission meeting request. The number of the draft request for orphan designation should be referenced in the pre-submission meeting request;
2. Follow steps 1 to 8 from 2.1. above, selecting "**Request for Pre-Submission Meeting**" as procedure type;
3. 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);
4. 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**";
5. Follow steps 15 and 16 from 2.1. above;
6. Your request for a Pre-Submission Meeting has now been submitted and will appear in your "**Draft Submissions**" list.

2.3. How to create a request for an Appeal (of a COMP Opinion)

1. From the IRIS home page, click on "**My submissions**";
2. Click on "**Ongoing submissions**";
3. Click "**Create new submission**" [a screen with the heading "Portal – New Submissions" opens showing 4 stages. The first stage "**1. Choose Sponsor Type**" is highlighted in blue];
4. From the drop-down arrow on the box below "**Are you applying as an individual or on behalf of an organisation?**" select as applicable 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" (the first 2 only if applying on behalf of an organisation);
6. Follow 4 in 2.1. above.
7. Use the search symbol to look up the submission types available, click on "**Appeal**" and then click "**Select**";
8. Click "**Create and Next**" – you will see the message "processing..." for a short while;
9. 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);
10. Click on "**Start Appeal**" and the "View Start Appeal Form" screen appears;
 - a. 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;
 - b. Click on one of the procedures listed then click "Select" and "Submit";
11. From the "**Submission Form**" screen, click on the "**Ground of appeal**" Section; fill in the relevant information in the mandatory "Applicant's grounds for appeal *" box and click "**Save and Return**";
12. If you need to upload documents, click on "**Documents from Industry**"; Click on "**Save and Return**" when you are done;
13. 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, then click on the "**Declaration and submission**" button;
14. 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;
15. 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.

2.4. How to submit an Annual Report for an 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 home page, click on "**My submissions**";
2. Click on "**Draft submissions**";
3. Click "**Create new submission**" [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 "**Are you applying as an individual or on behalf of an organisation?**" select as applicable " " 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" (the first 2 only if applying on behalf of an organisation);
6. Follow 4 in 2.1. above.
7. Use the search symbol to look up the submission types available, click on "**Annual Report**" and then click "**Select**";
8. Click "**Create and Next**";
9. 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);
10. 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);
 - a. In the "Regulatory Entitlement" window, **click on the magnifying glass symbol** to search through the existing orphan designations for your organisation;
 - b. 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;
11. 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**";
12. 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**";
13. Back in the Submission Form screen, if you need to upload documents, click on "**Documents from Industry**". While there is no maximum number of files or global size, there is a size limit of 50 Mb per file. For references, a single zip file can be used to contain individual files for each reference.
14. Click on "**Save and Return**" when you are done, and then click on "**Declaration**";
15. **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;
16. 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;
17. 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**";
18. Your **Annual Report** has now been submitted and will appear in your "**Ongoing Submissions**" after a couple of minutes;
19. To view it, from the **IRIS 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.

2.5. How to submit other post-designation procedures for orphan designation

All other post-designation procedures for existing orphan designations should be submitted via IRIS, choosing the appropriate procedure type. These include:

- Submission of a report for the Maintenance of the Designation Criteria at Marketing Authorisation (or extensions)
- Submission of a report for a Review of the Designation criteria after 5 years
- Request for an Amendment of an existing Orphan designation (to change the condition)
- Request to transfer an Orphan Designation
- Request of removal of an Orphan designation from the EC Orphan register
- Change of name and/or address of the Sponsor of an orphan designation.

The procedure is like those listed above and is not listed for brevity. For general information on these submission types, see the [Activities after orphan designation](#) webpage in the main EMA website.

3. ITF Briefing Meeting Requests

First stage (Creation of draft):

1. In [IRIS portal](#), **Sign-in** using your credentials from the EMA account registration. You will see your profile, which you will be able to amend and save.
2. Click on "**Draft submissions**", then on "**Create new submission**".
3. From the drop-down arrow in the box "**Are you applying as an individual or on behalf of an organisation?**" select either and click "**Next**"; if applying on behalf of an organisation, you will need to select which organisation, among those you are affiliated to, and subsequently the location (address). The organisation must be already registered in the EMA Organisation Management System (OMS). Refer to the [IRIS guide to registration](#) section '4. Organisation registration in OMS (SPOR).'
4. In '**Submission type**' window, use the search symbol to look up the submission types available, click on "**ITF Briefing Meeting Request**" and click on "**Select**". Then choose '**Manager**' from drop down list and add yourself. If applying on behalf of an organisation, you can also add other managers, among those also affiliated to that organisation with the role of Manager. It is recommended to have at least two managers.
5. Click on "**Create and Next**" / "**Submit**". A new screen appears, whose first step is to choose a Research Product Identifier (RPI).

Second stage (Research Product Identifier):

6. A RPI identifies a unitary research and development process, for a single product or a technology, methodology, multiple products. Click on "**Select RPI**", then on the **magnifying glass** search symbol to bring up a list of RPIs numbers already assigned to you (or your organisation) and select one to proceed, then click on "**Save and return**".

If you do not see the appropriate RPI in the list:

- a. Make sure you read the instruction in the RPI selection page. The RPI may already exist, but "owned" by another sister company in the same or a different country, a different company or a consultant. In such cases, it won't appear in the selection list, and you need either to request affiliation to the RPI "owner", or the "owner" should transfer the RPI to your company, depending on which company should be the sponsor of the orphan designation.
- b. For a new **single medicinal product**, please request one via IRIS following [the IRIS guide to registration](#) section: '8. How to create a 'Request for a 'Research Product Identifier'. This is a separate submission. After receiving communication from EMA that your RPI has been created, you can **go back to your draft submission and** proceed to the steps below.
- c. If your RPI is intended to cover **multiple products/ methodology/ technology/ method or other topic**, please contact ITFSecretariat@ema.europa.eu beforehand. You will be provided and requested to complete the '*ITF RPI request form*'. Upon receipt of the form the secretariat will create an RPI for you. These 'special' RPIs cannot be requested via IRIS.

Third stage (completion of the submission):

7. Open and complete all sections of the submission form, from "**Submission details**" until '**Declaration**' and click "**Save and Return**". **NOTE:** Mandatory fields marked with a red asterisk "*" must be completed. Please input "N/A" if the field is not relevant. You will see green ticks against completed sections.
8. Please ensure you carefully review the input and tick the agreement of the '**Declaration**' and click on '**Submit Application**'. **NOTE:** you may '**Generate your Application Form**' before submitting it by clicking on this option in this section; this creates a Word file with a summary of your application in the "Documents from Industry" section, which you can download.
9. Choose your SME status in '**Please indicate if you have SME status at submission**' section
10. Click on '**Submit your Application**'

NOTES:

The section "**Documents from applicant**" is available to upload any supporting documents. The section "**Documents from EMA**" is where you will find any documents provided by EMA to you, including the minutes from the meeting.

If you wish to complete your application at the later stage, you may do it so by clicking on '**Save and return**' under particular section and come back to the submission later. Your draft submission will be available in '**Draft Submissions**'. You may edit it by clicking on the downward-facing arrow and selecting '**Edit**'.

4. Common operations for all submission types

4.1. How to display and sort submissions

1. From the IRIS 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.

4.2. How to search for submissions

1. From the IRIS 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.

4.3. How to add contributors to a draft submission

You can only do this for the draft applications for which you have a "Manager" role (not if you are a Contributor).

From the IRIS 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.

4.4. How to delete a draft submission

You can only do this for the draft applications for which you have a "Manager" role (not if you are a Contributor).

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 want to delete your draft – you cannot undo this afterwards;
5. The draft has now been deleted from the portal.

4.5. How to respond to a notification email from EMA requesting changes

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

1. From the IRIS 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 Section 4.1. and 4.2. of 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**". 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.

4.6. 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 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**"; 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.