Investigator Initiated Research Portal
External User Guide

Contents

1. Registration & Login (New and Returning Users)

See the IIR Registration Guide

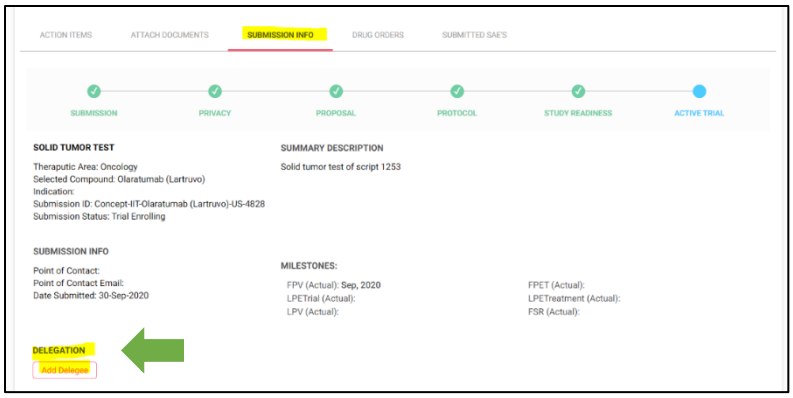
2. Add and Remove Delegees

(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

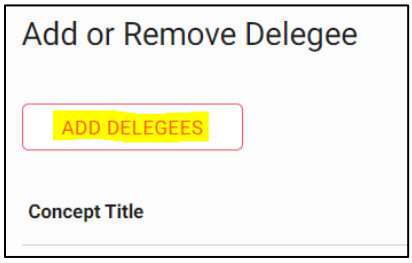


4. Complete the necessary attestations.

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



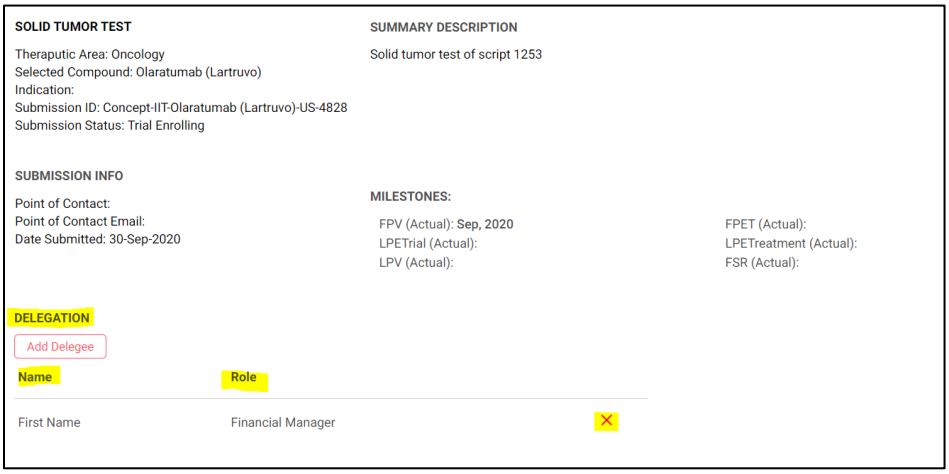
2. Complete the necessary attestations.
3. Check all the submissions for which you would like to add the delegee
4. Fill in the add delegee form.
5. Click Add

(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



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

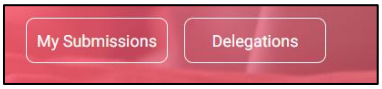
(ii) All Submissions

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

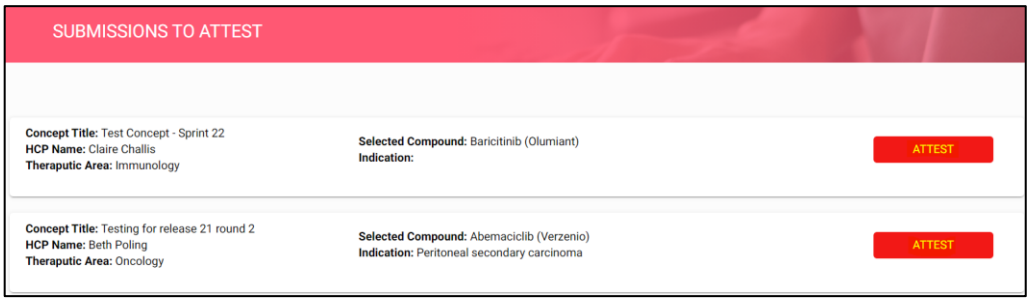
3. Or the Click the trash can icon next to the delegee name.

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.



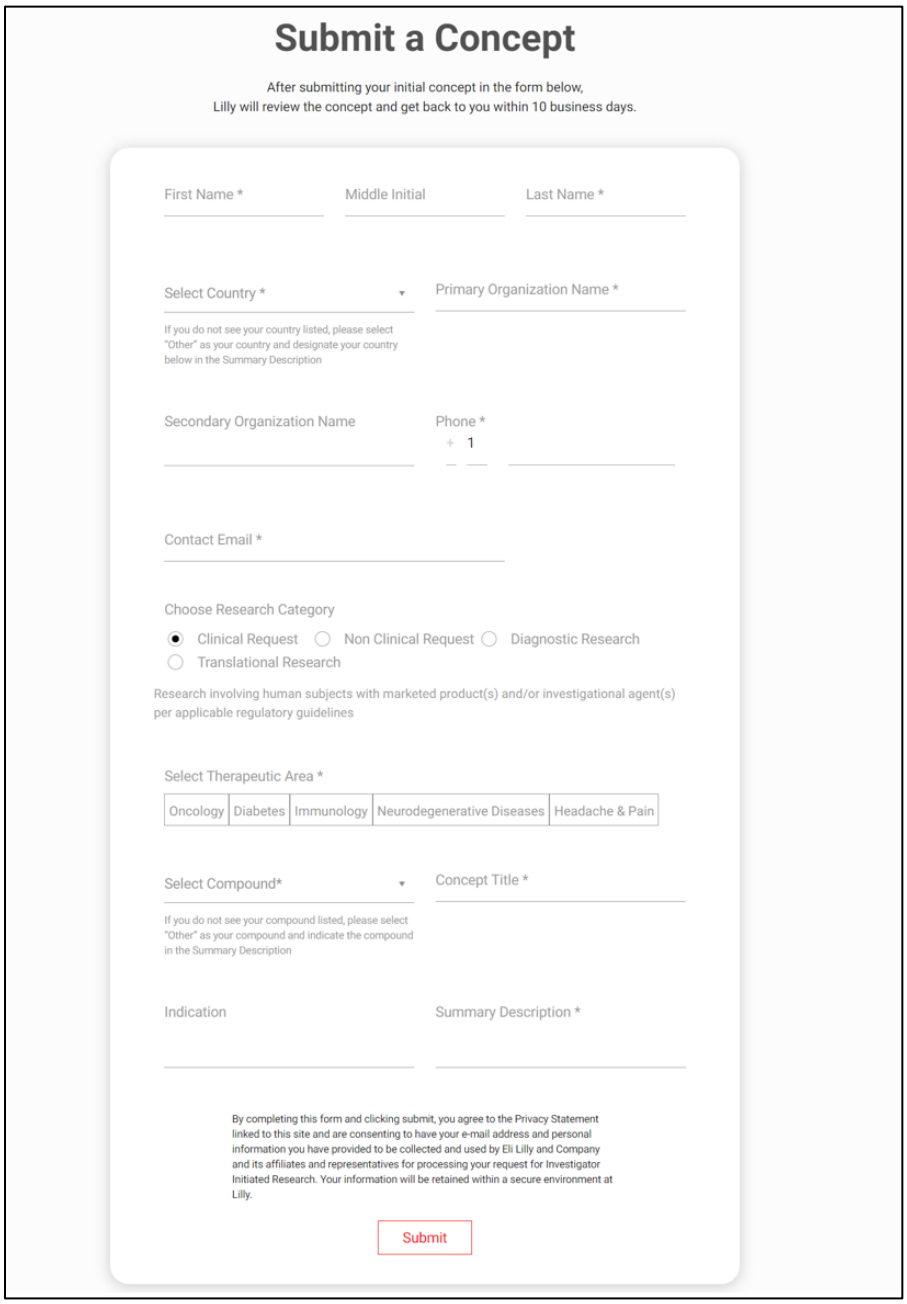
5. Once attestations are complete, delegee can see their submissions in, "My Submissions."

4. Submit a Concept

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

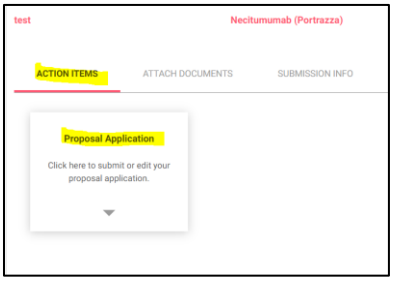
2. Complete the "Submit a Concept" form then click Continue. An attestation on confidentiality and sensitive personal information will pop up that must be completed for the concept to be submitted. All concept content must be non-confidential.

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.

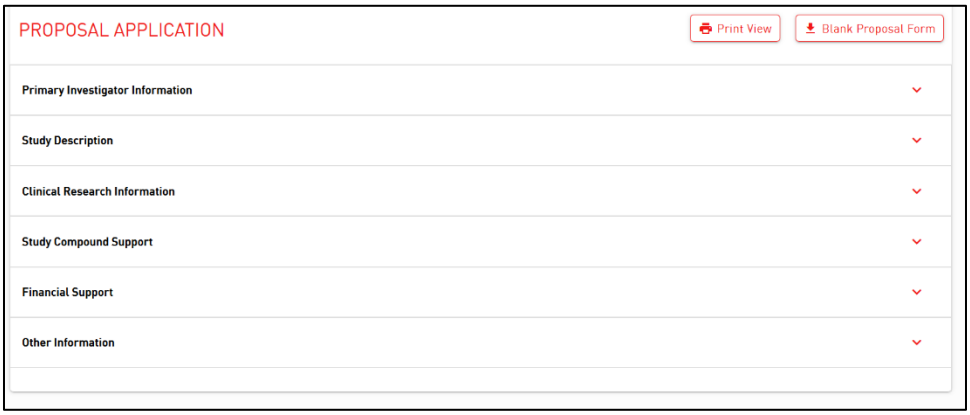


5. Submit a Proposal

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

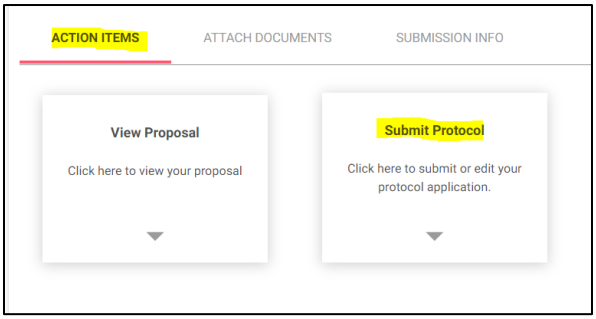


3. Each section expands to reveals fields. All required fields are marked with an (*) and must be completed. Ability to save after completing each section of the application is available, which allows for closing the form and returning later. Upon clicking the “Submit” button, an attestation screen will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

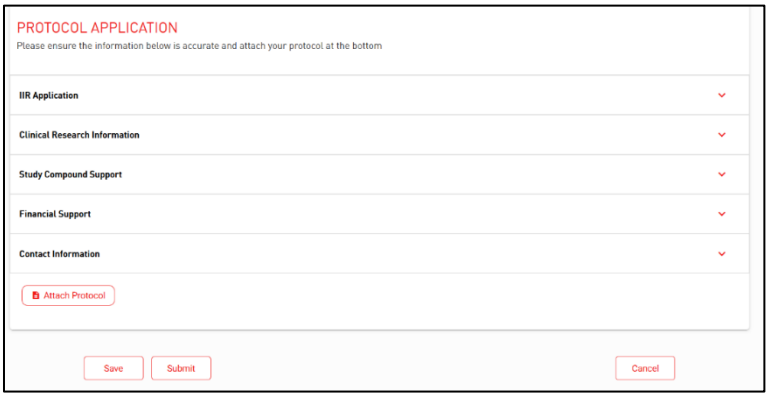


6. Submit a Protocol

1. 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.
2. 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.



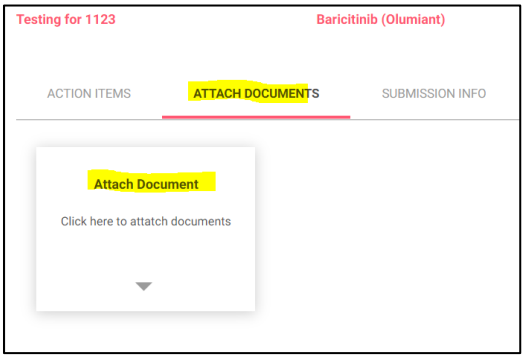
3. Click the “Submit” button when ready Protocol completed. A receipt confirmation email will automatically be sent following successful submission of the application.



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.

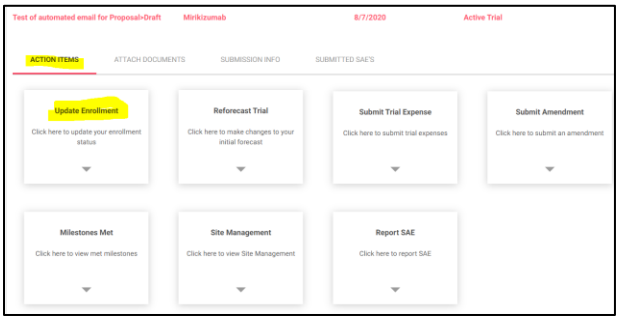


8. Update Enrollment (Quarterly)

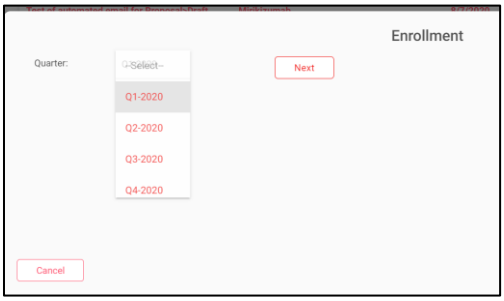
A ***quarterly update*** on the status of their Study is expected. The status includes but is not limited to the enrollment progress of the Study.

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

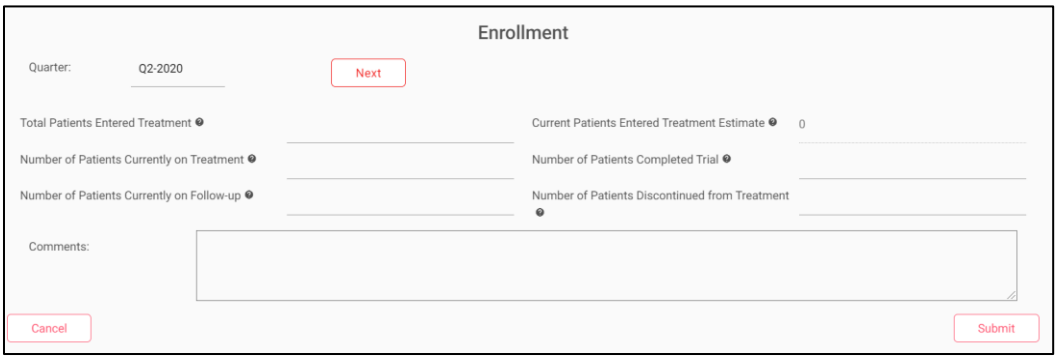
1. Log in to the IIR Portal and open your submission.
2. Click on the "Update Enrollment" button within the Action Items tab



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



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.)

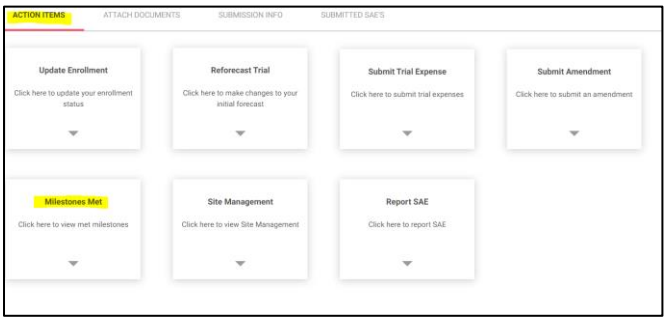


5. Click the Submit button
6. You will see a notification that informs you your enrollment was successfully updated

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



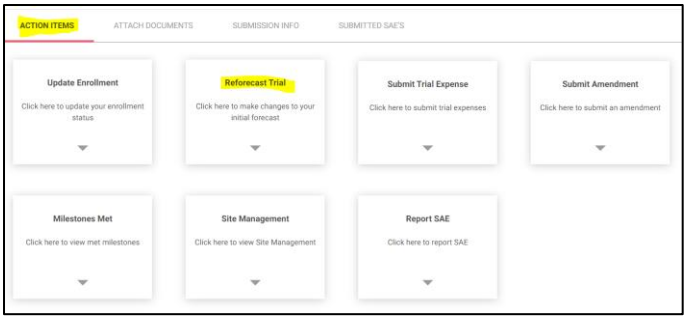
3. Select the date you achieved the milestone with the date picker

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

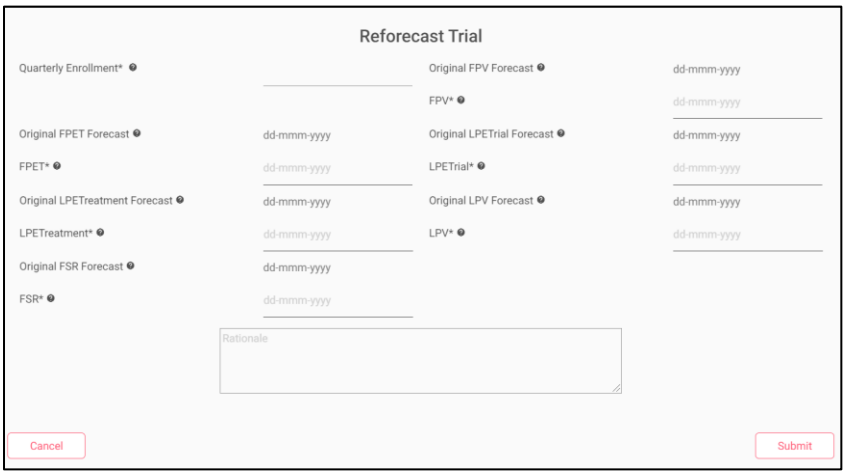
10. Reforecast Trial

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



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.)

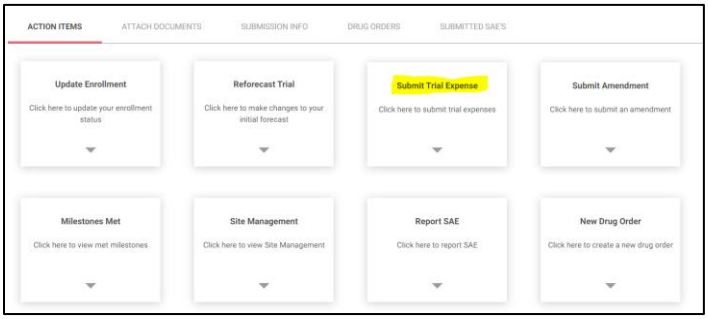


4. Click Submit
5. You will see a notification that informs you your reforecast request was successfully submitted

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.



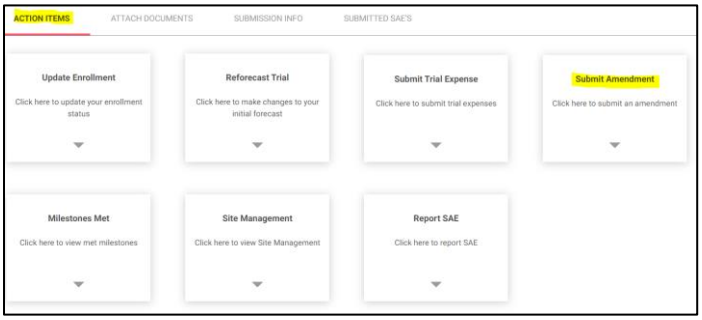
3. Enter the appropriate expense description and frequency.
4. Enter Comment and attach documentation as needed.

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

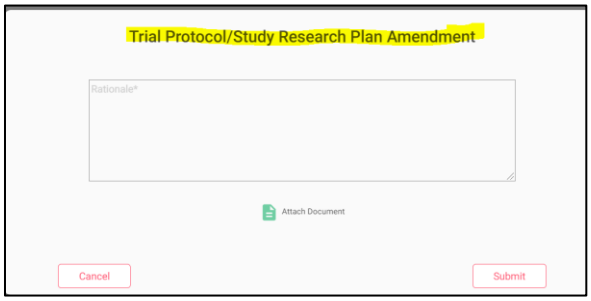
12. Submit Amendment

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)

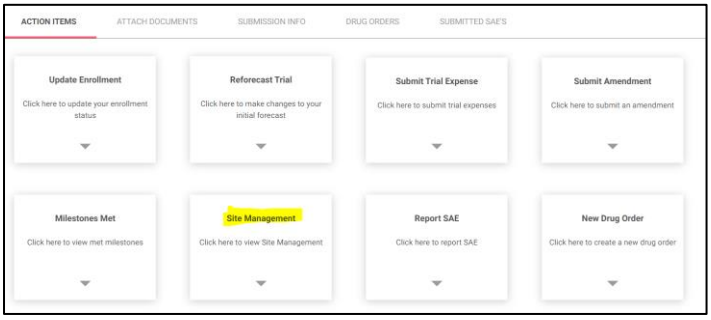


4. Click the Submit button
5. You will see a notification that informs you your amendment was successfully submitted

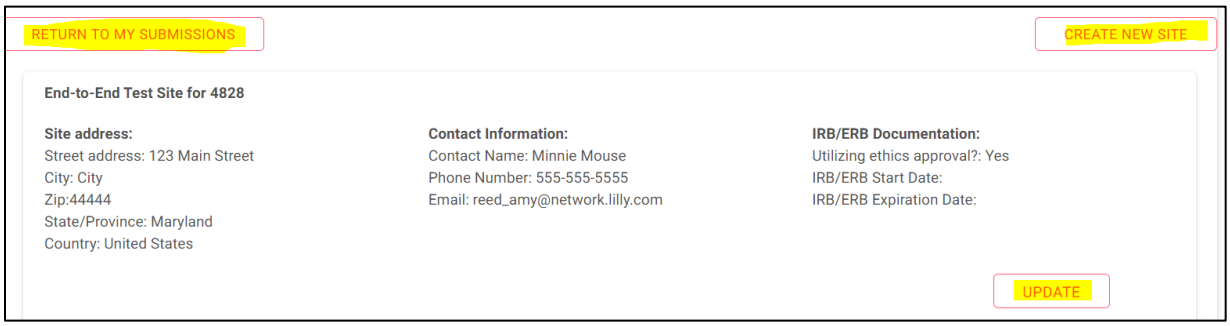
13. Site Management

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



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:

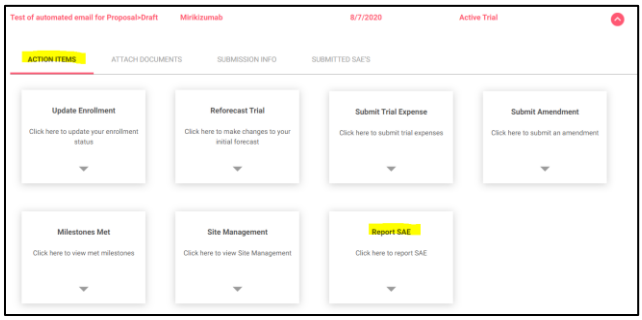
1. Death;
2. in-patient hospitalization or prolonged hospitalization;
3. life threatening;
4. persistent or significant disability or incapacity;
5. congenital anomaly or birth defect; or
6. other serious events that may jeopardize the patient and may require medical or surgical intervention to prevent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

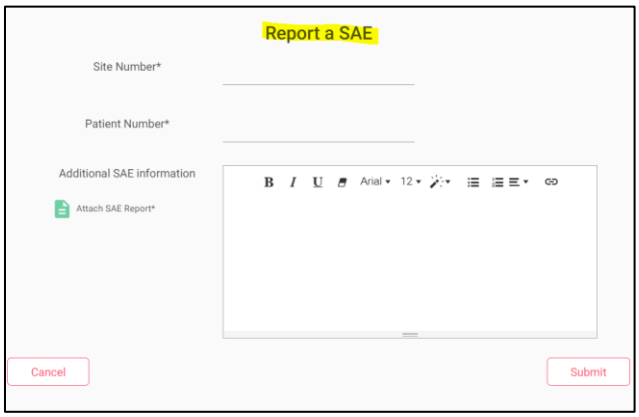
This function is ***only intended to be used for adverse events***, it is not to be used for product complaints, etc.

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

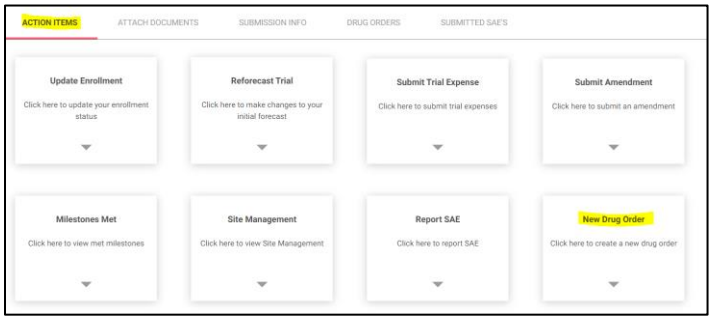


4. Click the “Submit” button
5. You will receive an email notification (within 3-5 minutes) informing you the SAE was successfully reported

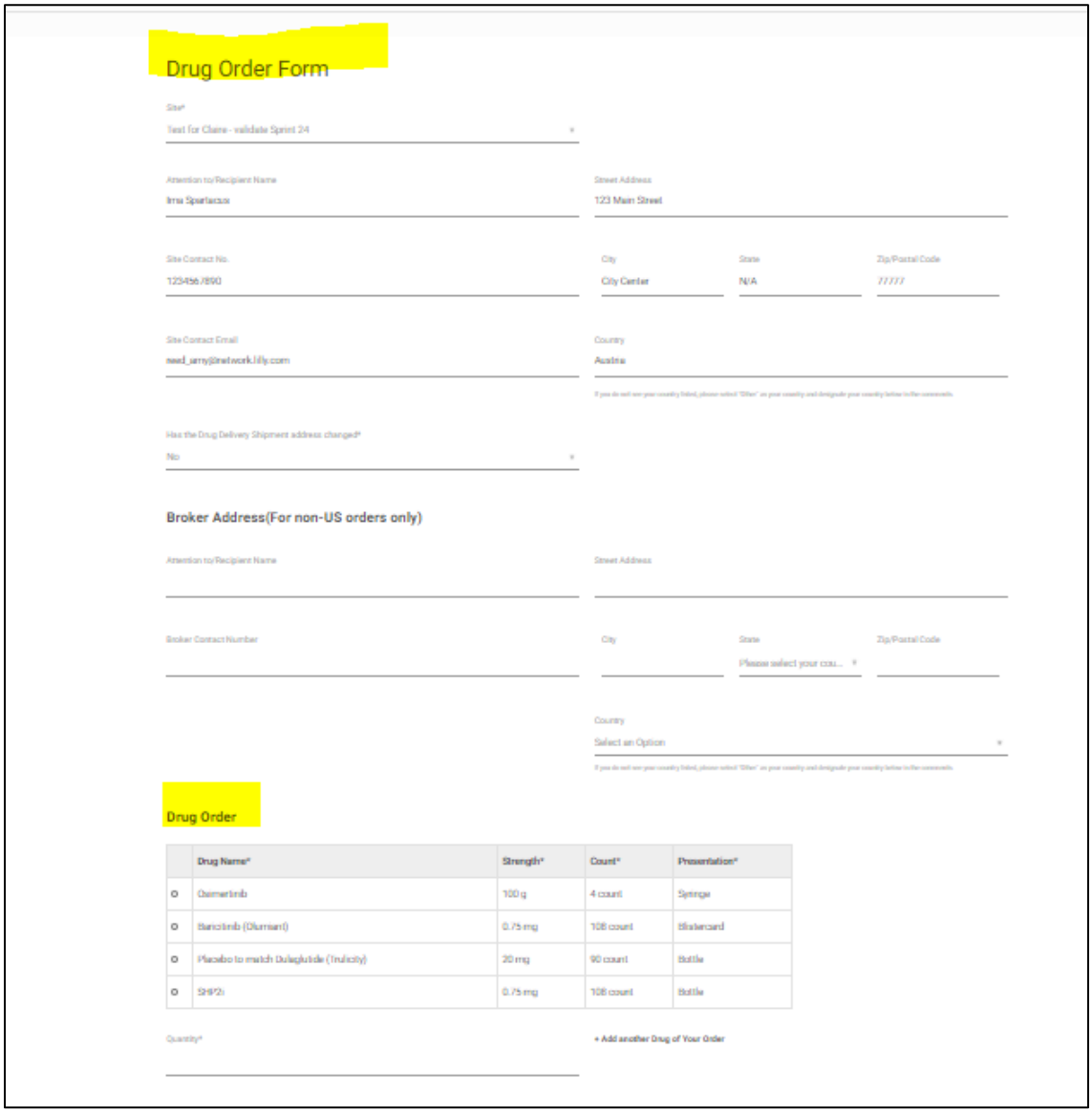
15. New Drug Order

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

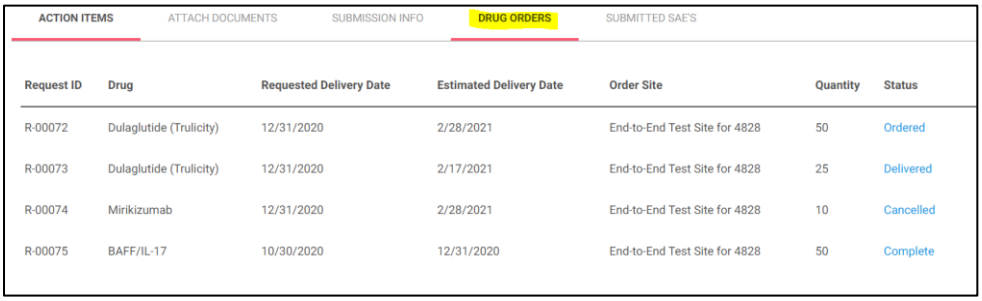
1. Log in to the IIR Portal and open your submission.
2. Click on the “New Drug Order” button in the Action Items tab.



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

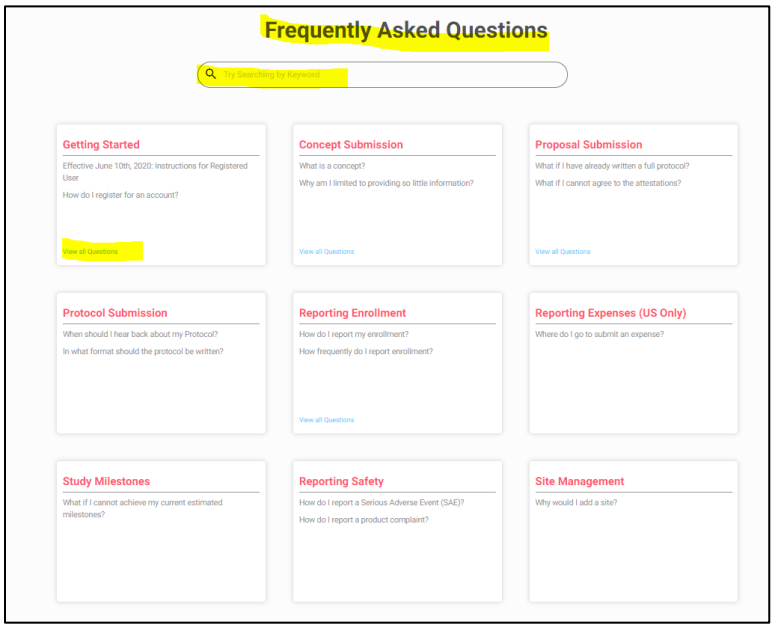


4. Review and confirm order before submitting. Upon clicking the “Submit” button, an attestation screen will pop up, with check boxes to be read and completed.
5. You will see a notification that informs you your drug order was successfully submitted
6. You also can track your drug orders in the Drug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



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.



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.