

# Investigator Initiated Research (IIR) Portal

## Quick Reference Guide

**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.**

### Contents

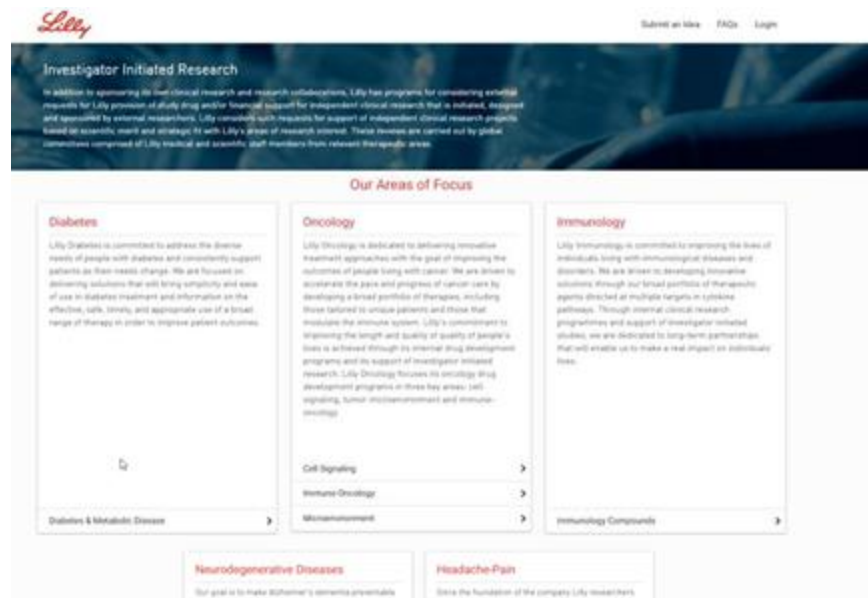
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## Accessing the Main Landing Page

- 1) Go to [lillyinvestigatorresearch.com](http://lillyinvestigatorresearch.com)

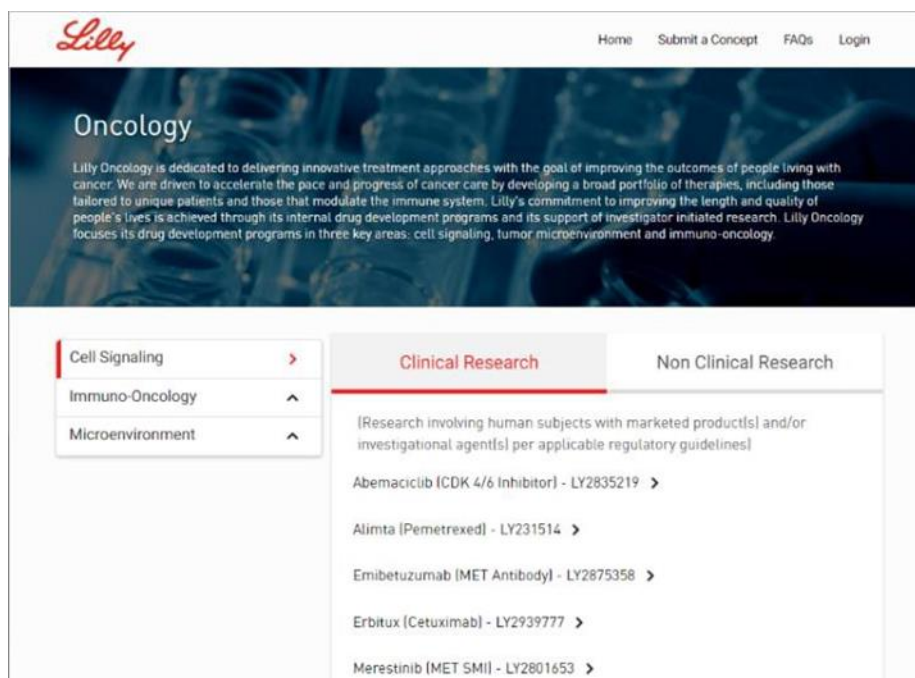
From here users are able to:

- 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.



**Lilly**

Home Submit a Concept FAQs Login

## Oncology

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.

Cell Signaling >

Immuno-Oncology ^

Microenvironment ^

**Clinical Research**

Non Clinical Research

[Research involving human subjects with marketed products] and/or investigational agents] per applicable regulatory guidelines]

Abemaciclib (CDK 4/6 Inhibitor) - LY2835219 >

Alimta (Pemetrexed) - LY231514 >

Emibetuzumab (MET Antibody) - LY2875358 >

Erbix (Cetuximab) - LY2939777 >

Merestinib (MET SMI) - LY2801653 >

**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

## Accessing the FAQ List and Asking a Question

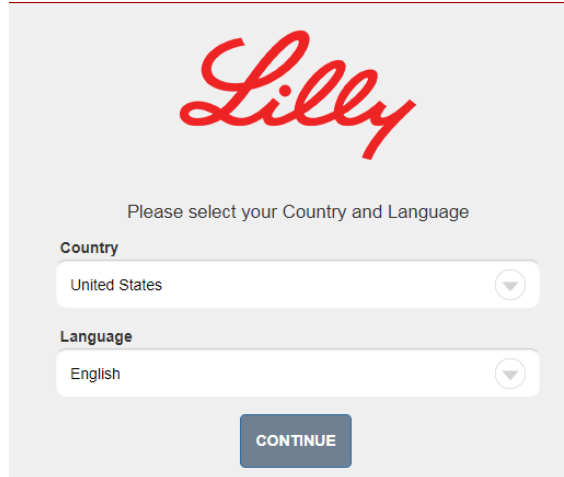
- 1) From the IIR homepage, click on the FAQs link located in the top right corner of the screen.
- 2) Review the FAQ listing located to the left side of the screen by clicking on the arrow to the right of each question.
- 3) To submit a new question, complete the "Ask a Question" submission form, check 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.

## Registration & Login

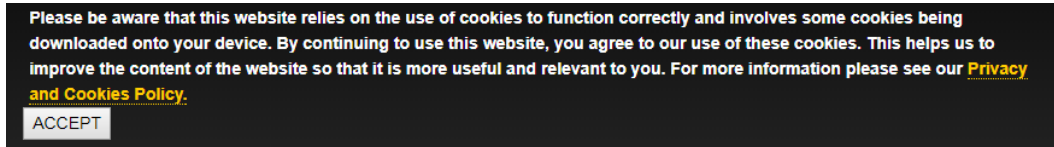
### Registration

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) Select your Country & Language then click Continue  
Note: This is only required the first time

A screenshot of the Lilly login portal. At the top is the red 'Lilly' logo. Below it, the text 'Please select your Country and Language' is centered. There are two dropdown menus: 'Country' with 'United States' selected, and 'Language' with 'English' selected. A blue 'CONTINUE' button is at the bottom.

- 3) EU ONLY  
(Optional) Accept cookies (this simplifies the login process in the future)

A dark grey banner with white text. The text reads: 'Please be aware that this website relies on the use of cookies to function correctly and involves some cookies being downloaded onto your device. By continuing to use this website, you agree to our use of these cookies. This helps us to improve the content of the website so that it is more useful and relevant to you. For more information please see our [Privacy and Cookies Policy](#).' Below the text is a white 'ACCEPT' button.

- 4) Input your Email Address then click Accept & Continue



\* You must enter an email address to continue


@ EliLilly@lilly.com

I acknowledge that I have had the opportunity to review the full privacy policy located [here](#).

I understand that Lilly will set a cookie to remember my login details, including the authentication provider selected and its association with my email address. I understand that my information will be used to authenticate my identity in order for me to gain access to some Lilly websites and that my information may be processed and stored outside of the country from which I am visiting and that, the level of legal protection for personal information is not the same in all countries. I acknowledge that I have reviewed the full privacy policy concerning how my personal information will be used by Lilly and its service providers and that by accepting and submitting my email, I am agreeing to have my information processed in accordance to the privacy policy and the information noted here.

ACCEPT & CONTINUE

5) Click Register



No results found for **Testaccount@gmail.com**

@ Testaccount@gmail.com

TRY AGAIN REGISTER

6) Complete the Registration Form (only fields with red asterisks are required) then click Next

7) Receive an email notification that we have received your request

Dear Test Account,

Your registration request for Exostar SAM account has been received. They will be responsible for the approval and authorization process. If your request is approved, you will receive another email notification that includes your login credentials and further instructions on how to get started.

Confirmation Code: SIG\_1516990530751

NEED HELP? <http://www.myexostar.com/myexostarAll.aspx?id=2438>

DO NOT reply to this email. This is an automated email and replies are not being monitored.

8) 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 across 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 system-specific 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 <http://www.myexostar.com/WorkArea/DownloadAsset.aspx?id=1814>

To complete the activation of your account please click the following link: <https://secureaccess.exostar.com/idprov/accesslogin/Process1Otp.faces?p1=dXNlckFjY2Vzc0FjY3RSZWY9NjA1OS00MjQ2LTk3OTctNzY1NiZwYXNzd2QxPUNKZ2RkWGcwRDV0UHBKRU9mMkhTVmlaRmZqM0FiXzk3UUIkTEJjc0dReWM9>

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.

9) Set your password

10) 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



## Password Reset Secrets

Please provide answers to the four questions below. You will be required to answer any two of these questions in order to reset your password

Minimum Length = 3 Characters

Question 1

What is your favorite food? ▼

Answer 1

•••••

•••••

11) Your account is created!

### Login

1. Click Login in the upper right hand corner of the IIR Portal
2. Select your Country & Language then click Continue

Note: This is only required the first time

Please select your Country and Language

Country

United States ▼

Language

English ▼

CONTINUE

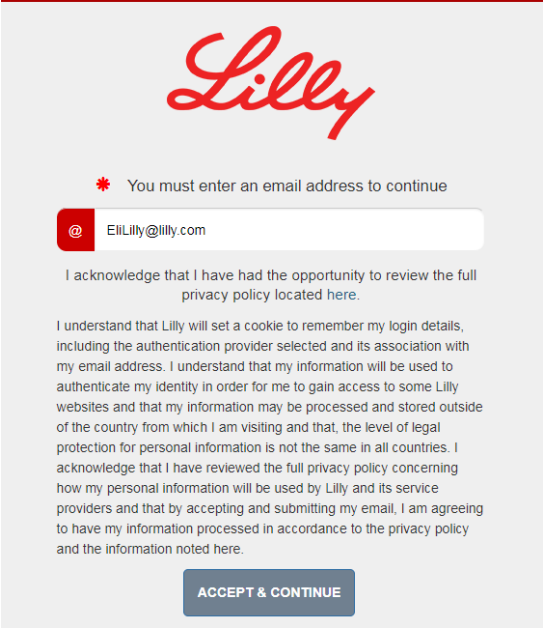
3. EU ONLY

(Optional) Accept cookies (this simplifies the login process in the future)

Please be aware that this website relies on the use of cookies to function correctly and involves some cookies being downloaded onto your device. By continuing to use this website, you agree to our use of these cookies. This helps us to improve the content of the website so that it is more useful and relevant to you. For more information please see our [Privacy and Cookies Policy](#).

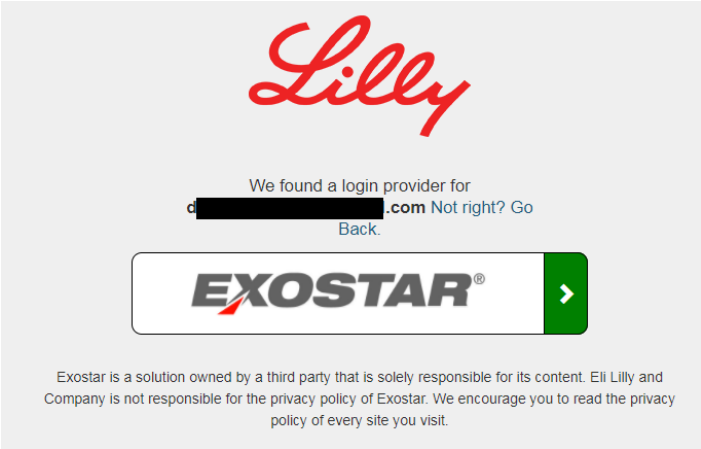
ACCEPT

4. Input your Email Address then click Accept & Continue




The screenshot shows the Lilly login interface. At the top is the red 'Lilly' logo. Below it is a red asterisk icon followed by the text 'You must enter an email address to continue'. There is an email input field with a red '@' icon on the left and the text 'EliLilly@lilly.com' inside. Below the input field is a paragraph of text: 'I acknowledge that I have had the opportunity to review the full privacy policy located [here](#).' This is followed by a longer paragraph: 'I understand that Lilly will set a cookie to remember my login details, including the authentication provider selected and its association with my email address. I understand that my information will be used to authenticate my identity in order for me to gain access to some Lilly websites and that my information may be processed and stored outside of the country from which I am visiting and that, the level of legal protection for personal information is not the same in all countries. I acknowledge that I have reviewed the full privacy policy concerning how my personal information will be used by Lilly and its service providers and that by accepting and submitting my email, I am agreeing to have my information processed in accordance to the privacy policy and the information noted here.' At the bottom is a blue button with the text 'ACCEPT & CONTINUE'.

5. Click the Exostar Button




The screenshot shows the Exostar login interface. At the top is the red 'Lilly' logo. Below it is the text 'We found a login provider for' followed by a redacted email address 'd[REDACTED].com' and the text 'Not right? Go Back.' Below this is a large button with the 'EXOSTAR' logo and a green arrow pointing right. At the bottom is a paragraph of text: 'Exostar is a solution owned by a third party that is solely responsible for its content. Eli Lilly and Company is not responsible for the privacy policy of Exostar. We encourage you to read the privacy policy of every site you visit.'

6. Login like normal with Exostar



One Account, Secure Access

 User ID/Email ID

Forgot User ID/Email ID? Contact Customer Service.

CONTINUE

Sign In 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

### Add Delegee

First Name \*

Awesome

Last Name \*

Test

Contact Email \*

awesometest@test.com

Nurse

CANCEL

BACK

ADD

5. Click Add

## All Submissions

1. Click the Add Delegees button

### CONCEPT DETAILS

ADD DELEGEEs

TEST

Therapeutic Area: Oncology

Selected Compound: Alimta (Pemetrexed)

Indication: test

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 delegates, this can only be accomplished by the HCP that submitted the concept.

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

### Individual Submission

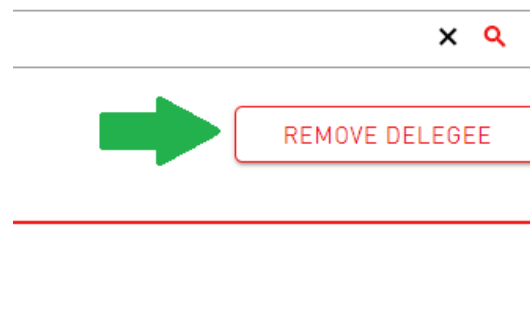
1. Click View More on your submission
2. Under Delegates click the Red X next to the delegatee

Name	Role	
Awesome Test	Nurse	X

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

### All Submissions

1. Click the Remove Delegee button

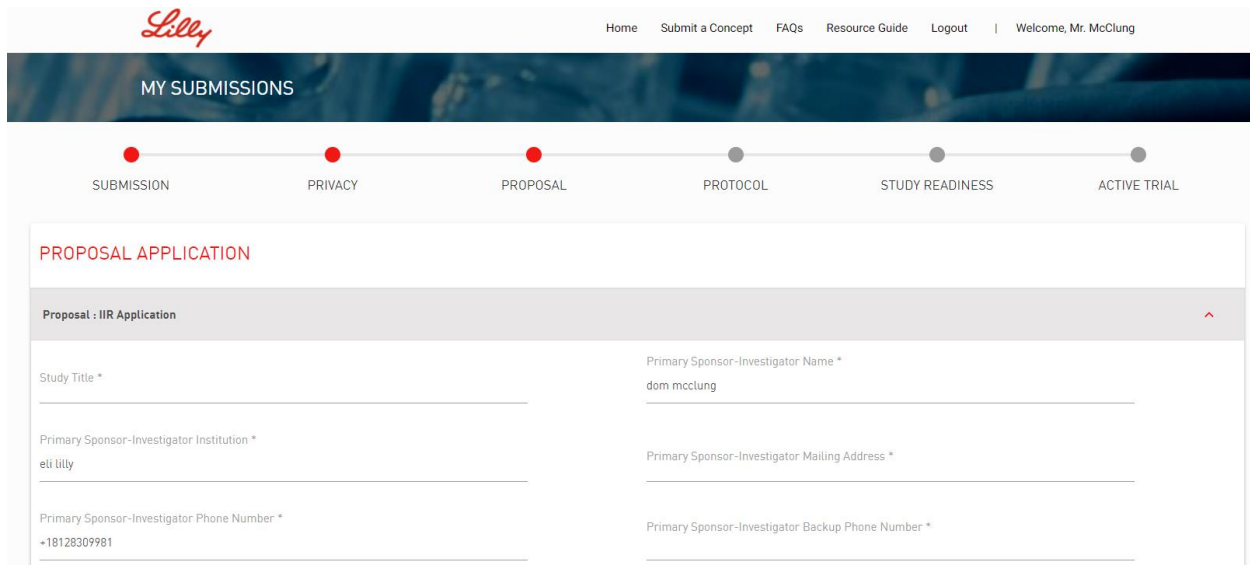


2. Select the Delegee
3. Click the Remove Delegee button

### 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 corner of the submission summary.



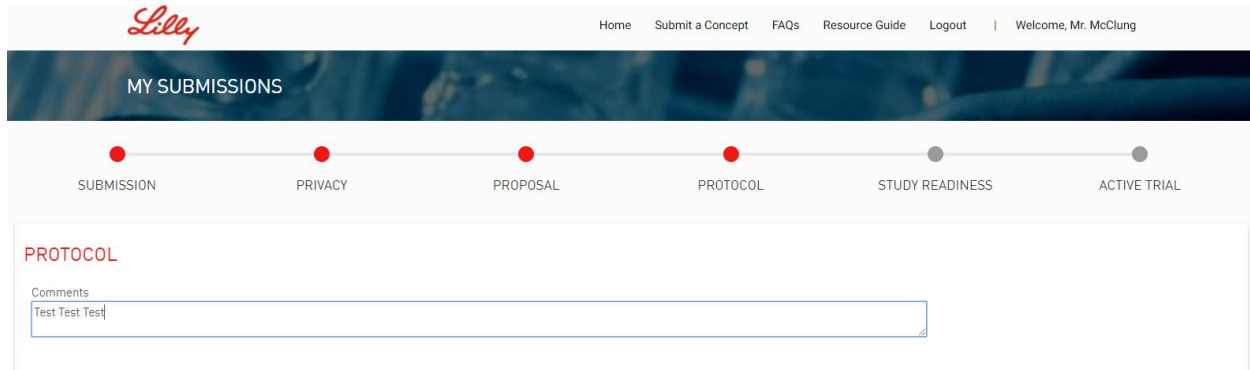
**PROPOSAL APPLICATION**

Proposal : IIR Application

Study Title *	Primary Sponsor-Investigator Name *
<input type="text"/>	<input type="text" value="dom mcclung"/>
Primary Sponsor-Investigator Institution *	Primary Sponsor-Investigator Mailing Address *
<input type="text" value="eli lilly"/>	<input type="text"/>
Primary Sponsor-Investigator Phone Number *	Primary Sponsor-Investigator Backup Phone Number *
<input type="text" value="+18128309981"/>	<input type="text"/>

## 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.



**PROTOCOL**

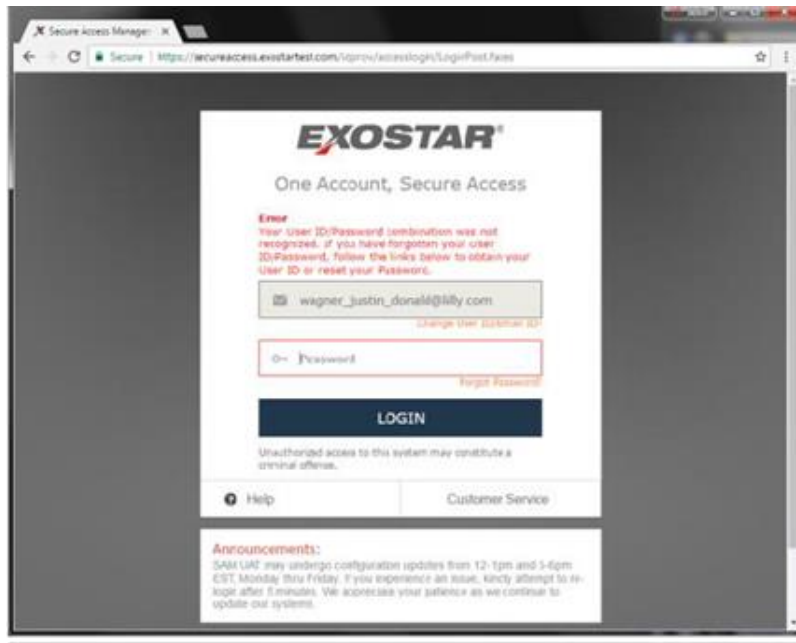
Comments

## Requesting a Country be added to the Country List

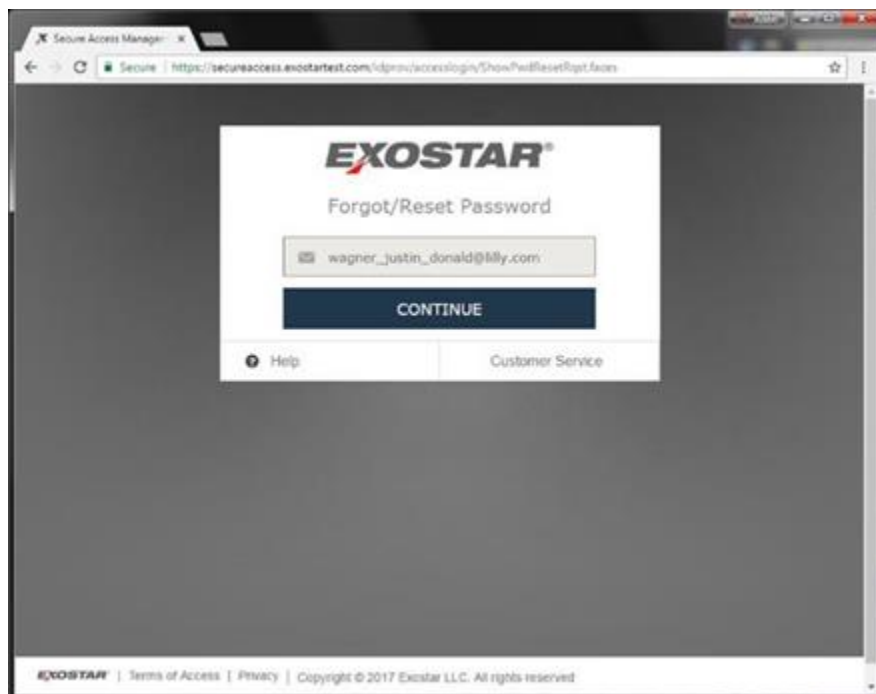
- 1) From the IIR homepage, click on the “FAQ”s link located in the top right corner of the screen
- 2) Review the FAQ listing located to the left side of the screen by clicking on the arrow to the right of each question. One of the FAQ listings addresses this topic and provides more instruction.  
NOTE: 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

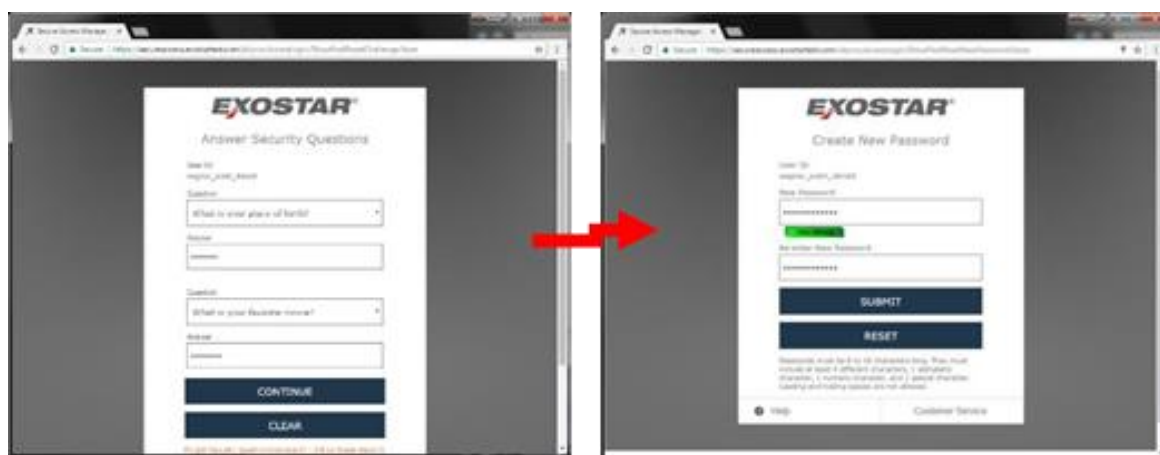
Please note: In addition to the below process you may call 1-703-793-7800 to have your password reset.



- 1) If a password is incorrectly entered, an error alert will pop up with instructions. If the password is not known, click the "Forgot 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.

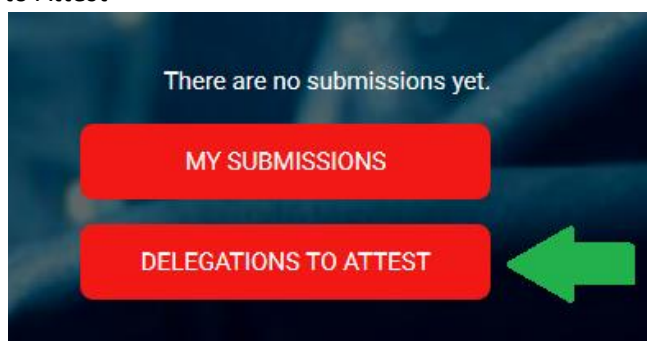


## Delegees

If you need assistance with registering your account, please see the account registration section

## 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

**HCP Name:**

**Therapeutic Area:**  
Oncology

**Selected Compound:**  
PI3 Kinase/mTOR Dual Inhibitor  
**Indication:**  
Colon Cancer



4. Submit the attestations
5. Navigate back to home and click on My Submissions
6. Choose the submission you want to work on