

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.

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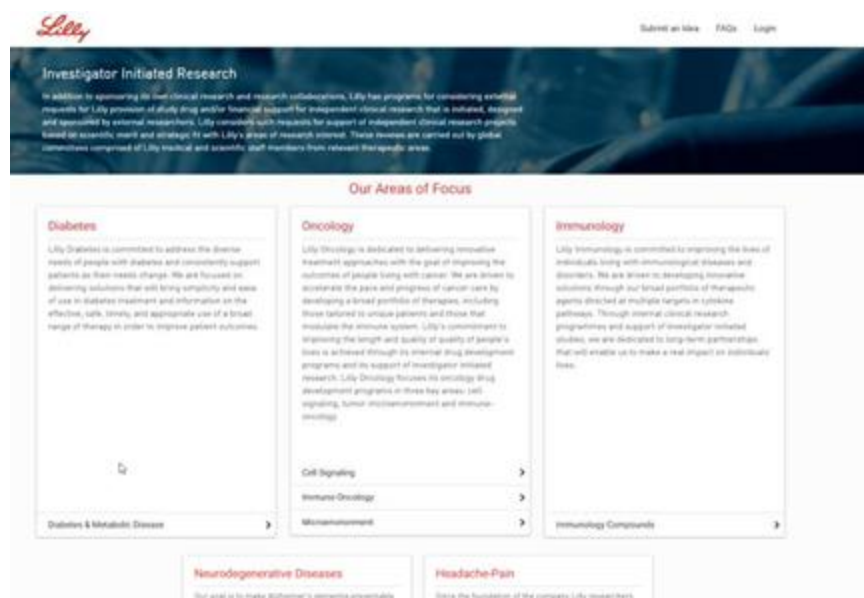
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Accessing the Main Landing Page

- 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.

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 >

Merestininib (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

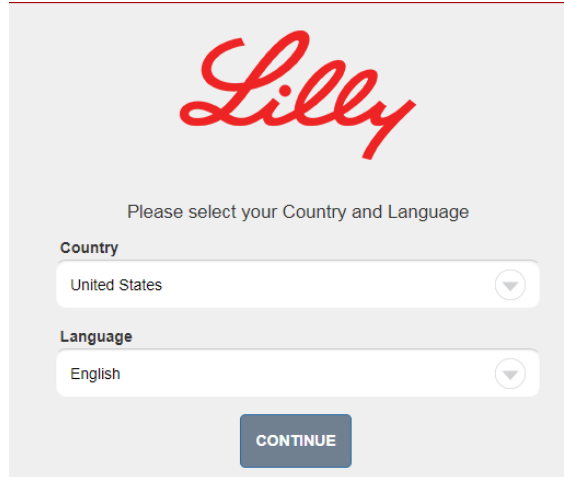
- 1) From the IIR homepage, click on the FAQs link located in the top right corner of the screen.
- 2) Review the FAQ listing located to the left side of the screen by clicking on the arrow to the right of each question.
- 3) To submit a new question, complete the "Ask a Question" submission form, check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

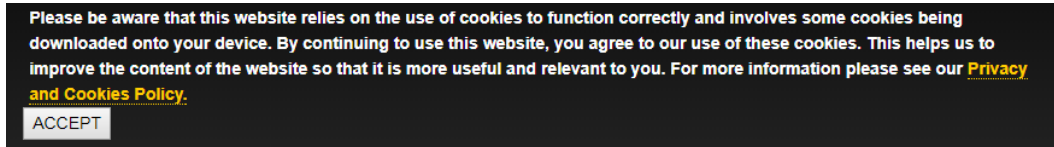
Registration

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

The image shows a login form for the Lilly IIR 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)

The image shows a dark grey cookie consent banner. It contains white text stating: '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 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=dXNlckFiY2Vzc0FiY3RSZWY9NiA1OS00MjQ2LTk3OTctNzY1NiZwYXNzd2QxPUNKZ2RkWGcwRDV0UHBKRU9mMkhTVmlaRmZqM0FiXzk3UUIkTEJjc0dReWM9>

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.

8) Set your password

9) 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

Answer 1

10) 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

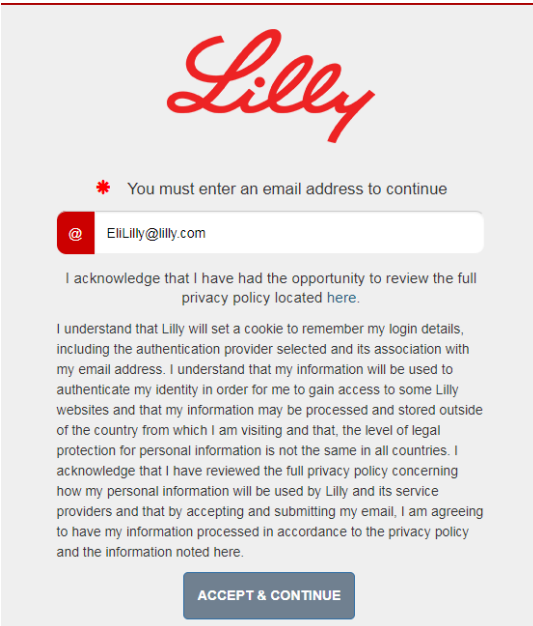
CONTINUE

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](#).

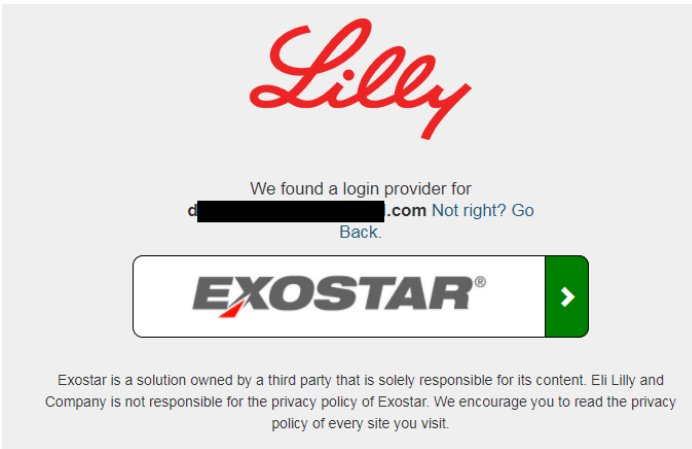
ACCEPT

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 Lilly login interface after clicking the 'ACCEPT & CONTINUE' button. 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]@[REDACTED].com'. To the right of the email address is a blue link '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.

MY SUBMISSIONS

SUBMISSION PRIVACY PROPOSAL PROTOCOL STUDY READINESS ACTIVE TRIAL

CONCEPT DETAILS DESCRIPTION

Search Criteria x

TEST TO CHECK SUBMISSION

Therapeutic Area: Immunology
 Selected Compound: Baricitinib (Olumiant)
 Indication: test to check submission
 Submission ID: Concept-IIT-Baricitinib (Olumiant)-US-1300
 Submission Status:

SUBMISSION INFO

Point of Contact:
 Point of Contact Email:
 Date Submitted: 2/7/2018
[Budget Template \(US Only\)](#) [Budget Guidelines \(US Only\)](#)

Attach Document Protocol Submission

VIEW LESS

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

TEST

Therapeutic Area: Oncology
 Selected Compound: Alimta (Pemetrexed)
 Indication: test
 Submission ID: Concept-IIT-Alimta (Pemetrexed)-AF-1288
 Submission Status: Approved

SUBMISSION INFO

Point of Contact:
 Point of Contact Email:
 Date Submitted: 2/16/2018
[Budget Template \(US Only\)](#) [Budget Guidelines \(US Only\)](#)

DELEGATION

• •

Add Delegee

SUMMARY DESCRIPTION

test

Attach Document Proposal Application

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 DELEGEEES

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

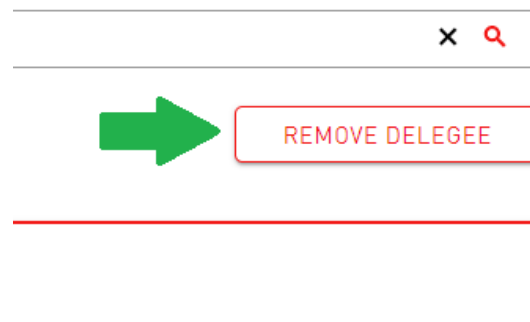
1. Click View More on your submission
2. Under Delegates click the Red X next to the delegatee

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 mclung"/>
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

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

BREAST CANCER WITH SWEET ONCO DRUG	SUMMARY DESCRIPTION
Therapeutic Area: Oncology Selected Compound: Dom's Sweet Onco Drug Indication: Breast Cancer Submission ID: Concept-IIT-Dom's Sweet Onco Drug-US-1623 Submission Status:	Treating Breast Cancer with the best oncology drug in the world. We expect a 70% reduction in breast cancer and no metastatic growth resulting in a 100% success rate.
SUBMISSION INFO Point of Contact: Margaret Pelton Point of Contact Email: mcclung_dominic@lilly.com Date Submitted: 05-Oct-2018	MILESTONES: FPV (Actual): Sep, 2018 FPET (Estimate): Dec, 2018 LPETrial (Estimate): Dec, 2020 LPETreatment (Estimate): Jan, 2021 LPV (Estimate): Feb, 2021 FSR (Estimate): Apr, 2021

Submit Achieved Milestones

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

1. Click on the “Milestones Met” button

MILESTONES:	
FPV (Actual): Sep, 2018	FPET (Estimate): Dec, 2018
LPETrial (Estimate): Dec, 2020	LPETreatment (Estimate): Jan, 2021
LPV (Estimate): Feb, 2021	FSR (Estimate): Apr, 2021
<input type="button" value="Attach Document"/> <input type="button" value="Update Enrollment"/> <input type="button" value="Reforecast Trial"/>	<input type="button" value="Submit Trial Expense"/> <input type="button" value="Submit Amendment"/> <input type="button" value="Milestones Met"/>

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

The screenshot shows a date picker overlay on a form. The date picker is set to October 2018. The date 11 is highlighted. The form in the background has fields for FPV, LPETrial, and LPV, each with a date input field. The date picker is positioned over the LPETrial field.

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

MILESTONES:

FPV (Actual): **Sep, 2018** FPET (Estimate): **Dec, 2018**
 LPETrial (Estimate): **Dec, 2020** LPETreatment (Estimate): **Jan, 2021**
 LPV (Estimate): **Feb, 2021** FSR (Estimate): **Apr, 2021**



2. Provide the following information

*All fields are required to submit your reforecast request

- Quarterly Enrollment – This is your estimated per quarter enrollment for all remaining quarters
- Original Milestone – These fields contain your original milestone estimations
- Milestone – Provide your new estimation for completing each of the remaining milestones
- Rationale – Provide the rationale for needing to reforecast (safety checkpoint, natural disaster, etc.)

Reforecast Trial

Quarterly Enrollment* ●	<input type="text" value="5"/>	Original FPET Forecast ●	<input type="text" value="01-Oct-2018"/>
		FPET* ●	<input type="text" value="01-Nov-2018"/>
Original LPETrial Forecast ●	<input type="text" value="01-Oct-2020"/>	Original LPETreatment Forecast ●	<input type="text" value="01-Nov-2020"/>
LPETrial* ●	<input type="text" value="dd-mmm-yyyy"/>	LPETreatment* ●	<input type="text" value="dd-mmm-yyyy"/>
Original LPV Forecast ●	<input type="text" value="01-Dec-2020"/>	Original FSR Forecast ●	<input type="text" value="01-Jan-2021"/>
LPV* ●	<input type="text" value="dd-mmm-yyyy"/>	FSR* ●	<input type="text" value="dd-mmm-yyyy"/>
Rationale* ●	<input type="text"/>		

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

- Click on the "Update Enrollment" button

MILESTONES:

FPV (Actual): **Sep, 2018**
 LPETrial (Estimate): **Dec, 2020**
 LPV (Estimate): **Feb, 2021**

FPET (Estimate): **Dec, 2018**
 LPETreatment (Estimate): **Jan, 2021**
 FSR (Estimate): **Apr, 2021**

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

Enrollment

Quarter: --Select--

2018-Q2
 2018-Q3
 2018-Q4
 2019-Q1

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.)

Enrollment

Quarter: 2018-Q2

Total Patients Entered Treatment	7	Current Patients Entered Treatment Estimate	7
Number of Patients Currently on Treatment	5	Number of Patients Completed Trial	0
Number of Patients Currently on Follow-up	2	Number of Patients Discontinued from Treatment	0

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

MILESTONES:

FPV (Actual): **Sep, 2018**

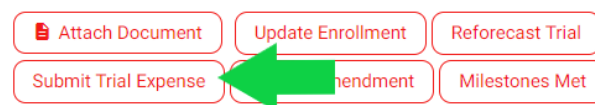
FPET (Estimate): **Dec, 2018**

LPETrial (Estimate): **Dec, 2020**

LPETreatment (Estimate): **Jan, 2021**

LPV (Estimate): **Feb, 2021**

FSR (Estimate): **Apr, 2021**



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

Trial Expenses	
Item Description	Frequency
MRI	2
X-Ray	3
Item 3	
Item 4	
Item 5	

Dominic Oct 18 Trial Expense Receipt.docx

Comments:

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

MILESTONES:

FPV (Actual): Sep, 2018	FPET (Estimate): Dec, 2018
LPETrial (Estimate): Dec, 2020	LPETreatment (Estimate): Jan, 2021
LPV (Estimate): Feb, 2021	FSR (Estimate): Apr, 2021

Attach Document

Update Enrollment

Reforecast Trial

Submit Trial Expense

Submit Amendment

Met

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

Trial Protocol/Study Research Plan Amendment

Rationale* I need to increase my patient population

Attach Document

Dominic Submission Amendment Eli Lilly.docx

CANCEL

SUBMIT

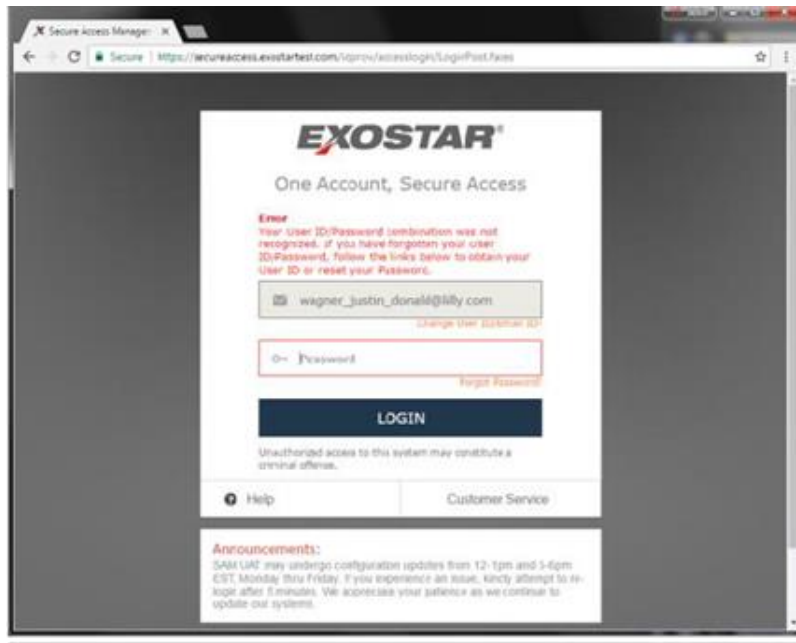
3. Click the Submit button
4. You will see a notification that informs you your amendment was successfully submitted

Requesting a Country be added to the Country List

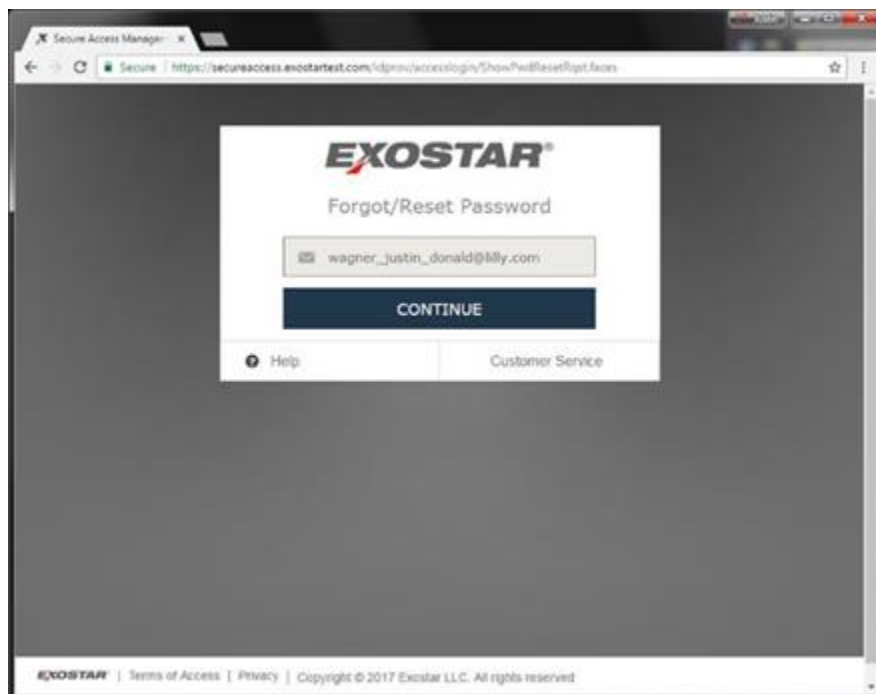
- 1) From the IIR homepage, click on the “FAQ”s link located in the top right corner of the screen
- 2) Review the FAQ listing located to the left side of the screen by clicking on the arrow to the right of each question. One of the FAQ listings addresses this topic and provides more instruction.
NOTE: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

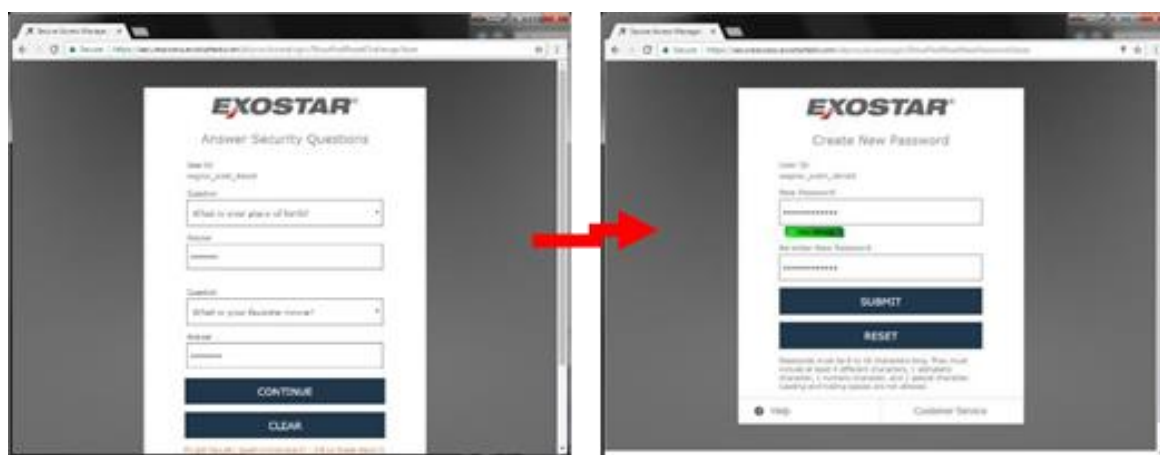
Please note: In addition to the below process you may call 1-703-793-7800 to have your password reset.



- 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.

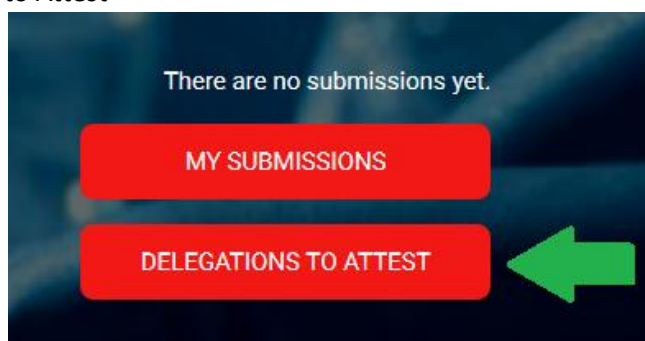


Delegees

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