



Investigator Initiated Research (IIR) Portal Quick Reference

NOTE: Serious Adverse Events/Adverse Events are not to be submitted via the IIR Portal. All information to be submitted should be reviewed with any references to serious adverse events or sensitive personal information removed.

Accessing the Main Landing Page

1. Go to www.lillyinvestigatorresearch.com

From this landing page or **Home**, 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 by invitation. For new users invited to register, please see Registration & Login section below. For registered users, click on “**Login**” and enter username and password. If login is successful, the user name appears in the upper right corner. If not successful or password unknown, see the section Password Reset.

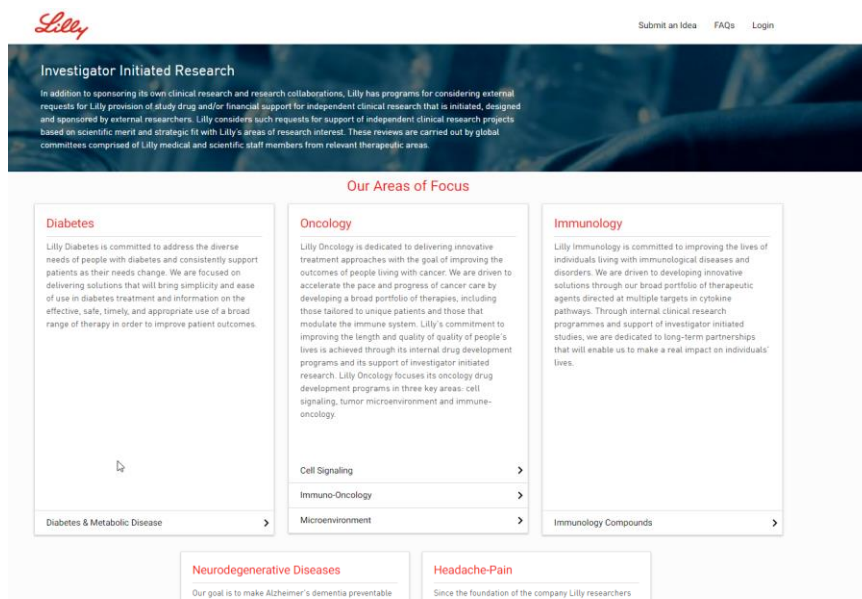


Figure 1 IIR Portal Homepage

Also see Password Reset and Registration & Login sections

Viewing the 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.

The screenshot shows the Lilly Oncology website. At the top left is the Lilly logo. In the top right are links for Home, Submit a Concept, FAQs, and Login. Below the logo is a blue banner with the word 'Oncology' and a paragraph of text: 'Lilly Oncology is dedicated to delivering innovative treatment approaches with the goal of improving the outcomes of people living with cancer. We are driven to accelerate the pace and progress of cancer care by developing a broad portfolio of therapies, including those tailored to unique patients and those that modulate the immune system. Lilly's commitment to improving the length and quality of people's lives is achieved through its internal drug development programs and its support of investigator initiated research. Lilly Oncology focuses its drug development programs in three key areas: cell signaling, tumor microenvironment and immuno-oncology.' Below the banner is a navigation menu with three items: 'Cell Signaling' (with a right arrow), 'Immuno-Oncology' (with an up arrow), and 'Microenvironment' (with an up arrow). To the right of the menu are two tabs: 'Clinical Research' (highlighted with a red underline) and 'Non Clinical Research'. Under the 'Clinical Research' tab is a description: '(Research involving human subjects with marketed product(s) and/or investigational agent(s) per applicable regulatory guidelines)'. Below this is a list of five investigational agents, each with a right arrow: Abemaciclib (CDK 4/6 Inhibitor) - LY2835219, Alimta (Pemetrexed) - LY231514, Emibetuzumab (MET Antibody) - LY2875358, Erbitux (Cetuximab) - LY2939777, and Merestinib (MET SMI) - LY2801653.

Figure 2 Compound Listing & Scope Statements

-
- **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.
-

Passwords and Obtaining Help

- Passwords expire every 60 days.
- Three failed attempts will lock out the account.
- If further help is required, please contact a Lilly Representative for assistance.

Also see [Password Reset and Registration & Login sections](#)

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, 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 receipt confirmation email will automatically be sent following successful submission of the concept.

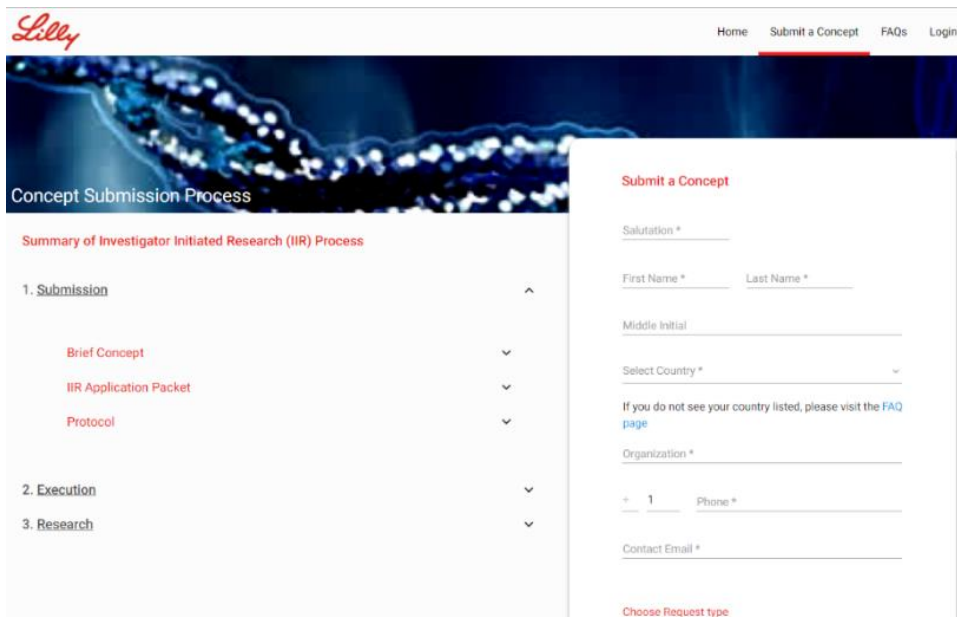


Figure 3 Submit a Concept

Accessing the FAQ List 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 FAQ listing located to the left side of the screen by clicking on the **arrow** (▾) to the right of each question.
3. To submit a new question, complete the “Ask a Question” submission form, check the three attestation boxes: no confidentiality/no sensitive personal information/measures have been taken to secure any intellectual property rights and the **"Submit"** button is now available.

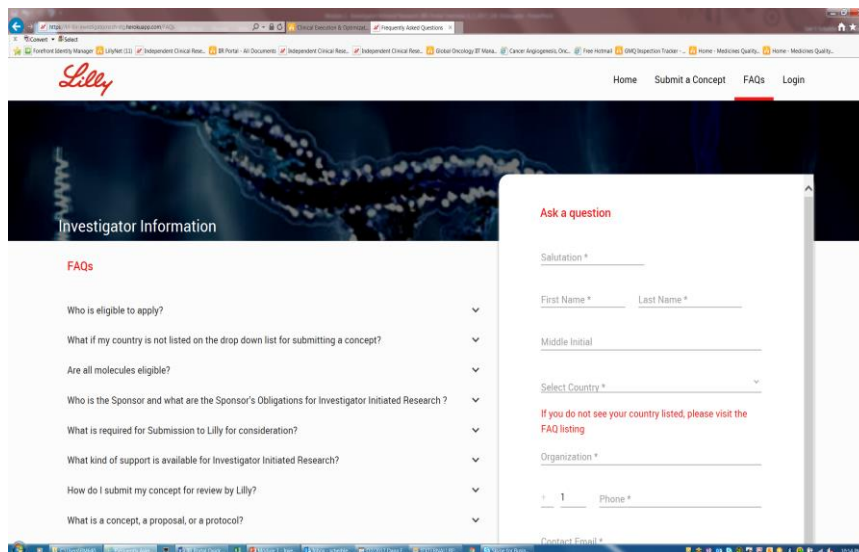


Figure 4 Ask a Question

Registration & Login

1. If a concept was submitted and approved, then an email with the decision and next steps for registration will be sent.
2. Complete **Registration** password set up and then click **"Submit"**. After verification, an activation email will be sent with the initial account information.
3. If already registered, then a user will log into their own personal homepage titled **My Submissions** from the IIR Portal homepage using their **username (email) & password** previously provided.

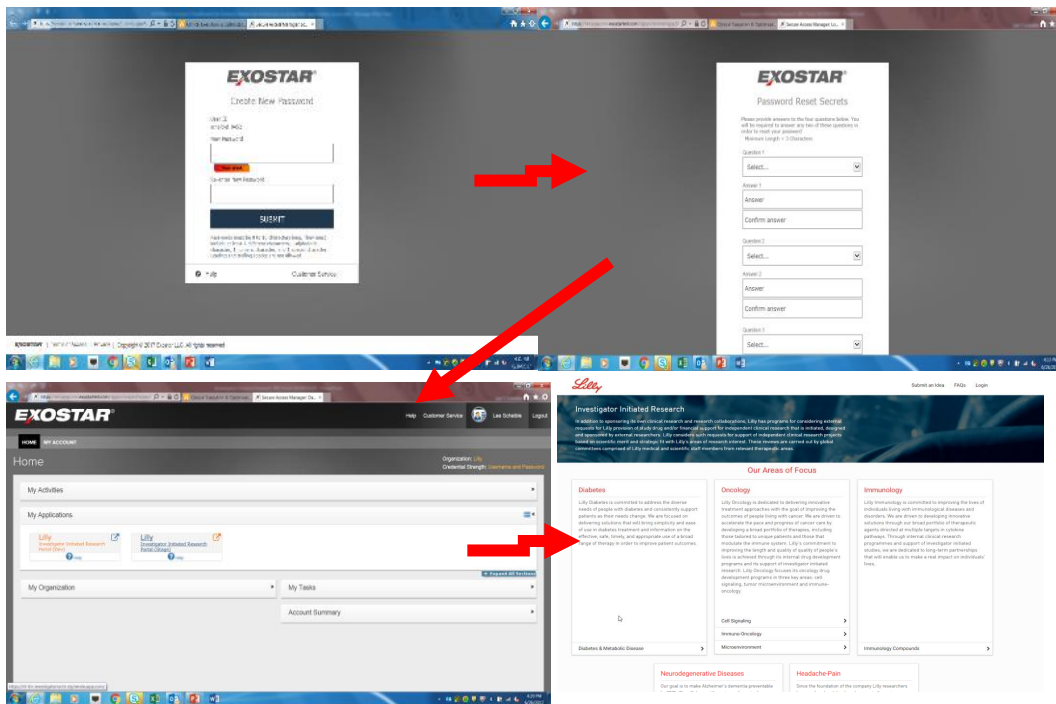


Figure 5 Registration & Login

4. If a user forgets the username or password, see Password Reset Section.

Note: When setting up your registration account, make sure to use your preferred name since that name format must be used exactly hence forth in the IIR Portal to access your personal homepage (example: full name, full middle name, and last name or full name, middle initial only, and last name initial.).

Note: A Letter of Confidentiality (LOC) must be executed and uploaded **prior to** submitting a proposal (see next section)

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 is invited to register into the system, 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).

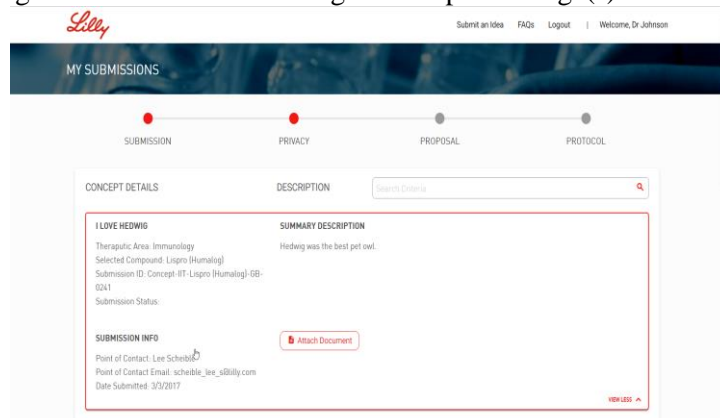


Figure 6 My Submissions

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.

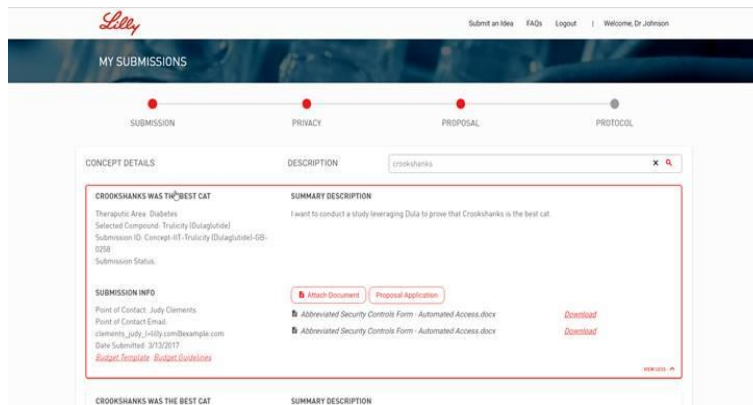


Figure 7 Proposal and Application

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 completed. 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 corner of the submission summary.

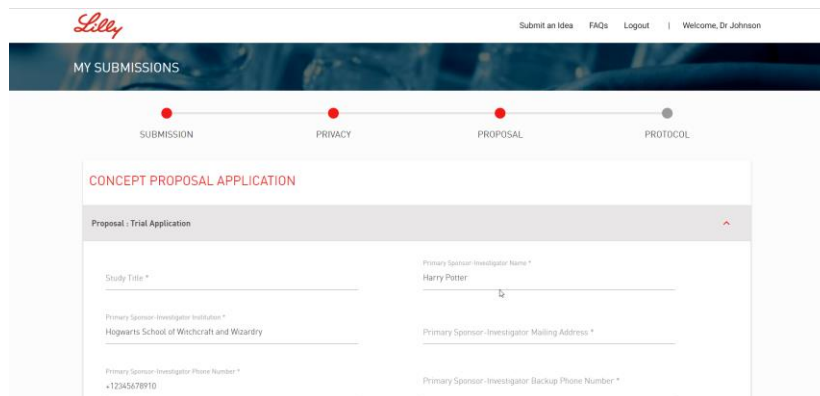


Figure 8 Proposal Application

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.

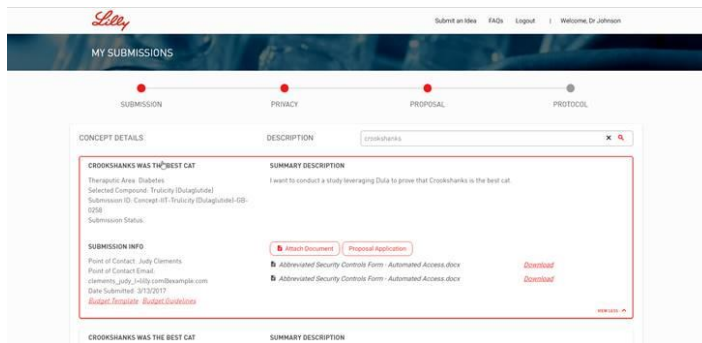


Figure 9 Protocol

- Comments and recommendations may be entered into the text field.

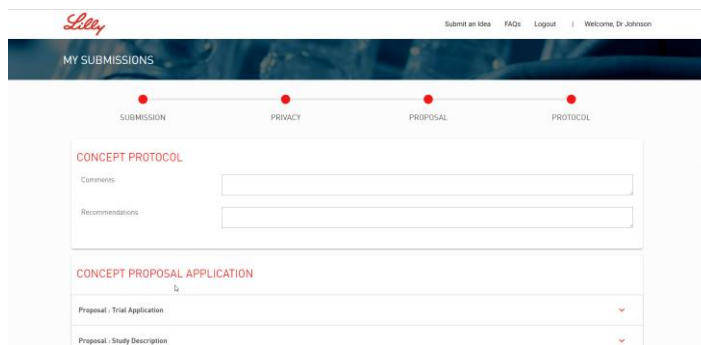


Figure 10 Comments and Recommendations

Requesting a Country be added to the Country List

- From the IIR homepage, click on the “FAQ”s link located in the top right corner of the screen
- 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.

Accessing the (IIR) Portal Quick Reference

Click on the “**Help**” link located at the bottom of each IIR Portal web page. The quick reference guide will open for reviewing and/or printing.

Password Reset

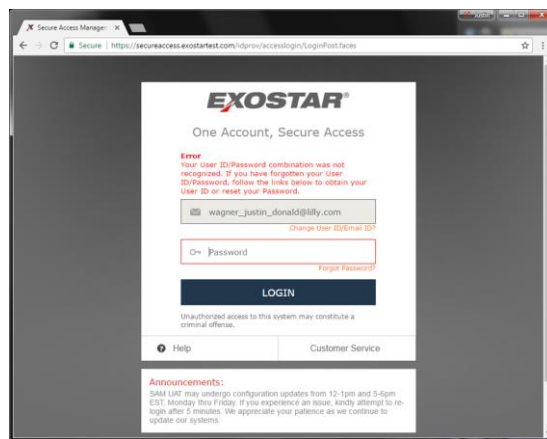


Figure 11 Error Alert/Forgot Password

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.

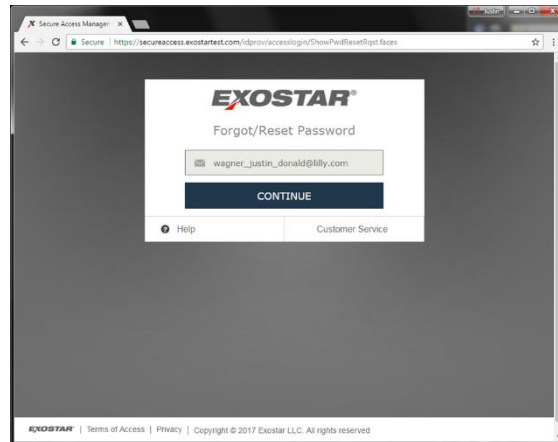


Figure 12 Reset Password

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.

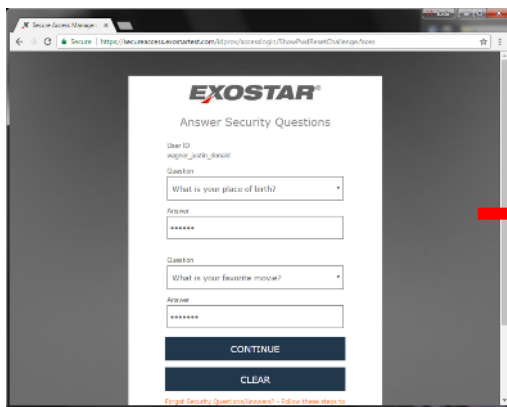


Figure 13 Reset Password

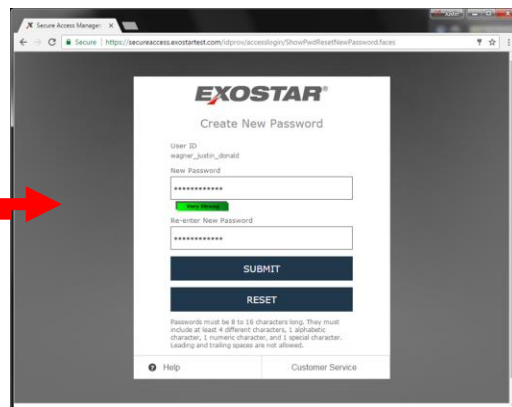


Figure 14 Reset Password