



Investigator Initiated Research Portal External User Guide

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1. Registration & Login (New and Returning Users)

See the [IIR Registration Guide](#)

2. Add and Remove Delegees

(a) Add a Delegee

Delegees can be added two ways: to each individual submission or to all the submission you own

i. Individual Submission

1. Log in to the IIR Portal and open your submission.
2. Click "Submission Info" to view more about your submission
3. Click the Add Delegee button

The screenshot shows the 'SUBMISSION INFO' page for a submission titled 'SOLID TUMOR TEST'. The page has a navigation bar with tabs: ACTION ITEMS, ATTACH DOCUMENTS, SUBMISSION INFO (selected), DRUG ORDERS, and SUBMITTED SAE'S. Below the navigation bar is a progress bar with steps: SUBMISSION, PRIVACY, PROPOSAL, PROTOCOL, STUDY READINESS, and ACTIVE TRIAL. The main content area is divided into two columns. The left column contains 'SUBMISSION INFO' with details like Therapeutic Area, Selected Compound, Indication, Submission ID, and Submission Status. The right column contains 'SUMMARY DESCRIPTION' and 'MILESTONES'. At the bottom left, there is a 'DELEGATION' button with a green arrow pointing to it.

4. Complete the necessary attestations.

The screenshot shows the 'Add Delegee' form. It has a title 'Add Delegee' at the top. Below the title are four input fields: 'First Name *', 'Last Name *', 'Contact Email *', and 'Co-Investigator (Will have access to everything)'. At the bottom left is a 'Cancel' button, and at the bottom right is an 'Add' button.

5. Fill in the add delegee form.
6. Click Add

ii. All Submissions

1. Log in to the IIR Portal and click the Add Delegees button

Add or Remove Delegee

ADD DELEGEEES

Concept Title

2. Complete the necessary attestations.
3. Check all the submissions for which you would like to add the delegee
4. Fill in the add delegee form.
5. Click Add

(b) Remove a Delegee

Delegees can be removed two ways: to each individual submission or to all the submissions you own

(i) Individual Submission

1. Click “Submission Info” to view more about your submission
2. Under Delegees click the Red X next to the delegee

SOLID TUMOR TEST Therapeutic Area: Oncology Selected Compound: Olaratumab (Lartruvo) Indication: Submission ID: Concept-IIT-Olaratumab (Lartruvo)-US-4828 Submission Status: Trial Enrolling	SUMMARY DESCRIPTION Solid tumor test of script 1253
SUBMISSION INFO Point of Contact: Point of Contact Email: Date Submitted: 30-Sep-2020	MILESTONES: FPV (Actual): Sep, 2020 LPETrial (Actual): LPV (Actual): FPET (Actual): LPETreatment (Actual): FSR (Actual):
DELEGATION	
Add Delegee	
Name	Role
First Name	Financial Manager
	X

3. Click the Confirm Button on the confirmation pop-up

(ii) All Submissions

1. Click the Remove Delegee button
2. Choose the delegee to delete

Add or Remove Delegee

ADD DELEGEEES

REMOVE DELEGEE

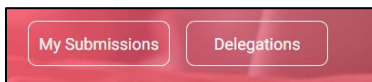
Concept Title

Name	Role
Ima Delegee	Financial Manager
Test First Name Test Last Name	Study Manager with Financials

3. Or the Click the trash can icon next to the delegee name.

3. Delegee Registration

1. The investigator needs to grant permission to the delegee before the delegee can start their process
2. Once done, the delegee will need to register in the portal via Okta (follow regular Okta registration guidelines)
3. After successful registration and login (please see Section I), the delegee needs to navigate to “Delegations.” This is visible on the right-hand side on the main page of the portal.



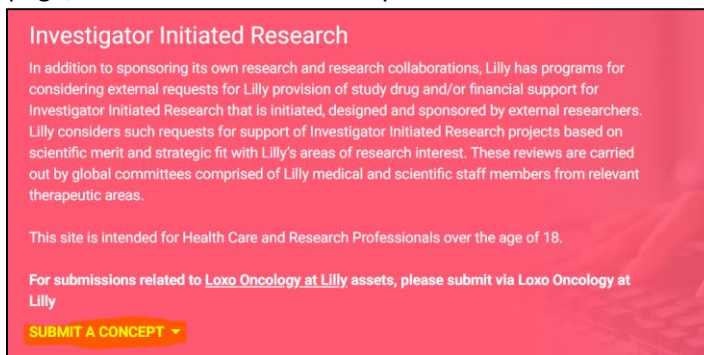
4. Here they will see the delegations that they need to attest (can be multiple if multiple studies have been delegated by the investigator).

SUBMISSIONS TO ATTEST		
Concept Title: Test Concept - Sprint 22 HCP Name: Claire Challis Therapeutic Area: Immunology	Selected Compound: Baricitinib (Olmiant) Indication:	ATTEST
Concept Title: Testing for release 21 round 2 HCP Name: Beth Poling Therapeutic Area: Oncology	Selected Compound: Abemaciclib (Verzenio) Indication: Peritoneal secondary carcinoma	ATTEST

5. Once attestations are complete, delegee can see their submissions in, “My Submissions.”

4. Submit a Concept

1. From the IIR homepage, click the “Submit a Concept” link in the header.



2. Complete the “Submit a Concept” form then click Continue. An attestation on confidentiality and sensitive personal information will pop up that must be completed for the concept to be submitted. All concept content must be non-confidential.
3. The "Submit" button should now be available at the bottom of the online form. A pop up will appear to inform you the submission has been successfully received as well as a receipt confirmation email will automatically be sent following successful submission of the concept.

Submit a Concept

After submitting your initial concept in the form below,
Lilly will review the concept and get back to you within 10 business days.

First Name *	Middle Initial	Last Name *
<hr/>		
Select Country *	Primary Organization Name *	
<small>If you do not see your country listed, please select "Other" as your country and designate your country below in the Summary Description</small>		
Secondary Organization Name	Phone *	
<hr/>	<div>+ 1</div> <div>-- --</div> <hr/>	
Contact Email *		
<hr/>		
Choose Research Category		
<input checked="" type="radio"/> Clinical Request <input type="radio"/> Non Clinical Request <input type="radio"/> Diagnostic Research		
<input type="radio"/> Translational Research		
<small>Research involving human subjects with marketed product(s) and/or investigational agent(s) per applicable regulatory guidelines</small>		
Select Therapeutic Area *		
<div>Oncology Diabetes Immunology Neurodegenerative Diseases Headache & Pain</div>		
Select Compound*	Concept Title *	
<small>If you do not see your compound listed, please select "Other" as your compound and indicate the compound in the Summary Description</small>		
Indication	Summary Description *	
<hr/>	<hr/>	
<small>By completing this form and clicking submit, you agree to the Privacy Statement linked to this site and are consenting to have your e-mail address and personal information you have provided to be collected and used by Eli Lilly and Company and its affiliates and representatives for processing your request for Investigator Initiated Research. Your information will be retained within a secure environment at Lilly.</small>		
<div>Submit</div>		

5. Submit a Proposal

1. After a concept is approved, Registration is required to submit a Proposal.
2. Access your submission and click Proposal Application in the Action Items tab

test

Neclitumumab (Portrazza)

ACTION ITEMS

ATTACH DOCUMENTS

SUBMISSION INFO

Proposal Application

Click here to submit or edit your proposal application.

▼

- Each section expands to reveals fields. All required fields are marked with an (*) and must be completed. Ability to save after completing each section of the application is available, which allows for closing the form and returning later. Upon clicking the “Submit” button, an attestation screen will pop up, with check boxes to be read and completed.
- A receipt confirmation email will automatically be sent following successful submission of the application.

6. Submit a Protocol

- After the Proposal has been approved, the online protocol application will become available within the “My Submissions” in the Action Items tab for the submission. Click on “Submit Protocol” button to bring up the online application and complete the form.
- Each section expands to reveals fields. All required fields are marked with an (*) and must be completed. Ability to save after completing each section of the application is available, which allows for you to save a draft and return later.

- Click the “Submit” button when ready Protocol completed. A receipt confirmation email will automatically be sent following successful submission of the application.

PROTOCOL APPLICATION
Please ensure the information below is accurate and attach your protocol at the bottom

IIR Application	▼
Clinical Research Information	▼
Study Compound Support	▼
Financial Support	▼
Contact Information	▼

[Attach Protocol](#)

[Save](#) [Submit](#) [Cancel](#)

7. Attach a Document

Lilly expects to be informed of any publications that arise from a Study.

1. Log in to the IIR Portal and open your submission.
2. Click on the “Attach Documents” tab and click the “Attach Document” button to select the document for uploading. Please note, once uploaded, the documents cannot be deleted or edited.

Testing for 1123 Baricitinib (Olumiant)

ACTION ITEMS **ATTACH DOCUMENTS** SUBMISSION INFO

Attach Document

Click here to attach documents

▼

8. Update Enrollment (Quarterly)

A **quarterly update** on the status of their Study is expected. The status includes but is not limited to the enrollment progress of the Study.

This function is used to update your trial’s enrollment on a quarterly basis

1. Log in to the IIR Portal and open your submission.
2. Click on the “Update Enrollment” button within the Action Items tab

Test of automated email for Proposa-Draft Mirikizumab 8/7/2028 Active Trial

ACTION ITEMS ATTACH DOCUMENTS SUBMISSION INFO SUBMITTED SAE'S

Update Enrollment
Click here to update your enrollment status
▼

Reforecast Trial
Click here to make changes to your initial forecast
▼

Submit Trial Expense
Click here to submit trial expenses
▼

Submit Amendment
Click here to submit an amendment
▼

Milestones Met
Click here to view met milestones
▼

Site Management
Click here to view Site Management
▼

Report SAE
Click here to report SAE
▼

3. Select the quarter you need to update and click next

The screenshot shows the 'Enrollment' form. At the top right is the title 'Enrollment'. On the left, there is a label 'Quarter:' followed by a dropdown menu. The dropdown menu is open, showing four options: 'Q1-2020', 'Q2-2020', 'Q3-2020', and 'Q4-2020'. To the right of the dropdown is a red 'Next' button. At the bottom left is a red 'Cancel' button.

4. Provide the following information
 - a. Total Patients Entered Treatment – This is the total amount of patients (excluding screen failures) that are participating in the study
 - b. Current Patients Entered Treatment Estimate – The total amount of patients you are currently estimated to have enrolled
 - c. Number of Patients Currently on Treatment – Number of patients that are currently undergoing treatment
 - d. Number of Patients Completed Trial – Number of patients who have successfully completed the study
 - e. Number of Patients Currently on Follow-up – Number of patients still undergoing follow-up post completion of treatment
 - f. Number of Patients Discontinued from Treatment – Number of patients that have ended treatment prior to completion (safety concerns, death, etc.)

The screenshot shows the 'Enrollment' form with the 'Quarter' dropdown set to 'Q2-2020'. The 'Next' button is red. Below the dropdown, there are five input fields with labels: 'Total Patients Entered Treatment', 'Current Patients Entered Treatment Estimate' (with a value of 0), 'Number of Patients Currently on Treatment', 'Number of Patients Completed Trial', and 'Number of Patients Discontinued from Treatment'. At the bottom left is a red 'Cancel' button. At the bottom right is a red 'Submit' button. There is also a 'Comments:' label and a text area for comments.

5. Click the Submit button
6. You will see a notification that informs you your enrollment was successfully updated

9. Milestones Met (Quarterly)

This process is used to submit the date(s) of achieved milestones.

1. Log in to the IIR Portal and open your submission.
2. Click on the “Milestones Met” button

The screenshot shows the 'ACTION ITEMS' tab in the IIR Portal. It contains seven buttons arranged in two rows. The top row includes 'Update Enrollment', 'Reforecast Trial', 'Submit Trial Expense', and 'Submit Amendment'. The bottom row includes 'Milestones Met' (highlighted in yellow), 'Site Management', and 'Report SAE'. Each button has a small description and a downward arrow icon.

3. Select the date you achieved the milestone with the date picker

The screenshot shows the 'Milestones Met' form. It has six date picker fields: FPV, FPET, LPE Trial, LPETreatment, LPV, and a 'Comments' text area. At the bottom, there are 'Cancel' and 'Submit' buttons.

4. Click Submit
5. You will see a notification that informs you your milestone was successfully updated

10. Reforecast Trial

This process is used to inform Lilly of new estimated dates of future milestones.

1. Log in to the IIR Portal and open your submission.
2. Click the "Reforecast Trial" button

The screenshot shows the 'ACTION ITEMS' tab in the IIR Portal, similar to the first screenshot. The 'Reforecast Trial' button is highlighted in yellow.

3. Provide the following information
 - *All fields are required to submit your reforecast request
 - a. Quarterly Enrollment – This is your estimated per quarter enrollment for all remaining quarters
 - b. Original Milestone – These fields contain your original milestone estimations
 - c. Milestone – Provide your new estimation for completing each of the remaining milestones
 - d. Rationale – Provide the rationale for needing to reforecast (safety checkpoint, natural disaster, etc.)



Reforecast Trial

Quarterly Enrollment*  _____

Original FPV Forecast  dd-mm-yyyy

FPV*  dd-mm-yyyy

Original LPET Forecast  dd-mm-yyyy

FPET*  dd-mm-yyyy

LPETrial*  dd-mm-yyyy

Original LPETreatment Forecast  dd-mm-yyyy

Original LPV Forecast  dd-mm-yyyy

LPETreatment*  dd-mm-yyyy

LPV*  dd-mm-yyyy

Original FSR Forecast  dd-mm-yyyy

FSR*  dd-mm-yyyy

Rationale

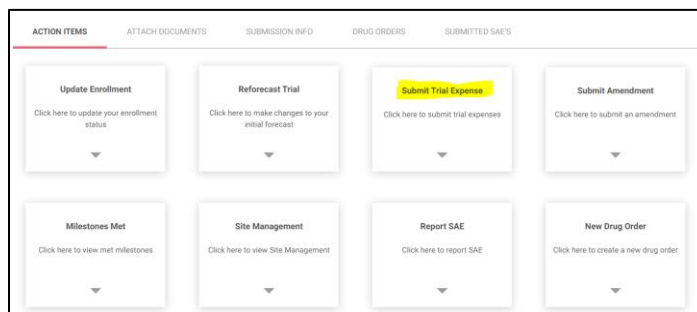
[Cancel](#) [Submit](#)

4. Click Submit
5. You will see a notification that informs you your reforecast request was successfully submitted

11. Submit Trial Expense

This process is used to submit expenses related to your Active Trial.

1. Log in to the IIR Portal and open your submission.
2. Click on the “Submit Expense” button in the Action Items tab.



ACTION ITEMS | ATTACH DOCUMENTS | SUBMISSION INFO | DRUG ORDERS | SUBMITTED SAE'S

Update Enrollment
Click here to update your enrollment status

Reforecast Trial
Click here to make changes to your initial forecast

Submit Trial Expense
Click here to submit trial expenses

Submit Amendment
Click here to submit an amendment

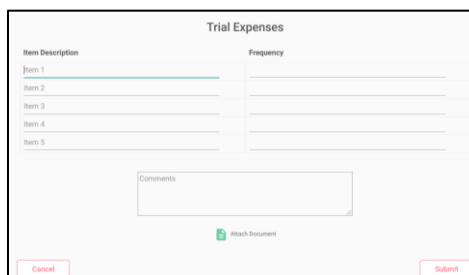
Milestones Met
Click here to view met milestones

Site Management
Click here to view Site Management

Report SAE
Click here to report SAE

New Drug Order
Click here to create a new drug order


3. Enter the appropriate expense description and frequency.
4. Enter Comment and attach documentation as needed.



Trial Expenses

Item Description	Frequency
Item 1	
Item 2	
Item 3	
Item 4	
Item 5	

Comments

 Attach Document

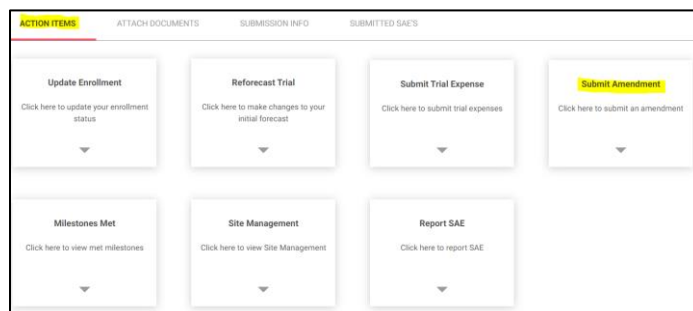
[Cancel](#) [Submit](#)

5. Click the Submit button
6. You will see a notification that informs you your expense was successfully submitted

12. Submit Amendment

This process is used to submit subsequent Amendments to your existing Trial Protocol.

1. Log in to the IIR Portal and open your submission.
2. Click on the “Submit Protocol Amendment” button



3. Provide Rationale and attach your amendment document (PDF and Word documents accepted)

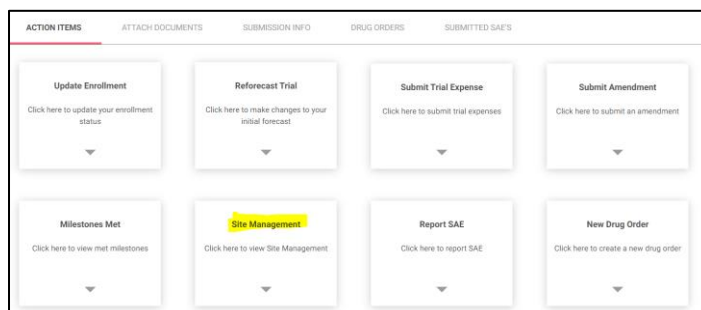
A screenshot of the 'Trial Protocol/Study Research Plan Amendment' form. The form has a title bar at the top. Below the title bar, there is a large text area labeled 'Rationale*'. Below the text area, there is a green icon with a document symbol and the text 'Attach Document'. At the bottom of the form, there are two buttons: 'Cancel' and 'Submit'.

4. Click the Submit button
5. You will see a notification that informs you your amendment was successfully submitted

13. Site Management

Site management is used to manage sites for drug orders and deliveries.

1. Log in to the IIR Portal and open your submission.
2. Click on the “Site Management” button in the Action Items tab.



3. You can create a new site or update an existing site prior to ordering a drug for an Active Trial.
4. Click the Submit button
5. You will see a notification that informs you your site was successfully submitted

RETURN TO MY SUBMISSIONS
CREATE NEW SITE

End-to-End Test Site for 4828

Site address: Street address: 123 Main Street City: City Zip: 44444 State/Province: Maryland Country: United States	Contact Information: Contact Name: Minnie Mouse Phone Number: 555-555-5555 Email: reed_amy@network.lilly.com	IRB/ERB Documentation: Utilizing ethics approval?: Yes IRB/ERB Start Date: IRB/ERB Expiration Date:
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UPDATE

14. Report SAE

Lilly would like to be notified within fifteen (15) calendar days of Investigator and/or Institution receiving notification of any “serious” adverse event experienced by a patient participating in the Study and receiving Study Drug that is possibly related, based on Investigator’s assessment, to the Study Drug.

For purposes of this requirement, “serious” means:

1. Death;
2. in-patient hospitalization or prolonged hospitalization;
3. life threatening;
4. persistent or significant disability or incapacity;
5. congenital anomaly or birth defect; or
6. other serious events that may jeopardize the patient and may require medical or surgical intervention to prevent one of the other five listed outcomes.

Serious adverse events should be reported to Lilly using a CIOMS Form or equivalent form in English. Investigator/Institution further agree to make available promptly to Lilly such records as may be necessary and pertinent for Lilly to further investigate an adverse event in the Study that is possibly associated with the Study Drug.

This function is ***only intended to be used for adverse events***, it is not to be used for product complaints, etc.

Submit the SAE report by following the instructions given below.

1. Select the trial you want to submit a copy of the SAE report by clicking on the correct submission

2. Once the submission section expands, click on the “Report SAE” button
3. Provide the Site & Patient Number you are reporting the SAE on. You may also add additional information in the free text field. Next, attach your SAE Report

Report a SAE

Site Number*

Patient Number*

Additional SAE information

Attach SAE Report*

B I U Arial 12

4. Click the “Submit” button
5. You will receive an email notification (within 3-5 minutes) informing you the SAE was successfully reported

15. New Drug Order

The New Drug Orders tab allows for eligible institutions to order drugs online for Active Trials.

1. Log in to the IIR Portal and open your submission.
2. Click on the “New Drug Order” button in the Action Items tab.

ACTION ITEMS ATTACH DOCUMENTS SUBMISSION INFO DRUG ORDERS SUBMITTED SAE'S

Update Enrollment Click here to update your enrollment status 	Reforecast Trial Click here to make changes to your initial forecast 	Submit Trial Expense Click here to submit trial expenses 	Submit Amendment Click here to submit an amendment
Milestones Met Click here to view met milestones 	Site Management Click here to view Site Management 	Report SAE Click here to report SAE 	New Drug Order Click here to create a new drug order

3. You will need to choose the appropriate Drug Order Delivery Site and complete the Drug Order form

Drug Order Form

Site*

Test for Chlamy - validate Sprint 24 *

Attention to Recipient Name

Irma Spantecos

Site Contract No.

1234567890

Site Contract Email

test_jerry@network.lilly.com

Has the Drug Delivery Shipment address changed?

No *

Street Address

123 Main Street

City

City Center

State

N/A

Zip/Postal Code

11111

Country

Austria

If you do not see your country listed, please select "Other" on your country and designate your country below in the comments.

Broker Address(For non-US orders only)

Attention to Recipient Name

Street Address

Broker Contract Number

City

State

Please select your country... *

Zip/Postal Code

Country

Select an Option *

If you do not see your country listed, please select "Other" on your country and designate your country below in the comments.

Drug Order

Drug Name*	Strength*	Count*	Presentation*
<input type="radio"/> Osimertinib	100 mg	4 count	Syringe
<input type="radio"/> Bupropion (Wellbutrin)	0.75 mg	100 count	Tablet
<input type="radio"/> Placebo to match Dulaglutide (Trulicity)	20 mg	90 count	Bottle
<input type="radio"/> SH92i	0.75 mg	100 count	Bottle

Quantity*

+ Add another Drug of Your Order

4. Review and confirm order before submitting. Upon clicking the "Submit" button, an attestation screen will pop up, with check boxes to be read and completed.
5. You will see a notification that informs you your drug order was successfully submitted
6. You also can track your drug orders in the Drug Orders tab to review status and history of your orders.

ACTION ITEMS		ATTACH DOCUMENTS		SUBMISSION INFO		DRUG ORDERS	SUBMITTED SAE'S	
Request ID	Drug	Requested Delivery Date		Estimated Delivery Date		Order Site	Quantity	Status
R-00072	Dulaglutide (Trulicity)	12/31/2020		2/28/2021		End-to-End Test Site for 4828	50	Ordered
R-00073	Dulaglutide (Trulicity)	12/31/2020		2/17/2021		End-to-End Test Site for 4828	25	Delivered
R-00074	Mirikizumab	12/31/2020		2/28/2021		End-to-End Test Site for 4828	10	Cancelled
R-00075	BAFF/IL-17	10/30/2020		12/31/2020		End-to-End Test Site for 4828	50	Complete

16. FAQ and Ask a Question

1. From the IIR homepage, click on the FAQs link located in the top right corner of the screen.
2. Review the Question categories and click on “View all Questions” to expand the box.
3. You can search on a question in the Search field.

Frequently Asked Questions

What are you looking for?

Getting Started
Effective June 10th, 2020: Instructions for Registered User
How do I register for an account?
[View all Questions](#)

Concept Submission
What is a concept?
Why am I limited to providing so little information?
[View all Questions](#)

Proposal Submission
What if I have already written a full protocol?
What if I cannot agree to the attestations?
[View all Questions](#)

Protocol Submission
When should I hear back about my Protocol?
In what format should the protocol be written?
[View all Questions](#)

Reporting Enrollment
How do I report my enrollment?
How frequently do I report enrollment?
[View all Questions](#)

Reporting Expenses (US Only)
Where do I go to submit an expense?
[View all Questions](#)

Study Milestones
What if I cannot achieve my current estimated milestones?
[View all Questions](#)

Reporting Safety
How do I report a Serious Adverse Event (SAE)?
How do I report a product complaint?
[View all Questions](#)

Site Management
Why would I add a site?
[View all Questions](#)

4. If you do not find the answer to your question, click on “Contact Us” at the bottom of the page to submit your question.

Didn't find your answer? [Contact Us](#)

Contact Us

Please fill out the form below with your contact information and question.
This form may not be used to submit SAEs, Product Complaints, or any other sensitive information.

Name* Email*

Phone Select Country*

Question*