



# Astellas ISR Connect

**External User Guide**

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# 1. ISR Request Concept Submission

## 1.1 Open a New ISR Request Concept

To open a new ISR Request Concept:

1. Click **Create New ISR Request**

The screenshot shows the Astellas user portal interface. At the top, there is a navigation bar with the Astellas logo, a 'Home' link, a 'Create New ISR Request' button (highlighted with a red box), and a 'FAQ's' link. Below the navigation bar, a greeting 'Hello Soren Millweather' is displayed. At the bottom, there is a 'My Open Activities' section with a green icon.

2. Complete each page of the Form (see sections below for guidance on each page)

**Note:** You can navigate to the other sections of the Form by clicking the sections in the sidebar. Alternatively, after completing a page, click **Save and Proceed** to move to the next page.

The screenshot shows the 'ISR' form interface. On the left, there is a sidebar with a list of sections: 'Study Description', 'Institution Information', 'Scientific Detail', 'Study Structure', 'Study Detail', 'Documents', and 'Complete Your Submission'. The 'Study Description' section is highlighted with a red box. On the right, the 'Study Description' form is displayed, showing a welcome message and fields for 'Concept Title' and 'Country of Study'.

## 1.2 Concept Submission – Complete Study Description Page

To complete the Study Description page:

1. Enter the **Concept Title**
2. Select the **Country of Study**

The screenshot shows the 'Study Description' form. It includes a welcome message and instructions. There are two main fields highlighted with red boxes: 'Concept Title' with the value 'Training Example Study' and 'Country of Study' with the value 'United States'.

**Note:** The exact fields shown on the Concept Submission Form will depend on the specifics of the study. This example uses a clinical Oncology study, so some fields specific to clinical studies and Oncology studies will be included in this example.

**Note:** All required fields are marked with a red asterisk \* in the Requester Portal.

3. Select the **Therapeutic Area**
4. Select the **Compound** involved in the study

\* Country of Study  
This must be the country of the Sponsor.  
United States ▼

Therapeutic Area  
Oncology ▼

\* Compound  
Select only one.  
1 Option Selected ▼  
enzalutamide X

**Note:** Compound options are based on your selection in the Country of Study field.

5. Select the **Study Category**
6. Complete the **Support Requested** field

\* Compound  
Select only one.  
1 Option Selected ▼  
enzalutamide X

\* Study Category  
Clinical - Interventional ▼

\* Support Requested  
Funding + Drug/Active Material ▼

7. Complete the **Product Label** field
8. Click **Save and Proceed** to move to the next page (or select a page in the sidebar)

\* Support Requested  
Funding + Drug/Active Material ▼

\* Product Label  
On Label ▼

Region

Save Save and Proceed

## 1.3 Concept Submission – Complete Institution Information Page

To complete the Institution Information page:

1. Click the **Institution Name** field, then search for and select the Institution for the study

**Institution Information**

\* Institution Name  
Please enter your institution or primary study site.

Lakeshore University

**Note:** If you do not find the Institution when searching in the Institution Name field, that indicates you will need to create the Institution in the Requester Portal. Click **New Institution Name** after searching, then enter the **Institution Name** and click **Add**.

**Institution Information**

\* Institution Name  
Please enter your institution or primary study site.

Meadowview

New Institution Name

2. Enter Institution address information:

- **Street Address**
- **City**
- **State/Province/Prefecture**
- **Zip/Postal Code**
- **Country**

\* Institution Name  
Please enter your institution or primary study site.

Lakeshore University

\* Street Address  
123 Example Street

\* City  
Chicago

\* State/Province/Prefecture  
Illinois

\* Zip/Postal Code  
60606

\* Country  
 United States

- (Optional) If the study is sponsored by an organization other than the Institution you entered above, click the **Sponsor Name** field, then search for and select the Sponsor for the study

Country  
United States

Sponsor Name  
Please enter Sponsor Name if different from the Institution Name. Investigator can be the sponsor.

Meadowview

Save and Previous Step Save Save and Proceed

**Note:** If you do not find the Sponsor when searching in the Sponsor Name field, that indicates you will need to create the Sponsor in the Requester Portal. Click **New Sponsor Name** after searching, then enter the **Institution Name** and click **Add**.

Country  
United States

Sponsor Name  
Please enter Sponsor Name if different from the Institution Name.

River Valley

+ New Sponsor Name

Save and Previous Step Save Save and Proceed

- Click **Save and Proceed** to move to the next page (or select a page in the sidebar)

Sponsor Name  
Please enter Sponsor Name if different from the Institution Name. Investigator can be the sponsor.

Meadowview

Save and Previous Step Save Save and Proceed

## 1.4 Concept Submission – Complete Scientific Detail Page

To complete the Scientific Detail page:

- Enter the **Scientific Background / Rationale** for the study
- Enter the **Objectives or Hypothesis** for the study

Scientific Detail

Please complete all required fields (as noted by red asterisk) in order to submit your concept.

\* Scientific Background / Rationale  
Describe how the concept will contribute to the scientific body of knowledge.

You may copy from a Microsoft Word or other document type and paste into this field. Text only; no figures, images or tables can be included in this field. If you would like to submit additional information for consideration (such as figures, images or tables), please upload a document that includes supporting information.

Training Example Scientific Background / Rationale

\* Objectives or Hypothesis  
Include either primary and secondary objectives, or the specific hypothesis to be tested.

You may copy from a Microsoft Word or other document type and paste into this field. Text only; no figures, images or tables can be included in this field. If you would like to submit additional information for consideration (such as figures, images or tables), please upload a document that includes supporting information.

Training Example Objectives or Hypothesis

3. Enter a **Brief Overview of Design** for the study
4. (Optional) Enter **References/Citations**
5. Click **Save and Proceed** to move to the next page (or select a page in the sidebar)

Training Example Objectives or Hypothesis

**\* Brief Overview of Design**  
Description of design such as: treatment arms, types of controls, blinding, analysis plan, sample size rationale, etc.

You may copy from a Microsoft Word or other document type and paste into this field. Text only; no figures, images or tables can be included in this field. If you would like to submit additional information for consideration (such as figures, images or tables), please upload a document that includes supporting information.

Training Example Brief Overview of Design

**References/Citations**  
You may copy from a Microsoft Word or other document type and paste into this field. Text only; no figures, images or tables can be included in this field. If you would like to submit additional information for consideration (such as figures, images or tables), please upload a document that includes supporting information.

Training Example References/Citations

Save and Previous Step      Save      **Save and Proceed**

## 1.5 Concept Submission – Complete Study Structure Page

To complete the Study Structure page:

1. Select the **Phase** for the study
2. Enter the **Planned Study Duration (Months)**

**\* Phase**

I

**\* Planned Study Duration (Months)**  
Please enter a number that represents the number of months from study start or the first subject in (FSI) to when the Final Study Report will be submitted.

12

**Note:** For non-clinical studies, select **Non-Clinical** in the **Phase** field.

Study Structure

Please complete all required fields (as noted by red asterisk) in order to submit your concept.

**\* Phase**

Non-Clinical

3. Select the **Subject Type** for the study
4. Enter the **Subject Disease**
5. Click **Save and Proceed** to move to the next page (or select a page in the sidebar)

**\* Subject Type**

Adult

**\* Subject Disease**

Prostate Cancer

Save and Previous Step      Save      **Save and Proceed**

## 1.6 Concept Submission – Complete Study Detail Page

To complete the Study Detail page:

1. Select the **Study Design Type**
2. Enter the **Planned Total Enrollment** number

Study Detail

Please complete all required fields (as noted by red asterisk) in order to submit your concept.

\* Study Design Type  
Please select the type of Study Design.

Randomized Control Trial

\* Planned Total Enrollment  
Please indicate the total number of subjects you expect to enroll. If none (or not applicable), please enter 0.

100

3. Enter the **Number of Cycles (per Patient)**
4. Enter the number of **Doses per Cycle**

\* Planned Total Enrollment  
Please indicate the total number of subjects you expect to enroll. If none (or not applicable), please enter 0.
100

\* Number of Cycles (per Patient)  
Please indicate the estimated number of cycles each patient will complete. In non-oncology study or not applicable, please enter 0.
5

\* Doses per Cycle  
Please indicate the number of doses per cycle. If non-oncology study or not applicable, please enter 0.
10

5. Enter the **Number of Days per Cycle**
6. Enter the number of **Doses per Patient per Day**

\* Doses per Cycle  
Please indicate the number of doses per cycle. If non-oncology study or not applicable, please enter 0.
10

\* Number of Days per Cycle  
Please indicate the number of days per cycle. If non-oncology study or not applicable, please enter 0.
5

\* Doses per Patient per Day  
Please indicate the number of doses per day each patient will receive. If none (or not applicable), please enter 0.
2

7. Enter the **Drug Strength**
8. Enter the **Total Daily Dose**

\* Doses per Patient per Day  
Please indicate the number of doses per day each patient will receive. If none (or not applicable), please enter 0.
2

\* Drug Strength  
Indicate drug strength. For example, 20 mg or 5 mg / 10 mL. If not applicable, please enter 0.
80 mg

\* Total Daily Dose  
Total Daily Dose in mg or g per day.
160 mg

9. Select the **Tumor Type**
10. Enter the **Tumor Subset**

\*Total Daily Dose  
Total Daily Dose in mg or g per day.

160 mg

\*Tumor Type  
Prostate

\*Tumor Subset  
Provide additional description regarding: tumor type, specifying histology, biomarker status, prior treatment failure, or other relevant description of tumor type.

Training Example Tumor Subset Information

11. Complete the **Treatment** field
12. (Optional) If a second Astellas drug will be used in the study, enter **Astellas Drug/ Active Material 2** information

\*Tumor Subset  
Provide additional description regarding: tumor type, specifying histology, biomarker status, prior treatment failure, or other relevant description of tumor type.

Training Example Tumor Subset Information

\*Treatment  
1 value(s) are selected.

Adjuvant X

Astellas Drug/ Active Material 2  
If applicable, please enter Astellas Drug 2 used in the study, including Daily Dose and Drug Strength.

**Note:** You can select multiple options in the Treatment field if needed.

13. (Optional) If a third Astellas drug will be used in the study, enter **Astellas Drug/ Active Material 3** information
14. (Optional) If any non-Astellas drug will be used in the study, enter **Non-Astellas Drug Information**

Astellas Drug/ Active Material 2  
If applicable, please enter Astellas Drug 2 used in the study, including Daily Dose and Drug Strength.

Astellas Drug/ Active Material 3  
If applicable, please enter Astellas Drug 3 used in the study, including Daily Dose and Drug Strength.

Non-Astellas Drug Information  
Please specify Non-Astellas drug(s) Information, if necessary.

15. (Optional) Enter the **List of Potential Participating Sites**

16. (Optional) If multiple countries are involved in the study, click the **Multi-Country Study** checkbox

Please specify Non-Astellas drug(s) information, if necessary.

List of Potential Participating Sites  
If applicable, indicate names of other potential participating sites.

Meadowview Clinic  
Lakeshore Hospital

Multi-Country Study  
☐

**Note:** If you click the Multi-Country Study checkbox, you will also need to enter the **List of Potential Participating Countries** in the field below.

List of Potential Participating Sites  
If applicable, indicate names of other potential participating sites.

Meadowview Clinic  
Lakeshore Hospital

Multi-Country Study  
☒

List of Potential Participating Countries  
Please list names of other potential participating countries.

United States, Canada

17. Enter the **Total Budget Requested from Astellas**

18. Select the **Currency for Budget Requested**

Multi-Country Study  
☐

\* Total Budget Requested from Astellas  
Estimated total budget (includes direct and indirect cost). If no funding requested, enter in 0.

100,000

\* Currency for Budget Requested  
USD - U.S. Dollar

Please note the currency for the budget that was requested in field above

**Note:** If you are not requesting funding from Astellas, enter **0** in the **Total Budget Requested from Astellas** field.

19. (Optional) If multiple sources of funding are involved, click the **Other Potential Source(s) of Funding** checkbox

\* Currency for Budget Requested  
USD - U.S. Dollar

Please note the currency for the budget that was requested in field above

Other Potential Source(s) of Funding  
Will this study include funding from multiple sources?

☐

**Note:** If you click the Other Potential Source(s) of Funding checkbox, you will also need to specify the sources and amounts of **Additional Funders** in the field below.

\* Currency for Budget Requested  
USD - U.S. Dollar

Please note the currency for the budget that was requested in field above

Other Potential Source(s) of Funding  
Will this study include funding from multiple sources?

☒

Additional Funders  
Please specify sources and amounts.

Example Organization - \$20000

20. Click **Save and Proceed** to move to the next page (or select a page in the sidebar)

Other Potential Source(s) of Funding  
Will this study include funding from multiple sources?  
☐

Save and Previous Step Save Save and Proceed

## 1.7 Concept Submission – Complete Documents Page

To complete the Documents page:

1. Click **Upload Files** in the Curriculum Vitae Upload section, then upload the file

Documents

Please upload all required documents (as noted by red asterisk) in order to submit your concept. Once files are uploaded, click **Save and Proceed** and click **Complete Your Submission**.

Please ensure no patient data is included in any document that is uploaded.

\* Curriculum Vitae Upload  
Documents must be uploaded in .pdf, .doc or .docx format. Max Size: 25MB

Upload Files Or drop files

2. Click **Done** when the file finishes uploading

Upload Files

Example Document.pdf  
34 KB

1 of 1 file uploaded

Done

3. (Optional) Repeat the two previous steps to upload additional Documents in the other sections:
  - **Budget**
  - **Concept – Letter of Intent**
  - **Supporting Documentation**
  - **Other Documentation**

\* Curriculum Vitae Upload  
Documents must be uploaded in .pdf, .doc or .docx format. Max Size: 20MB

Upload Files Or drop files

Example Document.pdf

Budget Upload  
Budget files are not required upon Concept Submission. Budgets must be uploaded as an Excel (.xls or .xlsx) document. Max Size: 20MB

Upload Files Or drop files

Concept - Letter of Intent Upload  
Documents must be uploaded in .pdf, .doc or .docx format. Max Size: 20MB

Upload Files Or drop files

Supporting Documentation Upload  
Documents must be uploaded in .pdf, .doc or .docx format. Max Size: 20MB

Upload Files Or drop files

Other Documentation Upload  
Documents must be uploaded in .pdf, .doc or .docx format. Max Size: 20MB

Upload Files Or drop files

4. (For Europe, Israel, and Canada only) Click the **I agree to the sharing of the ISR Terms and Conditions with my institution** checkbox

\* sharing of the ISR Terms and Conditions with my institution  
In case your ISR application is approved, a contract will be required.

Astellas will provide the contract that will contain several terms and conditions that are pre-defined.

You can find these pre-defined terms and conditions [here](#).

Please be aware that this document is not the actual contract that will be proposed. Astellas does not have the capacity to re-negotiate these terms and conditions on a bespoke basis. Therefore, prior to submitting your application, please verify within your institution that these terms and conditions are acceptable.

☒ I agree to the sharing of the ISR Terms and Conditions with my institution

[Save and Previous Step](#) [Save](#) [Save and Proceed](#)

**Note:** The Sharing of the ISR Terms and Conditions section will only be displayed if the Country of Study field on the Study Description page is set to Europe, Israel, or Canada. For ISR Requests outside these countries, this section will not be displayed.

**Note:** You can click the link in the Sharing of the ISR Terms and Conditions section to view the Terms and Conditions in your browser.

\* sharing of the ISR Terms and Conditions with my institution  
In case your ISR application is approved, a contract will be required.

Astellas will provide the contract that will contain several terms and conditions that are pre-defined.

You can find these pre-defined terms and conditions [here](#).

Please be aware that this document is not the actual contract that will be proposed. Astellas does not have the capacity to re-negotiate these terms and conditions on a bespoke basis. Therefore, prior to submitting your application, please verify within your institution that these terms and conditions are acceptable.

☒ I agree to the sharing of the ISR Terms and Conditions with my institution

5. Click **Save and Proceed** to move to the next page (or select a page in the sidebar)

☒ I agree to the Verification of ISR Terms and Conditions

[Save and Previous Step](#) [Save](#) [Save and Proceed](#)

## 1.8 Concept Submission – Complete Your Submission

To complete your submission:

- Review all information entered in each section of the Form

**Note:** Click  on any of the sections to view the contents. If you need to edit the information in the section, click **Edit** on the right, or click the section in the sidebar to return to that section.

- When you are ready to submit your ISR Request Concept, click **Complete Your Submission**

> Institution Information [Edit](#)

> Scientific Detail [Edit](#)

> Study Structure [Edit](#)

> Study Detail [Edit](#)

> Documents [Edit](#)

 You don't need to submit immediately. Your information has been successfully saved, and you can submit it whenever you're ready.

[Complete Your Submission](#)

## 2. Home Page Overview

The screenshot shows the Astellas ISR Connect Home Page. At the top, there is a navigation bar with the Astellas logo on the left and three main navigation items: 'Home' (1), 'Create New ISR Request' (2), and 'FAQ's' (3). On the right side of the navigation bar, there is a bell icon (4) and a person icon (5). Below the navigation bar, the user is greeted with 'Hello Soren Millweather'. The main content area is divided into two sections: 'My Open Activities (1)' (6) and 'My Requests (1)' (7). The 'My Open Activities' section displays a table with columns: Activity Name, Request Name, Due Date, and Status. The 'My Requests' section displays a table with columns: Request Name, Program Name, Stage, and Last Modified Date. At the bottom of the page, there is a footer message: 'Should you have any questions, please reach out the Medical Affairs contact in your Region or contact [isrdevsupport@astellas.com](mailto:isrdevsupport@astellas.com)'.

| Number | Section                | Description                                                                                                                                                                                                                                    |
|--------|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | Home                   | Click <b>Home</b> to navigate to the Home Page from another page in the Requester Portal.                                                                                                                                                      |
| 2      | Create New ISR Request | Click <b>Create New ISR Request</b> to start a new ISR Request Concept.                                                                                                                                                                        |
| 3      | FAQs                   | Click <b>FAQs</b> to access training materials and the list of Products and Areas of Interest/Areas of Non-Interest available for Investigator Sponsored Research in each country.                                                             |
| 4      | Bell Icon              | Whenever you are assigned an Activity or a Role on an ISR Request, you will receive an automated in-app notification. Click the bell icon to view your notifications.                                                                          |
| 5      | Person Icon            | Click the person icon to access account options: My Profile (view or edit), Change Password, Change Email Address, Logout.                                                                                                                     |
| 6      | My Open Activities     | Activities are action items assigned to you related to ISR Requests. My Open Activities shows your currently assigned Activities. You can click the Request Name link to open the Request related to each Activity.                            |
| 7      | My Requests            | My Requests shows a list of your ISR Requests and the Stage of each Request (includes Requests submitted by you and Requests submitted by others that include you as a Team Member). You can click the Request Name link to open each Request. |

## 3. ISR Request Proposal Submission

### 3.1 Open Proposal Draft Activity

If your ISR Request Concept is approved by Astellas, the next step is to submit a Proposal. Following approval of the Concept, you will automatically be assigned the Proposal Draft Activity requesting the details of your Proposal. To open the Proposal Draft Activity:

1. On the Home Page, click the **Request Name** in My Open Activities or My Requests

Hello Soren Millweather

**My Open Activities (1)**

| Activity Name  | Request Name |
|----------------|--------------|
| Proposal Draft | REQ-00142    |

**Note:** When you are assigned the Proposal Draft Activity, you will also automatically receive an email notification with a direct link to your ISR Request.

2. Click **View Activity** on the Proposal Draft Activity

Request REQ-00214

**Activities** Messages Team Members

All Activities ▾

**Proposal Draft** Open

Description  
Your concept has been approved for further evaluation. Please click [View Activity] and complete the required proposal information by the indicated Due Date.

Due Date  
Jul 22, 2026

Transfer View Activity

**Request Details** Request Forms Documents

Current Stage  
Proposal Submission

Request Name  
REQ-00214

Program  
ISR

3. Complete each page of the Form (see sections below for guidance on each page)

**Note:** You can navigate to the other sections of the Form by clicking the sections in the sidebar. Alternatively, after completing a page, click **Save and Proceed** to move to the next page.

**Proposal Draft**

Scientific Detail  
Study Timelines  
Study Detail  
Documents  
Complete Your Submission

Due Date  
Jan 27, 2026

Status  
Open

Instructions  
Please complete all required data upload all required documents to submit your proposal.

Study Timelines

## 3.2 Proposal Draft – Complete Scientific Detail Page

To complete the Scientific Detail page:

1. Enter the **Study Title**
2. Enter the **Study Objectives or Hypothesis**

Scientific Detail

Concept Title

Training Example Study

\* Study Title

You may copy from a Microsoft Word document and paste into this field.

Training Example Study

\* Study Objectives or Hypothesis

You may copy from a MS Word or other document type and paste into this field. Do not include figures, images, or tables.

Training Example Objectives or Hypothesis

**Note:** The exact fields shown on the Proposal Draft Form will depend on the specifics of the study. This example uses a clinical Oncology study, so some fields specific to clinical studies and Oncology studies will be included in this example.

3. Select the **Study Design Category**
4. Enter **Study Design** information

\* Study Objectives or Hypothesis

You may copy from a MS Word or other document type and paste into this field. Do not include figures, images, or tables.

Training Example Objectives or Hypothesis

Text Only - Please be brief - 7,000 character limit including spaces.

\* Study Design Category

Randomized Control Trial

\* Study Design

Provide a brief description of study design such as: treatment arms, types of controls, blinding, single or multi-center, sample size, etc. You may copy from a Microsoft Word or other document type and paste into this field. Text only; no figures, images or tables can be included in this field.

Training Example Study Design Information

Text Only - Please be brief - 7,000 character limit including spaces.

Save

Save and Proceed

5. Click **Save and Proceed** to move to the next page (or select a page in the sidebar)

\* Study Design

Provide a brief description of study design such as: treatment arms, types of controls, blinding, single or multi-center, sample size, etc. You may copy from a Microsoft Word or other document type and paste into this field. Text only; no figures, images or tables can be included in this field.

Training Example Study Design Information

Text Only - Please be brief - 7,000 character limit including spaces.

Save

Save and Proceed

### 3.3 Proposal Draft – Complete Study Timelines Page

To complete the Study Timelines page:

1. Enter the number of months from contract execution to when the first subject will enter the study or when the study will start in the **Study Start or First Subject In** field
2. Enter the number of months from contract execution to when 25% of the study is completed or 25% of the patients have enrolled in the **25% Study or Enrollment Complete** field

Study Timelines

\* Study Start or First Subject In (months)  
Please enter a number that represents the number of months from contract execution to when the first subject will enter the study or to when the study will start.

\* 25% Study or Enrollment Complete (months)  
Please enter a number that represents the number of months from contract execution to when 25% of the study is completed or 25% of patients have been enrolled.

3. Enter the number of months from contract execution to when 50% of the study is completed or 50% of the patients have enrolled in the **50% Study or Enrollment Complete** field
4. Enter the number of months from contract execution to when 100% of the study is completed or 100% of the patients have enrolled in the **100% Study or Enrollment Complete** field

\* 25% Study or Enrollment Complete (months)  
Please enter a number that represents the number of months from contract execution to when 25% of the study is completed or 25% of patients have been enrolled.

\* 50% Study or Enrollment Complete (months)  
Please enter a number that represents the number of months from contract execution to when 50% of the study is completed or 50% of patients have been enrolled.

\* 100% Study or Enrollment Complete (months)  
Please enter a number that represents the number of months from contract execution to when last subject will enter the study or 100% of study is complete.

5. Enter the number of months from contract execution to when the last subject will exit the study or when the database will be locked in the **Last Subject Out or Database Lock** field
6. Enter the number of months from contract execution until the final report is provided to Astellas in the **Final Report Expected** field
7. Click **Save and Proceed** to move to the next page (or select a page in the sidebar)

\* 100% Study or Enrollment Complete (months)  
Please enter a number that represents the number of months from contract execution to when last subject will enter the study or 100% of study is complete.

\* Last Subject Out or Database Lock (months)  
Please enter a number that represents the number of months from contract execution to when last subject will exit the study or when database will be locked.

\* Final Report Expected (months)  
Please enter a number that represents the number of months from contract execution to when the final report will be provided.

## 3.4 Proposal Draft – Complete Study Detail Page

To complete the Study Detail page:

1. Enter the **Planned Total Enrollment** number
2. Enter the number of **Doses per Cycle**

Study Detail

Please complete all required fields (as noted by red asterisk) in order to submit your proposal.

\* Planned Total Enrollment  
Please indicate the total number of subjects you expect to enroll. If none (or not applicable), please enter 0.

100

\* Doses per Cycle  
Please indicate the number of doses per day each patient will receive. If a range is appropriate, please estimate or use an average. If none, please enter 0.

10

3. Enter the number of **Doses per Patient per Day**
4. Enter the **Number of Cycles (per Patient)**

\* Doses per Cycle  
Please indicate the number of doses per day each patient will receive. If a range is appropriate, please estimate or use an average. If none, please enter 0.

10

\* Doses per Patient per Day  
Please indicate the number of doses per day each patient will receive. If a range is appropriate, please estimate or use an average. If none (or not applicable), please enter 0.

2

\* Number of Cycles (per Patient)  
Please indicate the estimated number of cycles each patient will complete. If non-oncology study or not applicable, please enter 0.

5

5. Enter the **Number of days per Cycle (for Oncology only)**
6. Enter the **Drug Strength**

\* Number of Cycles (per Patient)  
Please indicate the estimated number of cycles each patient will complete. If non-oncology study or not applicable, please enter 0.

5

Number of days per Cycle (for Oncology only)  
Please indicate the number of days per cycle. If non-oncology study or not applicable, please enter 0.

5

\* Drug Strength  
Indicate drug strength. For example, 20 mg or 5 mg / 10 ml. If not applicable, please enter 0.

80 mg

7. Enter the **Total Daily Dose**
8. Enter the **Total Required Amount**

\* Drug Strength  
Indicate drug strength. For example, 20 mg or 5 mg / 10 ml. If not applicable, please enter 0.

80 mg

\* Total Daily Dose  
Total Daily Dose in mg or g per day

160 mg

\* Total Required Amount  
For non-clinical studies only, indicate the total amount of drug that is being requested in milligrams (mg). If not applicable, please enter 0.

400,000

9. Enter the **Total number of Doses requested per Patient**
10. (Optional) If a second Astellas product will be used in the study, enter **Astellas Drug/ Active Material 2** information

**\* Total Required Amount**  
For non-clinical studies only, indicate the total amount of drug that is being requested in milligrams (mg). If not applicable, please enter 0.

400,000

**\* Total number of Doses requested per Patient**  
Please indicate the total number of doses you expect per patient.

50

**Astellas Drug/ Active Material 2**  
If applicable, please enter Astellas Drug 2 used in the study including Daily Dose and Drug Strength.

11. (Optional) If a third Astellas product will be used in the study, enter **Astellas Drug/ Active Material 3** information
12. (Optional) If a non-Astellas product will be used in the study, enter **Non-Astellas Drug Information**

**Astellas Drug/ Active Material 2**  
If applicable, please enter Astellas Drug 2 used in the study including Daily Dose and Drug Strength.

**Astellas Drug/ Active Material 3**  
If applicable, please enter Astellas Drug 3 used in the study including Daily Dose and Drug Strength.

**Non-Astellas Drug Information**  
Please specify Non-Astellas drug(s) Information, if necessary.

13. (Optional) Enter the **List of Potential Participating Sites**
14. (Optional) If multiple countries are involved in the study, click the **Multi-Country Study** checkbox, then enter the **List of Potential Participating Countries** in the field below

**List of Potential Participating Sites**  
If applicable, indicate names of other potential participating sites.

Meadowview Clinic  
Lakeshore Hospital

7,000 character limit including spaces.

**Multi-Country Study**  
☐

Save and Previous Step Save Save and Proceed

**Note:** If you click the Multi-Country Study checkbox, you will also need to enter the **List of Potential Participating Countries** in the field below.

**List of Potential Participating Sites**  
If applicable, indicate names of other potential participating sites.

Meadowview Clinic  
Lakeshore Hospital

7,000 character limit including spaces.

**Multi-Country Study**  
☒

**List of Potential Participating Countries**  
Please list names of other potential participating countries.

United States, Canada

15. Click **Save and Proceed** to move to the next page (or select a page in the sidebar)

**Multi-Country Study**  
☐

Save and Previous Step Save Save and Proceed

## 3.5 Proposal Draft – Complete Documents Page

To complete the Documents page:

1. Click **Upload Files** in the Protocol section, then upload the file

Please upload all required documents as noted by a red asterisk in order to submit your proposal. Once files are uploaded, click **Save and Proceed** and click **Submit**.

Please ensure no patient data is included in any of the documents uploaded.

\* Protocol  
Documents must be uploaded in .pdf, .doc or .docx format. Max Size: 20MB

**Upload Files** Or drop files  
Max Size: 20MB

2. Click **Done**

**Upload Files**

 Example Protocol.pdf  
34 KB

1 of 1 file uploaded

**Done**

3. (Optional) Repeat the two previous steps to upload additional Documents in the other sections:
  - **Budget** (NOTE: a budget document is required if funding support is requested)
  - **Letter of Request**
  - **ISR Withdrawal Correspondence**
  - **Other Supporting Documentation**

Example Protocol.pdf   
Max Size: 20MB

**Budget Upload**  
Budgets must be uploaded as an Excel (.xls or .xlsx) document for funding requests.

**Upload Files** Or drop files  
Max Size: 20MB

**Letter of Request**  
Documents must be uploaded in .pdf, .doc or .docx format. Max Size: 20MB

**Upload Files** Or drop files  
Max Size: 20MB

**ISR Withdrawal Correspondence**  
Documents must be uploaded in .pdf, .doc or .docx format. Max Size: 20MB

**Upload Files** Or drop files  
Max Size: 20MB

**Other Supporting Documentation Upload**  
Documents must be uploaded in .pdf, .doc or .docx format. Max Size: 20MB

**Upload Files** Or drop files  
Max Size: 20MB

4. Click **Save and Proceed** to move to the next page (or select a page in the sidebar)

**Upload Files** Or drop files  
Max Size: 20MB

**Save and Previous Step** **Save** **Save and Proceed**

## 3.6 Proposal Draft – Complete Your Submission

To complete your submission:

1. Review all information entered in each section of the Form

**Note:** Click  on any of the sections to view the contents. If you need to edit the information in the section, click **Edit** on the right, or click the section in the sidebar to return to that section.

2. When you are ready to submit your ISR Request Proposal, click **Submit**



The screenshot shows a form interface with two sections: "Study Detail" and "Documents". Each section has a chevron icon to its left and an "Edit" button to its right. Below these sections is a status message: "You don't need to submit immediately. Your information has been successfully saved, and you can submit it whenever you're ready." To the right of this message is a "Submit" button with a checkmark icon.

## 4. Respond to Request for More Information

In some cases, Astellas may require more information on your ISR Request while reviewing your ISR Request Concept or Proposal. When this occurs, the Astellas team will assign you an Activity instructing you to add the required information to the Form. To update the Form and complete the Activity:

1. On the Home Page, click the **Request Name** in My Open Activities or My Requests

Hello Soren Millweather

**My Open Activities (1)**

| Activity Name                                   | Request Name |
|-------------------------------------------------|--------------|
| PI - Request for Additional Info/Clarifications | REQ-00277    |

**Note:** The Astellas team could request additional information during either Concept Evaluation or Proposal Review. This example covers additional information being requested during Concept Evaluation, but the same process applies if additional information was requested during Proposal Review.

**Note:** When you are assigned an Activity, you will also automatically receive an email notification with a direct link to your ISR Request.

2. Click **View Activity** on the PI - Request for Additional Info/Clarifications Activity

Request REQ-00277

Activities Messages Team Members

All Activities ▼

**PI - Request for Additional Info/Clarifications** Open

Description  
The committee has requested additional information and/or clarifications. Please click [View Activity], review the instructions that outline the additional information or clarifications being requested and address each item.

Due Date  
May 11, 2026

Transfer View Activity

Request Details Request Forms Documents

Current Stage  
Concept Revision

Country Name  
United States

Request Name  
REQ-00277

Concept Title  
Training Example Study

Program  
ISR

3. After clicking View Activity, review the top section to view the Due Date for the Activity as well as the requested clarifications and/or additional information under the Instructions section

Due Date  
May 10, 2026

Status  
Open

Instructions  
More information required on study design

Study Description

4. All fields in each section of the Form will be editable. Use the sidebar to open the Form page you need to update, then update the Form as needed. If a revised document needs to be uploaded to address the clarifications, click **Documents** and upload a Document as applicable
5. Once you are finished updating the Form and addressing the requested clarifications, click **Complete Your Submission** in the sidebar

PI – Request for Additional Info/Clarifications

Study Description

Institution Information

Scientific Detail

Study Structure

Study Detail

Documents

**Complete Your Submission**

Due Date: May 11, 2026

Status: **Open**

Instructions: More information required on study design

Study Description

Welcome to the Astellas Concept Submission Form

Please complete all required fields (as noted by red asterisk) in order to submit your concept.

\* Concept Title

Title for Study: Training Example Study

6. Click **Complete Your Submission**

> Institution Information

> Scientific Detail

> Study Structure

> Study Detail

> Documents

**Complete Your Submission**

You don't need to submit immediately. Your information has been successfully saved, and you can submit it whenever you're ready.

**Complete Your Submission**

## 5. ISR Request Study Startup

If your ISR Request Proposal is approved by Astellas, you will automatically be assigned the Study Startup Regulatory Activity. To complete the Study Startup Regulatory Activity:

1. On the Home Page, click the **Request Name** in My Open Activities or My Requests

Hello Soren Millweather

**My Open Activities (1)**

| Activity Name            | Request Name |
|--------------------------|--------------|
| Study Startup Regulatory | REQ-00147    |

2. Click **View Activity** on the Study Startup Regulatory Activity and enter requested information as it becomes available and as applicable for the study

Request REQ-00264

Activities Messages Team Members

**Request Details** Request Forms Documents Milestones Enrollments

Current Stage: Study Startup  
Country Name: United States  
Request Name: REQ-00264  
Concept Title: Training Example Study  
Program: ISR

**Activities**

All Activities ▾

**Proposal Draft** Closed

Description: Your concept has been approved for further evaluation. Please click [View Activity] and complete the required proposal information by the indicated Due Date.

Completed Date: May 04, 2026  
Decision: Submitted

[View Details](#)

**Study Startup Regulatory** Open

Description: Please click View Activity to review the information that is to be entered as it becomes available and as applicable for the study.

Due Date: Jul 02, 2026

[Transfer](#) [View Activity](#)

3. Enter the **Regulatory Trial Reference #**
4. Enter the **Research Register ID**

Is product used as per label?  
If no, then it is requested that the Sponsor file an application for IND, CTA, or other, as applicable.

Yes

Regulatory Trial Reference #  
Enter the Regulatory authorization reference (if applicable).  
(e.g. IND number, EudraCT-number, or other)

123456

Research Register ID  
Enter the National Research Registry ID (e.g. [ClinicalTrials.gov](https://clinicaltrials.gov), EU Clinical Trials Register, UMIN-CTR, or other)

654321

5. Enter the **Research Ethics Committee (REC) Approval Date**
6. Enter the **REC Expiration Date**
7. Enter the **Additional REC Approval Date** (applicable if another Ethics Committee approval is also required)

Research Register ID  
Enter the National Research Registry ID (e.g. [ClinicalTrials.gov](https://clinicaltrials.gov), EU Clinical Trials Register, UMIN-CTR, or other)

654321

Research Ethics Cmt. (REC) Appvl. Date  
Enter the approval date from Ethics Committee (if applicable)  
(e.g. IRB, IEC, or other)

Apr 1, 2026

REC Expiration Date  
If you have updated the REC (Research Ethics Committee) Expiration Date, please remember to add a new Document on the "Upload Documents" page.

Apr 1, 2036

Additional REC Approval Date (if applicable)

Apr 7, 2026

**Note:** Any person the Astellas team may need to work with for your ISR Request can be included as a Contact. Contacts are not users of the Requester Portal (and they do not need to register before you add them as a Contact); examples of a Contact could include a Contracting Contact or a Drug Shipment Contact.

8. Click **Add Record** in the Contact Information section

Additional REC Approval Date (if applicable)

Apr 7, 2026

Contact Information  
These contacts will not be users in the system.

| First Name *                        | Last Name * | Contact Type * | Contact Type - Ot... | Email * |
|-------------------------------------|-------------|----------------|----------------------|---------|
| <p>No Records</p> <p>Add Record</p> |             |                |                      |         |

9. Enter Contact information:
  - **First Name**
  - **Last Name**
  - **Contact Type**
  - **Contact Type - Other** (complete this field if you set the Contact Type to Other)
  - **Email**
10. Click **Add**

**Add New Record**

|                                       |                         |
|---------------------------------------|-------------------------|
| * First Name<br>Lena                  | * Last Name<br>Tondeval |
| * Contact Type<br>Contracting Contact | Contact Type - Other    |
| * Email<br>example@example.com        |                         |

11. (Optional) Repeat the three previous steps to add any other required Contacts
12. Click **Save and Proceed**

Contact Information  
These contacts will not be users in the system.

| First Name * | Last Name * | Contact Type        | Contact Type - Ot... | Email *            |
|--------------|-------------|---------------------|----------------------|--------------------|
| Lena         | Tondeval    | Contracting Contact |                      | example@example... |

+ Add Record

Save Save and Proceed

13. Review all information entered on the Form

**Note:** Click **Edit** if you need to make any changes.

Regulatory Form Edit

Is product used as per label?  
Yes

14. When you are ready to submit, click **Complete**

Additional REC Approval Date (if applicable)  
Apr 6, 2026

Contact Information

| First Name * | Last Name * | Contact Type        | Contact Type - Ot... | Email *            |
|--------------|-------------|---------------------|----------------------|--------------------|
| Lena         | Tondeval    | Contracting Contact |                      | example@example... |

You don't need to submit immediately. Your information has been successfully saved, and you can submit it whenever you're ready.

Complete

## 6. ISR Request Management

### 6.1 View Milestones

Milestones are created by the Astellas team to track the progress of the ISR study. If funding support is provided, these milestones will align with the final executed contract. To view Milestones, click the **Milestones** tab on the ISR Request.

### 6.2 Add Completed Date to Milestone

Once a Milestone is completed, you can edit the Milestone to add the Completed Date. To add the Completed Date to a Milestone:

1. Click  on the Milestone
2. Click **Edit**

3. Enter the **Completed Date**
4. Click **Save**

## 6.3 Reforecast a Milestone

If the Target Date for a Milestone needs to be reforecasted, you can edit the Milestone and submit a new Requested Target Date for review by Astellas. To submit a reforecasted Target Date for a Milestone:

1. Click  on the Milestone
2. Click **Edit**

| Request Details Request Forms Documents <b>Milestones</b> Enrollments More ▾                                                                         |                     |                       |                  |                        |                                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|-----------------------|------------------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  <b>Milestones (5)</b> <span>5 items • Updated 3 minutes ago</span> |                     |                       |                  |                        |                                                                                                                                                                            |
| Milestone Name ▾                                                                                                                                     | Current Mileston... | Last Forecast Targ... | Completed Date ▾ | Invoice Received ... ▾ |                                                                                                                                                                            |
| 1 Study Start                                                                                                                                        | USD 10,000.00       | 7/6/2026              | 7/6/2026         |                        |                                                                                                                                                                            |
| 2 25% Enrolled                                                                                                                                       | USD 10,000.00       | 9/6/2026              |                  |                        |                                                                                                                                                                            |
| 3 50% Enrolled                                                                                                                                       | USD 10,000.00       | 11/6/2026             |                  |                        | <br> |

3. Enter the new **Requested Target Date**
4. Click **Save**

Completed Date

Requested Target Date

Requested Target Date

9/13/2026

Name

M-00066

Request

REQ-00264

Cancel

Save

**Note:** After you click Save, the Astellas team will be sent an email notifying them to review your Requested Target Date.

## 6.4 View Drug and Placebo Records

Drug and Placebo records are created by the Astellas team to track shipments of medication or placebos sent out for a study. To view Drug and Placebo records:

1. On the ISR Request, click **More**
2. Click **Drugs & Placebos**

Request REQ-00273

Activities Messages Team Members

All Activities ▾

Proposal Draft

Closed

Request Details Request Forms Documents Milestones Enrollments **More ▾**

Current Stage

Study Monitoring

Request Name

REQ-00273

Program

ISR

Country Name

United States

Concept Title

Training Example Study

Drugs & Placebos

Publications

Request Contacts

### 3. Review the Drugs and Placebos section

| Request Details Request Forms Documents Milestones <b>Drugs &amp; Placebos</b> More ▾ |                  |        |                |              |                   |          |
|---------------------------------------------------------------------------------------|------------------|--------|----------------|--------------|-------------------|----------|
| <b>Drugs and Placebos (1)</b> 1 Item • Updated a few seconds ago                      |                  |        |                |              |                   |          |
| Compound Na...                                                                        | Drug Order Nu... | Type   | Total Quantity | How Supplied | Drug Expiratio... |          |
| 1                                                                                     | enzalutamide     | 123456 | Drug           | 10000        | Blisters          | 5/4/2029 |

[View All](#)

## 6.5 Create an Enrollment Record

During an ongoing study, you will need to create Enrollment records to document patient enrollments. To create an Enrollment record:

### 1. On the ISR Request, click **Enrollments**

The screenshot shows the 'Request' page for REQ-00273. The 'Enrollments' tab is highlighted in the top navigation bar. On the left, the 'Activities' section shows a 'Proposal Draft' with a 'Description' and 'Completed Date' of May 05, 2026. The main area displays 'Request Details' with fields for 'Current Stage' (Study Monitoring), 'Country Name' (United States), 'Request Name' (REQ-00273), 'Concept Title' (Training Example Study), and 'Program' (ISR).

2. Enter the **Enrollment Reporting Date**
3. Enter the **Number Enrolled Since Last Update**

The screenshot shows the 'Enrollments' page for REQ-00273. The 'Past Enrollments' section shows 0 of 0 items. The 'Create New Enrollment' section has three input fields: 'Enrollment Reporting Date' (Jul 1, 2026), 'Number Enrolled Since Last Update' (25), and 'Patients Currently on Treatment'. The 'Create Enrollment' button is at the bottom.

4. Enter the number of **Patients Currently on Treatment**
5. Click **Create Enrollment**

This is a closer view of the 'Create New Enrollment' form. The 'Enrollment Reporting Date' is Jul 1, 2026, 'Number Enrolled Since Last Update' is 25, and 'Patients Currently on Treatment' is 25. The 'Create Enrollment' button is highlighted with a red box.

6. Attaching an Enrollment Log Document is optional if you do not have an update. If you do need to attach an Enrollment Log, enter the **Document Name** for the Enrollment log
7. Enter a **Description** of the Enrollment Log
8. Click **Create Document**

**Create New Enrollment**

\* Enrollment Reporting Date: Jul 1, 2026

\* Number Enrolled Since Last Update: 25

\* Patients Currently on Treatment: 25

Create Enrollment

Enrollment successfully created.

**Create Document for Enrollment Log**

\* Document Name: Training Enrollment Log

Description: Enrollment Log created for training documentation

Create Document

9. Click **Upload Files**, then upload the file

**Create Document for Enrollment Log**

\* Document Name: Training Enrollment Log

Description: Enrollment Log created for training documentation

Create Document

Document successfully created.

**Upload Enrollment Log File**

Enrollment Log

Upload Files Or drop files

Finish

10. Click **Done** when the file finishes uploading

**Upload Files**

PDF Example Enrollment Log.pdf 34 KB

1 of 1 file uploaded

Done

11. Click **Finish**

**Upload Enrollment Log File**

Enrollment Log

Upload Files Or drop files

[Example Enrollment Log.pdf] has been uploaded.

Finish

## 6.6 Upload a Document

Documents can be uploaded on the Documents tab of an ISR Request. Repeat this process each time there is a new version of the Document to create a separate Document record for each version. To upload a Document:

1. On the ISR Request, click **Documents**
2. Click **Add Document**

The screenshot shows the 'Request REQ-00273' interface. The 'Documents' tab is selected, displaying a table of existing documents. The 'Add Document' button is highlighted in the top right corner of the Documents section.

| File                     | Name     | Document Type                 | Description                                       | Created By ID     | Created Date           |
|--------------------------|----------|-------------------------------|---------------------------------------------------|-------------------|------------------------|
| Example Document         | DOC-0455 | Budget supporting Information |                                                   | Soren Millweather | 05/05/2026, 04:15 P... |
| Example Enrollment Log   | DOC-0454 | Enrollment Log                | Enrollment Log created for training documentation | Soren Millweather | 05/05/2026, 02:14 P... |
| Example Protocol         | DOC-0453 | Protocol                      |                                                   | Soren Millweather | 05/05/2026, 11:29 ...  |
| Example Curriculum Vitae | DOC-0452 | Curriculum Vitae              |                                                   | Soren Millweather | 05/05/2026, 11:20 ...  |

3. Enter the **Document Title**
4. Click the **Document Type** field, then search for and select the Document Type

The 'New Document' form is shown. The 'Document Title' field contains 'Training Final Study Report'. The 'Document Type' dropdown menu is open, showing 'Final Study Report' selected.

**Note:** Refer to the [Document Types](#) section to see all available Document Type options.

5. (Optional) Enter a **Description**
6. Click **Save**

The 'New Document' form is shown. The 'Document Title' field contains 'Training Final Study Report'. The 'Document Type' dropdown menu is open, showing 'Final Study Report' selected. The 'Description' field contains 'FSR created for training documentation'. The 'Request' field shows 'REQ-00273'. The 'Save' button is highlighted.

7. Click **Upload Files** in the Files section, then upload the file

The 'Document DOC-0588' interface is shown. The 'Document Title' field contains 'Training Final Study Report'. The 'Document Type' dropdown menu is open, showing 'Final Study Report' selected. The 'Description' field contains 'FSR created for training documentation'. The 'Request' field shows 'REQ-00273'. The 'Files (0)' section shows the 'Upload Files' button highlighted.

- Click **Done** when the file finishes uploading

## 6.7 Create a Draft Publication Record and Add First Version

Publications related to an ISR Request can be documented as Publication records. Any Publication related to an ISR study must be submitted to Astellas for review before submitting to the journal or congress. To create a draft Publication record and add the first version:

- Click **More** on the ISR Request
- Click **Publications**

- Click **New**

- Enter the **Abbreviated Title**
- Enter a **Description**

6. Enter the **Author(s)**
7. Select the **Type**

Abbreviated Title: Training Example Publication

Description: Publication created for training documentation

Author(s): Example Author 1, Example Author 2

Type: Manuscript

8. Complete the **Version** field (for initial versions, select Interim)
9. Enter the planned **Submission Date** (submission to the journal or congress)

Type: Manuscript

Version: Interim

Submission Date: 5/6/2027

10. If the publication will be submitted to a congress, enter the name of the **Target Medical Scientific Meeting**

Submission Date: 5/6/2027

Meeting Details

Target Medical Scientific Meeting:

11. If the publication will be submitted to a journal, enter the name of the **Target Journal**
12. Click **Save**

Target Medical Scientific Meeting:

Journal Details

Target Journal: Advances in Clinical Oncology

Published Title:

Journal Citation:

Publication Date:

DOI:

Buttons: Cancel, Save & New, Save

**Note:** The other fields on the Publication record will be completed after publishing.

13. Click the **Abbreviated Title** to open the Publication record

| Request Details   Request Forms   Documents   Milestones   Enrollments <b>Publications</b> More ▾ |                                              |            |                   |                  |          |
|---------------------------------------------------------------------------------------------------|----------------------------------------------|------------|-------------------|------------------|----------|
| Publications (1)                                                                                  |                                              |            |                   |                  |          |
| 1 item • Updated a minute ago                                                                     |                                              |            |                   |                  |          |
| Abbreviated Title ▾                                                                               | Description ▾                                | Type ▾     | Published TI... ▾ | Submission ... ▾ |          |
| 1 Training Example Publicati...                                                                   | Publication created for training document... | Manuscript |                   | 5/6/2027         | View All |

14. Click **Related**



Publication  
**Training Example Publication**

DETAILS

RELATED

15. Click **New** in the ISR Documents section



Publication  
**Training Example Publication**

DETAILS

RELATED



ISR Documents (0)

New

16. Enter the **Document Title**

17. Click the **Document Type** field, then search for and select **Publication** as the Document Type

New Document

\* = Required Information

Information

\* Document Title

Training Example Publication

\* Document Type

Publication

18. (Optional) Enter a **Description**

19. Click **Save**

\* Document Title

Training Example Publication

\* Document Type

Publication

Description

Publication created for training documentation

Request

Cancel

Save & New

Save

20. Click the **Name** link

| Name     | Document Type | Description                       | Created By                     |
|----------|---------------|-----------------------------------|--------------------------------|
| DOC-0551 | Publication   | Publication created for traini... | Soren Millweather, 5/21/202... |

21. Click **Upload Files** in the Files section, then upload the file

Document  
DOC-0551

Document Title: Training Example Publication  
Document Type: Publication  
Description: Publication created for training documentation  
Request

Files (0)  
Add Files  
Upload Files  
Or drop files

22. Click **Done** when the file finishes uploading

Upload Files

Example Document.pdf  
34 KB

1 of 1 file uploaded

Done

## 6.8 Add Updated Version of a Publication

Updated versions of Publications can be uploaded as needed. Complete the process in this section to create a new Document record on the Publication record for each version of the Publication, including the final version. To add an updated version of a Publication:

1. Click **More** on the ISR Request
2. Click **Publications**

Request  
REQ-00273

Activities Messages Team Members

Request Details Request Forms Documents Milestones Enrollments More

Drugs & Placebos  
Publications  
Request Contacts

Current Stage: Study Monitoring  
Country Name: United States  
Request Name: REQ-00273  
Program: ISR  
Concept Title: Training Example Study

3. Click the **Abbreviated Title** to open the Publication record

Request Details Request Forms Documents Milestones Enrollments Publications More

Publications (1)  
1 item • Updated a minute ago

|   | Abbreviated Title             | Description                                  | Type       | Published TL... | Submission ... |
|---|-------------------------------|----------------------------------------------|------------|-----------------|----------------|
| 1 | Training Example Publicati... | Publication created for training document... | Manuscript | 5/6/2027        |                |

4. Click **Related**

Publication  
Training Example Publication

DETAILS **RELATED**

5. Click **New** in the ISR Documents section

Publication  
Training Example Publication

DETAILS **RELATED**

ISR Documents (1) **New**

| Name | Document Type | Description | Created By |
|------|---------------|-------------|------------|
|------|---------------|-------------|------------|

6. Enter the **Document Title**7. Click the **Document Type** field, then search for and select **Publication** as the Document Type

Information \* = Required Information

\* Document Title

\* Document Type

8. (Optional) Enter a **Description**9. Click **Save**

\* Document Title

\* Document Type

Description

Request

Cancel Save & New **Save**

10. Click the **Name** link

DETAILS **RELATED**

ISR Documents (2) **New**

| Name            | Document Type | Description                       | Created By                     |
|-----------------|---------------|-----------------------------------|--------------------------------|
| DOC-0586        | Publication   | Publication created for traini... | Soren Millweather, 6/8/2026... |
| <b>DOC-0604</b> | Publication   | Publication created for traini... | Soren Millweather, 6/24/202... |

[View All](#)

11. Click **Upload Files** in the Files section, then upload the file

Document  
DOC-0604

Document Title  
Training Example Publication v2

Document Type  
Publication

Description  
Publication created for training documentation

Request

Files (0) Add Files

Upload Files

Or drop files

12. Click **Done** when the file finishes uploading

Upload Files

Example Document.pdf  
34 KB

1 of 1 file uploaded

Done

## 6.9 Add Final Publication Information

Once your Publication has been accepted or published by the journal or congress, add the final Publication information to the Publication record. You will also need to add the final version of the Publication at this point (refer to the [Add Updated Version of a Publication](#) section). To add final Publication information:

1. Click **More** on the ISR Request
2. Click **Publications**

Request  
REQ-00273

Activities Messages Team Members

Request Details Request Forms Documents Milestones Enrollments More

Drugs & Placebos  
Publications  
Request Contacts

Current Stage  
Study Monitoring

Country Name  
United States

Request Name  
REQ-00273

Concept Title  
Training Example Study

Program  
ISR

3. Click the **Abbreviated Title** to open the Publication record

Request Details Request Forms Documents Milestones Enrollments Publications More

Publications (1)

1 item • Updated a minute ago

|   | Abbreviated Title             | Description                                  | Type       | Published Ti... | Submission ... |
|---|-------------------------------|----------------------------------------------|------------|-----------------|----------------|
| 1 | Training Example Publicati... | Publication created for training document... | Manuscript | 5/6/2027        |                |

View All

4. Click **Edit**

Publication Training Example Publication

**Edit**

**DETAILS** RELATED

| Abbreviated Title                  | Description                                    |
|------------------------------------|------------------------------------------------|
| Training Example Publication       | Publication created for training documentation |
| Author(s)                          |                                                |
| Example Author 1, Example Author 2 |                                                |
| Type                               |                                                |
| Manuscript                         |                                                |
| Version                            |                                                |
| Interim                            |                                                |
| Submission Date                    |                                                |
| 5/6/2027                           |                                                |

5. Click the **Version** field, then select **Final**6. If the Submission Date needs to be updated, enter the updated **Submission Date**

Type  
Manuscript

Version  
Final

Submission Date  
5/6/2027

7. If the publication is being presented at a congress, review the **Target Medical Scientific Meeting** field and ensure the name listed is current

Submission Date  
5/6/2027

**Meeting Details**

Target Medical Scientific Meeting

## 8. If the publication is being published in a journal, complete the Journal Details section:

- **Target Journal** (ensure the name listed is correct if entered earlier)
- **Published Title**
- **Journal Citation**
- **Publication Date**
- **DOI**

9. Click **Save**

**Journal Details**

Target Journal  
Advances in Clinical Oncology

Published Title  
Training Example Publication

Journal Citation  
Example Author 1, Example Author 2. Training Example Publication. Advances in Clinical Oncology. Published 11/25/2027

Publication Date  
5/25/2027

DOI  
10.1111/11111

Cancel Save & New **Save**

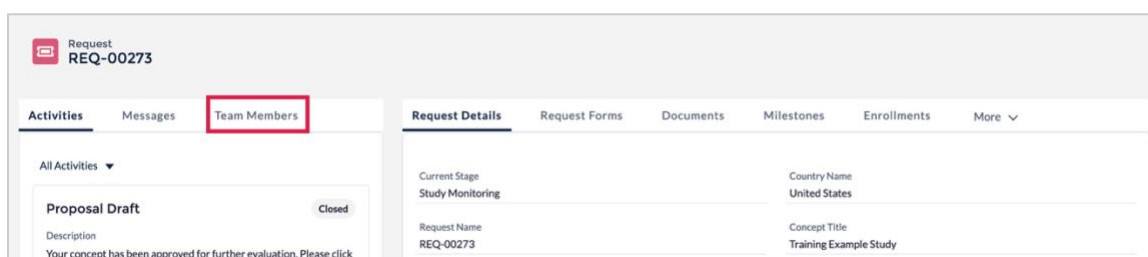
## 6.10 Add Team Members

If any other study colleagues will need to work on your ISR Request, you can include them as a Team Member. To add a Team Member:

**Note:** Users need to register for the Requester Portal before you can add them as a Team Member. If you need to add a user who is not registered yet, send them the link to the Requester Portal login page and instruct them to register for the Requester Portal first.

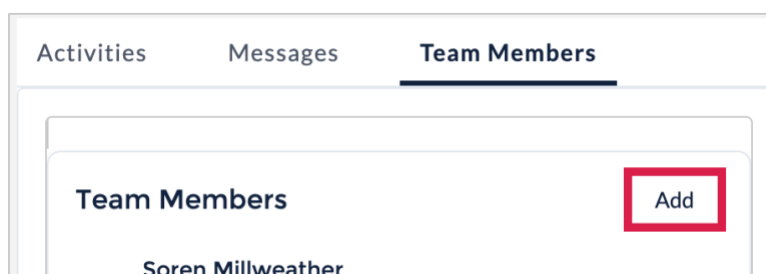
Requester Portal login page link: [astellas-medical-domain.my.site.com/ISRRequesterPortal/s/](https://astellas-medical-domain.my.site.com/ISRRequesterPortal/s/)

1. On the Request, click **Team Members**



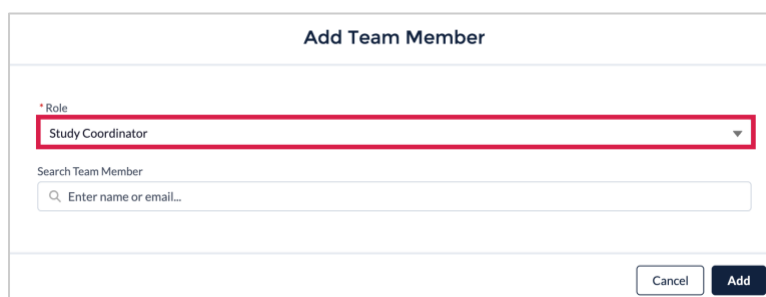
The screenshot shows the Requester Portal interface for Request REQ-00273. The 'Team Members' tab is highlighted in the top navigation bar. Below the navigation bar, there are sections for 'All Activities' (showing 'Proposal Draft' with a 'Closed' status) and 'Request Details' (showing 'Current Stage: Study Monitoring', 'Country Name: United States', 'Request Name: REQ-00273', and 'Concept Title: Training Example Study').

2. Click **Add**



The screenshot shows the 'Team Members' section of the interface. It displays the name 'Soren Millweather' and an 'Add' button, which is highlighted with a red box.

3. Select the **Role**



The screenshot shows the 'Add Team Member' dialog box. It features a dropdown menu for 'Role' with 'Study Coordinator' selected, highlighted by a red box. Below the dropdown is a search field labeled 'Search Team Member' with the placeholder text 'Enter name or email...'. At the bottom right, there are 'Cancel' and 'Add' buttons.

4. Enter the user's name in the **Search Team Member** field
5. Click the user in search results

The screenshot shows the 'Add Team Member' form. At the top, there is a dropdown menu for 'Role' with 'Study Coordinator' selected. Below it is a search bar labeled 'Search Team Member' containing the text 'Elara'. Under the search bar, it says 'Showing results for "Elara"'. Below that is a section titled 'Search Results' which contains a single result: 'Elara Vance-Kovak' with email 'jschwid+2@mavens.com' and role 'External Portal User'. At the bottom right of the form are 'Cancel' and 'Add' buttons.

6. Click **Add**

This screenshot shows the same 'Add Team Member' form, but the search bar now contains 'Enter name or email...'. Below the search bar, the user 'Elara Vance-Kovak' is listed with a close button (X). The 'Add' button at the bottom right is highlighted with a red box.

## 6.11 Reassign an Activity

If any Activity assigned to a Requester Portal user needs to be reassigned, reach out to the Astellas team and let them know who needs to be assigned to the Activity. The Astellas team will then reassign the Activity as needed.

## 6.12 Send Message to Astellas Team

You can use the Messages section on an ISR Request to send a message to the Astellas team. To send a message to the Astellas team:

1. On the Request, click **Messages**

The screenshot shows the 'Request REQ-00273' page. The 'Messages' tab is selected and highlighted with a red box. The 'Activities' tab shows a 'Proposal Draft' activity with a description: 'Your concept has been approved for further evaluation. Please click'. The 'Request Details' tab shows fields for 'Current Stage' (Study Monitoring), 'Country Name' (United States), 'Request Name' (REQ-00273), and 'Concept Title' (Training Example Study).

2. Enter the **Subject**
3. Enter the **Message**
4. Click **Send Message**

Activities

Messages

Team Members

 **Message Request Owner**

Your message will be sent to the owner of this ISR Request.

\* Subject

Example Question

\* Message

Example Message Text

Send Message

**Note:** Astellas will send responses to messages via email.

## 6.13 Document Types

The table below lists all available Document Type options.

|                                                      |                                                     |                                              |
|------------------------------------------------------|-----------------------------------------------------|----------------------------------------------|
| Amendment Notification                               | Application Form                                    | Budget                                       |
| Budget supporting information                        | Certificate of Drug Destruction                     | Clinical Trials Posting                      |
| Clinical Trials Results Posting                      | Concept - Letter of Intent                          | Concept Approval Letter                      |
| Concept Denial Letter                                | Confidentiality Agreement (CDA)                     | Contract                                     |
| Contract Amendment                                   | Correspondence                                      | Curriculum Vitae                             |
| Drug Accountability Form                             | Drug Order                                          | Drug Return Form                             |
| Enrollment Log                                       | Ethics and/or Regulatory Authority Approval         | Ethics and/or Regulatory Authority Rejection |
| Final Study Report                                   | IND Assignment Letter                               | IND Waiver/Exemption                         |
| Institutional Animal Care and Use Committee Approval | Institutional Animal Care and Use Committee Renewal | Interim Study Report                         |
| Investigational Drug Shipping Order - Fully Executed | Invoice - Milestone                                 | Invoice - Pass-through                       |
| Invoice Supporting Documentation                     | IRB                                                 | IRB Closure Letter                           |
| IRB Renewal                                          | ISR Withdrawal Correspondence                       | Letter of Intent                             |
| Letter of Request                                    | Medwatch Form                                       | Other                                        |
| Product Forecast from Investigator                   | Product Request Form                                | Proposal Approval Letter                     |
| Proposal Denial Letter                               | Protocol                                            | Protocol Amendment                           |
| Protocol amendment summary of changes                | Protocol amendment tracked changes                  | Provision of Materials Agreement             |
| Publication                                          | Purchase Order                                      | Reference safety information                 |
| Site Drug Request                                    | Statement of Research                               | Study progress report                        |
| Sub-site agreement                                   | Support Subject to Contract Letter                  | Supporting Document                          |
| Synopsis                                             | Technical Agreement                                 | Termination Agreement                        |
| W9                                                   |                                                     |                                              |