Investigator Initiated Research (IIR) Portal
Quick Reference Guide

Serious Adverse Events/Adverse Events not associated with approved IIRs are not to be submitted via the IIR Portal. All information within concepts, proposals, or protocols being submitted should be reviewed with any references to serious adverse events or sensitive personal information removed.

Contents
Accessing the Main Landing Page ................................................................. 3
Viewing Compound Lists ............................................................................... 3
Submitting a Concept .................................................................................... 4
Registration & Login ..................................................................................... 5
  Registration .................................................................................................. 5
  Login ........................................................................................................... 8
  Error .......................................................................................................... 9
Uploading/Attaching a Document ................................................................. 9
Delegee Administration .................................................................................. 10
  Adding Delegee .......................................................................................... 10
    Individual Submission ............................................................................. 10
    All Submissions ...................................................................................... 11
  Removing Delegee ..................................................................................... 11
    Individual Submission ............................................................................. 12
    All Submissions ...................................................................................... 12
Submitting a Proposal and Application ......................................................... 12
Uploading a Protocol and Supporting Documentation .................................... 13
Active Trial ..................................................................................................... 13
  Milestones .................................................................................................. 13
    Submit Achieved Milestones ................................................................. 14
    Reforecast Future Milestones ............................................................... 14
Submit Quarterly Enrollment ......................................................................... 15
Submit Trial Expense (US Only) ................................................................... 17
Submit Protocol Amendment ......................................................................... 17
Site Management ........................................................................................... 18
Creating a new Site ......................................................................................................................... 18
Updating an existing site .................................................................................................................. 19
Report an SAE ................................................................................................................................ 19
Requesting a Country be added to the Country List ........................................................................ 20
Password Reset ................................................................................................................................. 20
Delegees .......................................................................................................................................... 22
Attesting to Submissions ..................................................................................................................... 22
Accessing the Main Landing Page

1) Go to lillyinvestigatorresearch.com
   From here users are able to:
   - Review areas of research focus
   - Find compound scope statements and listings
   - Access frequently asked questions (“FAQ”)
   - Access the form to submit new questions (“FAQ”)
   - Access the form to submit a high-level concept (“Submit a Concept”).

2) Login requires registration through Exostar. This is detailed below in the “Registration & Login” Section.

Viewing Compound Lists

1) From the IIR homepage, select the therapeutic area of interest. Click on the arrow link to the right of the research focus of interest.

2) The compound list for that research focus will expand. Select the research category of interest (Clinical; Non-Clinical) to view available compounds. Review the compound specific scope statement by clicking on the arrow to the right of the compound of interest.
Note: If the compound of interest is not listed, go to the FAQs page. Submit a question leaving the “Compound” field empty, reference desired compound in the “Question title” field, enter the high-level concept details in the “Question” field and complete the required attestations to submit.

Submitting a Concept

1) From the IIR homepage, click the “Submit a Concept” link in the top right corner
2) Review the IIR process step descriptions located to the left side of the screen by clicking on the arrow to the right of each process step title to understand the IIR submission process.
3) 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. 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.
   - Primary Organization Name is a predictive field, however, if you’re organization is not autopopulated you may still fill in the field
Registration & Login

Registration

Users may register for the IIR Portal at any time in order to track their submitted concepts. The registration process is detailed below:

1) Click the Login button in the upper right hand corner of the IIR Portal
2) EU ONLY  
   (Optional) Accept cookies (this simplifies the login process in the future)

3) Click HERE under Clinical Research Login
4) Provide your First Name, Last Name & Email Address and click Next

5) Complete the Registration Form, then click Next
6) Receive an email that your account has been authorized, and click the activation link

Lilly is partnering with a provider, Exostar, to enable a user to utilize a single username and password access multiple Lilly clinical trial applications.

The same email address will be used to access multiple systems and each person must have a unique account (no group email addresses are allowed). You may also receive systemspecific communications with additional instructions.

In order to access these applications you have been invited to activate your account in Exostar’s Secure Access Manager. This service is used to provide secure access to Lilly’s business and collaboration tools. Read More [link](http://www.myexostar.com/WorkArea/DownloadAsset.aspx?id=1814)

To complete the activation of your account please click the following link: [http://secureaccess.exostar.com/idproc/accesslogin/Process10p.faces?p1=e%5Kn3%ef%Y3Yca%EY3RS2/YW5nA10500MEc2lTe%36eY3%36/oeYW5nS3QpPUNK/ZI/ksW6wRDYD/OUHBBKRU7maMk7Ymldb3M7/98F9zkJ8eUEjZe9RZ WM9](http://secureaccess.exostar.com/idproc/accesslogin/Process10p.faces?p1=e%5Kn3%ef%Y3Yca%EY3RS2/YW5nA10500MEc2lTe%36eY3%36/oeYW5nS3QpPUNK/ZI/ksW6wRDYD/OUHBBKRU7maMk7Ymldb3M7/98F9zkJ8eUEjZe9RZ WM9)

Need Help? Please contact your primary Lilly clinical trial contact. DO NOT reply to this email. This is an automated email and replies are not being monitored.

7) Set your password

8) Set your security questions and click submit

   Optional: you may click the checkbox for “Add Phone Number for additional security (Optional)” this will result in a text message being sent when you login, instead of having to answer security questions
9) Your account is created!

Login
1. Click Login in the upper right hand corner of the IIR Portal
2. EU ONLY
   (Optional) Accept cookies (this simplifies the login process in the future)
3. Click “Clinical Researcher Login”
4. Login like normal with Exostar
Error
If you see the below error please contact your local IT about enabling Java or Cookies

Uploading/Attaching a Document
The ability to upload a document is not available from either the FAQ or Submit a Concept pages. If an investigator’s concept submission is in scope, then the ability to attach and submit documents is available for that specific submission on the “My Submission” page.

1) Click on the “My Submissions” button to open your personal homepage.
2) Click on the submission of interest (outlines in Red once selected).
3) Click on the “View More” arrow to the far right to open up the detailed submission view.
4) Click the “Attach Document” button and select the document needing to be uploaded. Examples of documents that will be needed are; an executed confidential disclosure agreement, curriculum vitae (CV), proposal summary, and a draft protocol. Please note, once uploaded, the documents cannot be deleted or edited.
Note: Status of each submission is viewable on “My Submissions” page. As seen in the following screen shot, the dots represent each stage with the red dot denoting the completed stage(s).

Delegee Administration

Adding Delegee

If you have delegees that you would like to have work on the submission with you (Understudies, Study Coordinators, etc.), they can be added at any time after reaching the stage Proposal. Delegees have the same access as the HCP that submitted the concept originally, except those delegated to the submission cannot add other delegees, this can only be accomplished by the HCP that submitted the concept.

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

Individual Submission

1. Click view more on your submission
2. Click the Add Delegee button
3. Complete the necessary attestations  
a. This is required for the first delegee for each submission  

4. Fill in the add delegee form  
a. If “Other” is selected as a role, please fill in the role  

5. Click Add  

All Submissions  
1. Click the Add Delegees button  

2. Check all the submissions for which you would like to add the delegee  
3. Complete the necessary attestations  
a. This is required for the first delegee for each submission  
4. Fill in the add delegee form  
a. If “Other” is selected as a role, please fill in the role  
5. Click Add  

Removing Delegee  
If you have delegees that you would like to have work on the submission with you (Understudies, Study Coordinators, etc.), they can be added at any time after LoC approval. Delegees have the same access as
the HCP that submitted the concept originally, except those delegated to the submission cannot add other delegees, this can only be accomplished by the HCP that submitted the concept.

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

**Individual Submission**
1. Click View More on your submission
2. Under Delegees click the Red X next to the delegee
3. Click the Confirm Button on the confirmation pop-up

**All Submissions**
1. Click the Remove Delegee button
2. Select the Delegee
3. Click the Remove Delegee button

**Submitting a Proposal and Application**
1) After completing the letter of confidentiality phase, the online proposal application will become available within the “My Submissions” on the personal homepage. Click on the “Proposal Application” button to bring up the online application and complete the form.
2) 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 application and returning later. Upon clicking the “Submit” button, an attestation screen will pop up, with two check boxes to be read and complete. A receipt confirmation email will automatically be sent following successful submission of the application.
3) In addition, curriculum vitae (CV), a proposal summary or protocol must be attached. If applicable, a draft budget* should also be attached. Click the “Attach Document” button and select the document needing to be uploaded. Please note, once uploaded, the documents cannot be deleted or edited.
*For US only submissions, links to a budget template and guidelines are available in the lower left left corner of the submission summary.
Uploading a Protocol and Supporting Documentation

1) To upload a protocol (if not provided when completing the application form), click on the submission of interest which will then be outlined in Red. Click on the “Attach Document” button and then select the document for uploading. Please note, once uploaded, the documents cannot be deleted or edited.

2) Comments and recommendations may be entered into the text field.

Active Trial

Milestones

When viewing your submission, you will see either the month your milestone was achieved or the month you are currently estimated to achieve the milestone.

Achieved Milestones will display as *Milestone Name* (Actual) MMM, YYYY

Estimated Milestones will display as *Milestone Name* (Estimate) MMM, YYYY
Submit Achieved Milestones
This process is used to submit the date(s) of achieved milestones.

1. Click on the “Milestones Met” button

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

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

Reforecast Future Milestones
This process is used to provide Lilly staff with new estimated dates for completing unachieved milestones.

1. Click the “Reforecast Trial” button
2. **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](image)

<table>
<thead>
<tr>
<th>Reforecast Trial</th>
</tr>
</thead>
</table>
| Quarterly Enrollment* | 5  
| Original LPETrial Forecast | 01-Oct-2020  
| LPETrial* | dd-mm-yyyy  
| Original LPV Forecast | 01-Dec-2020  
| LPV* | dd-mm-yyyy  
| Original FPET Forecast | 01-Oct-2018  
| FPET* | 01-Nov-2018  
| Original LPETreatment Forecast | 01-Nov-2020  
| LPETreatment* | dd-mm-yyyy  
| Original FSR Forecast | 01-Jan-2021  
| FSR* | dd-mm-yyyy  
| Rationale* |  

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

**Submit Quarterly Enrollment**  
This process is used to update your trial’s enrollment on a quarterly basis

1. **Click on the “Update Enrollment” button**
2. Select the quarter you need to update and click next

3. 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.)
4. Click the Submit button
5. You will see a notification that informs you your enrollment was successfully updated

Submit Trial Expense (US Only)
This process is used to submit any expense related to your trial that is not tied to enrollment. For example this could be an MRI, X-Ray, etc.

1. Click on the “Submit Trial Expense” button

2. Provide the following information
   a. Up to 5 Expenses (Item Description) and their Quantity (Frequency)
      If you have more than 5 separate expenses you’ll need to submit multiple Expense forms
   b. Comments are optional
   c. Attaching a receipt or additional documentation is optional

3. Click the Submit button
4. You will see a notification that informs you your expenses were submitted successfully

Submit Protocol Amendment
This process is used to Submit Amendments to your existing Trial Protocol.

1. Click on the “Submit Protocol Amendment” button
2. **Provide Rationale and attach your amendment document (PDF and Word documents accepted)**

3. **Click the Submit button**

4. **You will see a notification that informs you your amendment was successfully submitted**

**Site Management**

The site management tool is used to maintain all of your sites and their IRB/ERBs

**Creating a new Site**

1. **Click on the “Site Management” button**

2. **Click the “Create New Site” button**

3. **Fill out the required fields and attach your IRB/ERB document**

   *Note: an IRB/ERB document is not required if the site is utilizing an existing central IRB*
4. Click the Submit button
5. You will see a notification that informs you your site was successfully created

Updating an existing site
1. Click on the “Site Management” button

2. Click the “Update” button on the site you’d like to update
3. Update the necessary information and/or attach the new IRB/ERB document
4. Click the Submit button
5. You will see a notification that informs you your amendment was successfully submitted

Report an SAE
This process is used to submit Serious Adverse Events (SAEs) to Lilly.
Note: this is only intended to be used for adverse events, it is not to be used for product complaints, etc.

1. Click on the “Report SAE” button
2. Provide the Site & Patient Number you are reporting the SAE on
   Attach your SAE Report
   Note: you may also add additional information in the free text field

   ![SAE Report Form]

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

**Requesting a Country be added to the Country List**

1) From the IIR homepage, click on the “FAQ”s link located in the top right corner of the screen
2) Review the FAQ listing located to the left side of the screen by clicking on the arrow to the right of each question. One of the FAQ listings addresses this topic and provides more instruction.
   NOTE: Due to privacy concerns in each region, a country must be listed in the country drop down list for concepts to be submitted.

**Password Reset**

Please note: In addition to the below process you may call 1-703-793-7800 to have your password reset.
1) If a password is incorrectly entered, an error alert will pop up with instructions. If the password is not known, click the “Forget password?” link and reset the password. Three failed attempts to enter a password will lock out the account.

2) Upon submitting the request for a password reset, a notification is sent with instructions. It will be necessary to complete the security questions, before logging into the system.
Attesting to Submissions

1. Login to the Portal
   a. For help with registering an account, please see the account registration section
2. Click on Delegations to Attest
3. Click on Attest for the submission you’d like to attest to
   - Concept Title: A phase II study
   - Selected Compound: PI3 Kinase/mTOR Dual Inhibitor
   - Indication: Colon Cancer
   - HCP Name:
   - Therapeutic Area: Oncology
4. Submit the attestations
5. Navigate back to home and click on My Submissions
6. Choose the submission you want to work on