



# EXELIXIS INVESTIGATOR SPONSORED TRIAL (IST) PORTAL INVESTIGATOR REFERENCE GUIDE



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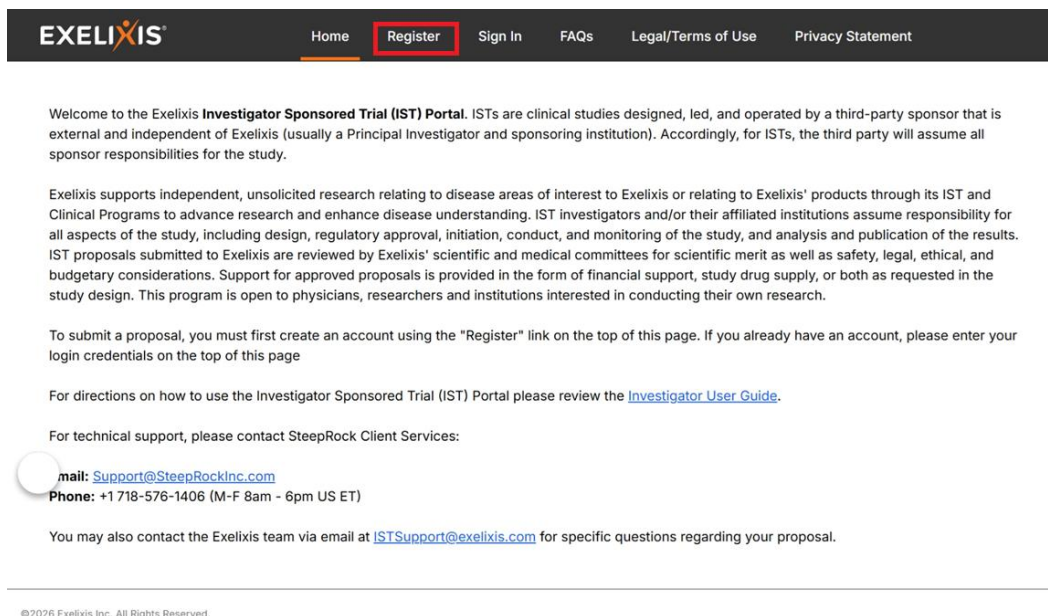
## **Purpose**

This Investigator Guide will assist with basic navigation and frequently used features within the Exelixis Investigator Sponsored Trial (IST) Portal, including:

- Registration for access
- Start/submit a new study
- Save a study as a draft
- Submit requested clarifications for study
- Submit progress updates
- Submit an amendment
- Submit a report/manuscript
- Study closeout
- Study termination or withdrawal

## **Registration**

Open a web browser\* and navigate to <https://ist.exelixis.com/>. Register yourself by clicking on the **Register** button at the top of the screen.



\* Internet Explorer 10+, Chrome, and Firefox are the preferred browsers. Please reference **Helpful Settings** at the end of this guide for pop-up windows guidance.



Select **Register** and complete the **New User Registration** form.

**New User Registration**

Details

Your password must contain at least 8 characters and must be combination of at least three of the following: lowercase letters, uppercase letters, numbers and symbols.

Salutation\*

First Name\*

Middle Name / Middle Initial

Last Name\*

Degree(s)\*

Primary Site / Institution\*

Department\*

Address 1\*

Address 2\*

City\*

Country\*

Postal Code\*

Telephone\*

Email\*

Password\*

Password (Confirm)\*

▲ You have 14 incomplete fields.

SAVE



Follow the instructions below to complete your registration. **Please Note:** All the fields marked with **red outlines/asterisk/exclamation marks** are required. You will not be able to save the record if one of the required fields is not completed. Additional fields may appear dependent upon a selection made in a previous field. Use the dropdown arrow to select your **Salutation** and **Degree(s)**. Enter your **First Name** and **Last Name** using free text.

A screenshot of the "New User Registration" form. The form has a blue header bar with a close button (X) and the title "New User Registration". Below the header, there is a "Details" section with a dropdown arrow. A password requirement note states: "Your password must contain at least 8 characters and must be combination of at least three of the following: lowercase letters, uppercase letters, numbers and symbols." The form contains several input fields: "Salutation\*" (with a dropdown arrow and a red exclamation mark), "First Name\*" (with a red exclamation mark), "Middle Name / Middle Initial" (empty), "Last Name\*" (with a red exclamation mark), and "Degree(s)\*" (with a dropdown arrow and a red exclamation mark). Red arrows point to the dropdown arrows in the "Salutation" and "Degree(s)" fields.

To select your **Primary Site / Institution** click on the

A screenshot of the "Primary Site / Institution" search field. It is a wide text input field with a red exclamation mark and a magnifying glass icon on the right side. A red arrow points to the magnifying glass icon.

Use the filter option on the top of the window to search for your **Primary Site / Institution**. Click on the the row of the **Institution** to select it. If your Institution is not listed click the **+ ADD NEW** button to add it.



**Select**

**Filters**

Country  Address 1  State / Province

City

| Institution                           | Type                                 | Address 1                           | Address 2  | City             | State / Province | Country       |
|---------------------------------------|--------------------------------------|-------------------------------------|------------|------------------|------------------|---------------|
| AGILE Research Foundation             | Academic Institution                 | 1661 Massachusetts Ave              | PO BOX 427 | Lexington        | Massachusetts    | United States |
| Augusta University Research Institute | Academic Institution                 | 1120 15th Street, CJ 3301           |            | Augusta          | Georgia          | United States |
| Beverly Hills Cancer Center           | Academic Institution                 | 8900 Wilshire Blvd.                 |            | Beverly Hills    | California       | United States |
| Cedars-Sinai Medical Care Foundation  | Medical Associations                 | 11800 Wilshire Boulevard, Suite 300 |            | Los Angeles      | California       | United States |
| Cedars-Sinai Medical Center (CSMC)    | Academic Institution                 | 8700 Beverly Blvd.                  |            | Los Angeles      | California       | United States |
| City of Hope National Medical Center  | Cancer Center                        | 1500 E Duarte Rd                    |            | Duarte           | California       | United States |
| Cleveland Clinic Foundation           | Academic Institution                 | 9500 Euclid Avenue CA 60            |            | Cleveland        | Ohio             | United States |
| Criterion, Inc.                       | Contract Research Organization (CRO) | 358 Broadway                        | Suite 201  | Saratoga Springs | New York         | United States |
| CTEP-NCI                              | Other                                | 9609 Medical Center Dr              |            | Rockville        | Maryland         | United States |

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DISPLAYING 1 - 100 OF 103 DISPLAY 100

**+ ADD NEW** **CLEAR SELECTION**

After you click on or add your Institution, you will be returned to the **New User Registration** page. Use free text to complete the remaining required fields and click **SAVE**.

**New User Registration**

Department\*

Address 1\*

Address 2\*

City\*

This field is required.

Country\*

Postal Code\*

Telephone\*

This field is required.

Email\*

Password\*

Password (Confirm)\*

**SAVE**

▲ You have 14 incomplete fields.



To log in to your account, open the website <https://ist.exelixis.com/> and click the Sign In button at the top of the page. Enter your **Email Address** and **Password**, then click on **SIGN IN**.

A screenshot of the EXELIXIS website's Sign In page. The top navigation bar is dark grey with the EXELIXIS logo on the left and links for Home, Register, Sign In (highlighted with a red box), FAQs, Legal/Terms of Use, and Privacy Statement on the right. The main content area is white and titled "Sign In". It contains two input fields: "Email address" and "Password". Below these is an orange "Sign in" button. A link "Forgot your password?" is located below the button. On the left side of the page, there is a faint circular logo. At the bottom, a horizontal line separates the footer from the main content, which contains the text "©2026 Exelixis Inc. All Rights Reserved."

**Note:** E-mail notifications will be sent to the registered user account throughout the process to acknowledge registration, receipt of submission, and to convey the review committee's decision.



## Submitting a Concept

After logging in, you will see your Homepage. On your Homepage, click on the **+New Study** tile. You will be brought to the **Add Study** page to enter the concept details.

### Homepage view:

Welcome Sample Investigator,

The Exelixis Investigator Sponsored Trial (IST) Portal will enable you to submit your IST research proposal for review, track the progress of your existing proposal, and report on ongoing studies.

Exelixis supports independent, unsolicited research relating to disease areas of interest to Exelixis or relating to Exelixis' products through its IST and Clinical Programs to advance research and enhance disease understanding. IST investigators and/or their affiliated institutions assume responsibility for all aspects of the study, including design, regulatory approval, initiation, conduct, and monitoring of the study, and analysis and publication of the results.

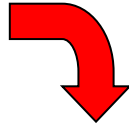
IST proposals submitted to Exelixis are reviewed by Exelixis' scientific and medical committees for scientific merit as well as safety, legal, ethical, and budgetary considerations. Support for approved proposals is provided in the form of financial support, study drug supply, or both as requested in the study design. This program is open to physicians, researchers and institutions interested in conducting their own research. You may submit a new request by clicking on the 'New Study' button below.

For technical support, please contact SteepRock Client Services:  
Email: support@steeprockinc.com  
Phone: 1-718-578-1426 (M-F 8AM-6PM US ET)  
You may also contact Exelixis team via email at ISTSupport@exelixis.com for specific questions regarding your proposal.

| Tracking #   | Study Title              | Sponsor-Investigator | Support Requested | Therapeutic Area(s)        | Total Study Budget     | Overall Study Status               |
|--------------|--------------------------|----------------------|-------------------|----------------------------|------------------------|------------------------------------|
| IST-2021-002 | EK Study D               | Investigator, Sample | Drug and Funding  | Brain Cancer               | \$580,191.00 USD       | Full Protocol and Budget Requested |
| IST-2021-003 | EK Study A               | Kym, Goma            | Drug and Funding  | Sarcoma                    | \$921,921.00 USD       | Concept Resubmitted                |
| IST-2021-004 | EK Study B               | Investigator, Sample | Drug and Funding  | Carcinoid Tumors           | \$174,718.00 USD       | Study ISTRC Declined               |
| IST-2021-005 | EK Study C - Post Rev... | Investigator, Sample | Drug and Funding  | Breast Cancer              | \$1.00 USD             | Concept Resubmitted                |
| IST-2021-006 | EK Study H               | Investigator, Sample | Drug and Funding  | Colorectal Cancer (CRC)... | \$248,092,184.0... USD | Protocol/Budget Resubmitted        |
| IST-2021-007 | EK Study E               | Investigator, Sample | Drug and Funding  | Leukemia; Pancreatic...    | \$600,000.00 USD       | Protocol/Budget Resubmitted        |

**+ New Study**

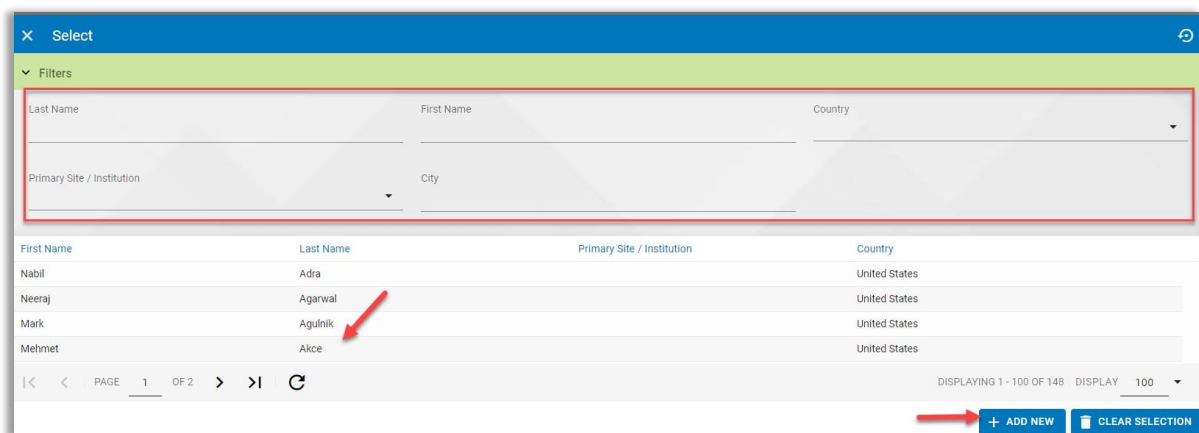
**Settings** **Help**



**Please Note:** All the fields marked with **red outlines/asterisk/exclamation marks** are required. You will not be able to submit the record if one of the required fields is not completed. Additional fields may appear dependent upon a selection made in a previous field. The progress tree on the left hand side of the page allows you to track your progress. If you are unable to complete the entire form at one time, you may save as a draft and return to it when ready. You must enter a Study Title to save as a draft.

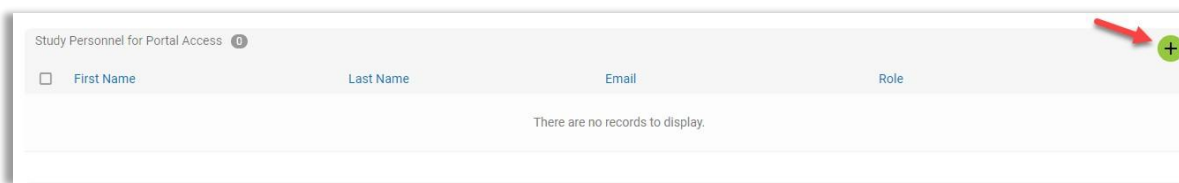


Use free text to enter the **Study Title**. Use the dropdown arrow to answer Yes or No to **Are you the Sponsor-Investigator for the study?** If you select Yes, your name will appear in the **Sponsor-Investigator** field. If you select no, use the  to search for and select the Sponsor-Investigator. If the Sponsor-Investigator is not in the list, click **+ADD NEW** to enter their information.



| First Name | Last Name | Primary Site / Institution | Country       |
|------------|-----------|----------------------------|---------------|
| Nabil      | Adra      |                            | United States |
| Neeraj     | Agarwal   |                            | United States |
| Mark       | Agulnik   |                            | United States |
| Mehmet     | Akce      |                            | United States |

Use the  to add all additional study personnel such as Co-Investigators, Research Coordinators, Safety Contacts, Pharmacy contacts, etc. in the **Study Personnel for Portal Access** field.



| First Name | Last Name | Email | Role |
|------------|-----------|-------|------|
|------------|-----------|-------|------|

There are no records to display.



The **New Study Personnel** page will open. Enter their **First Name**, **Last Name**, **Phone**, **Email** and **Role**. Click **SAVE** and repeat as many times as need to add all personnel.

A screenshot of the "New Study Personnel" form. The form has a blue header bar with a close button (X) and the title "New Study Personnel". Below the header is a section titled "Details" with a dropdown arrow. There are five input fields: "First Name\*", "Last Name\*", "Phone\*", "Email\*", and "Role\*". Each field has a red "1" icon to its right. A red arrow points to the "Role\*" field, which has a dropdown arrow on its right. At the bottom of the form, there is a red bar with a warning icon and the text "You have 5 incomplete fields." To the right of this bar is a "SAVE" button, which is highlighted with a red arrow.

Select your **Proposal Type** from the dropdown menu

A screenshot of the "Proposal Type" dropdown menu. The dropdown is open, showing three options: "Clinical - Interventional", "Clinical - Non-Interventional", and "Pre-Clinical". A red arrow points to the dropdown arrow on the right side of the "Proposal Type\*" field.

Use free text to enter your **Study Rationale/Background** and **Hypothesis**.

A screenshot of the text input areas for "Study Rationale/Background\*" and "Hypothesis\*". Both fields are large, rectangular text boxes with a light gray background and a thin border. The "Study Rationale/Background\*" field has a small icon in the top right corner. The "Hypothesis\*" field is below it.



Click on the dropdown arrows to select the **Therapeutic Area(s)**, **Study Indication(s)** and **Phase of Study**.

*\*Study Indication options are subject to the Therapeutic Area selected.*

A form with three stacked input fields. The first field is labeled "Therapeutic Area(s)\*" and has a red arrow pointing to a dropdown arrow on the right. The second field is labeled "Study Indication(s)" and also has a red arrow pointing to a dropdown arrow. The third field is labeled "Phase of Study\*" and has a red arrow pointing to a dropdown arrow. Each field has a small red circle with an exclamation mark icon on the right side.

Enter the **Line of Therapy**, **Primary Endpoint(s)** and **Secondary Endpoint(s)** using free text.

A form with three stacked text input fields. The first field is labeled "Line of Therapy\*", the second is labeled "Primary Endpoint(s)\*", and the third is labeled "Secondary Endpoint(s)".

Use the dropdown to select the **Study Design(s)**

A single text input field labeled "Study Design\*". A red arrow points to a dropdown arrow on the right side of the field. There is also a small red circle with an exclamation mark icon on the right side.

The **Study Treatment** field is a Rich Text Format field. You can use free text, upload files or drag and drop images, files, etc into the field.

A Rich Text Format (RTF) editor field labeled "Study Treatment Schedule\*". It features a toolbar with various icons for text formatting (bold, italic, underline, etc.), alignment, and other functions. The main area is a large text box for entering the treatment schedule.



Enter the **Key Eligibility (Brief Inclusion/Exclusion Criteria)** and **Statistical Plan**.

Key Eligibility (Brief Inclusion/Exclusion Criteria)\*

Statistical Plan\*

Select Yes or No for **Will you be enrolling patients?** If you select Yes, enter the **Total number of patients to be enrolled on this trial**. Enter the **Expected monthly accrual rate (across all sites if multi-site trial)** and select Yes or No for **Are you going to use a multi-center consortium and /or CRO?** If yes, you will be required to identify the organization. Enter the **Planned number of participating centers**, any number greater than one requires you to identify the participating centers.

Will you be enrolling patients?\*

Yes

Total number of patients to be enrolled on this trial\*

This field is required.

Expected monthly accrual rate (across all sites if multi-site trial)\*

Are you going to use a multi-center consortium and/or CRO?\*

Planned number of participating centers\*



Select Yes or No for **Correlative Studies**. If yes, additional fields regarding correlative studies will appear.

Correlative Studies\*

Yes

Collections

Schedule of Collections

Correlative Hypothesis

Technique



Use the dropdown arrow to select the **Support Requested**. If “Drug” or “Drug and Funding” are selected, the Product will auto populate, use the dropdown to select the Starting Dose. Enter the **Institutional Start Up timeline (months to study activation)**, **Data Dissemination Plan** and **References**.

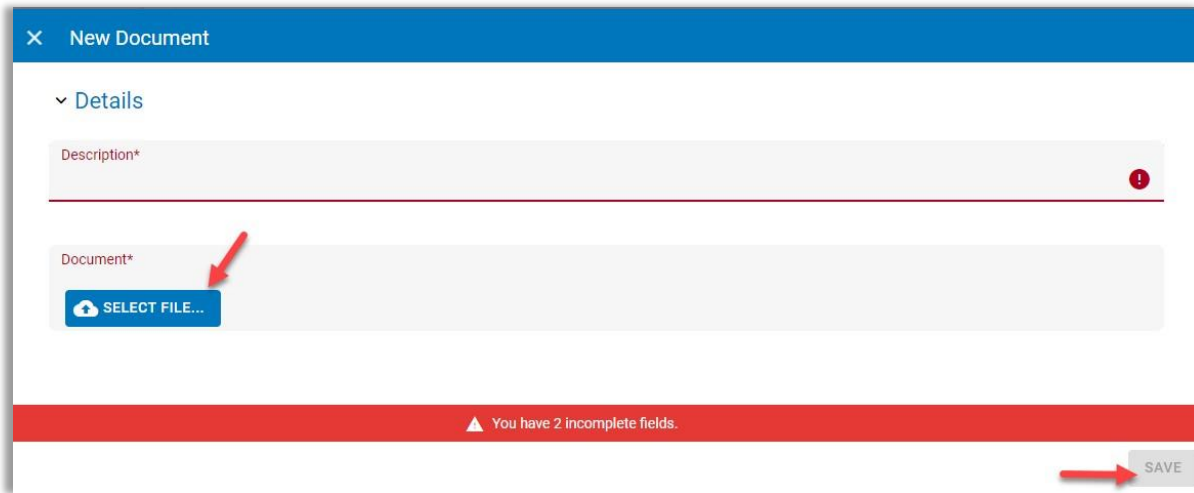
A screenshot of a web form with several input fields. The first field is "Support Requested\*" with a dropdown arrow pointing down, highlighted by a red arrow. The second field is "Product\*" with the text "Cabozantinib (XL184)" and a dropdown arrow, also highlighted by a red arrow. The third field is "Starting Dose\*" with a dropdown arrow and a red exclamation mark icon, highlighted by a red arrow. Below this field is a red error message: "This field is required." The fourth field is "Institutional Start Up timeline (months to study activation)\*" with a red exclamation mark icon. The fifth field is "Data Dissemination Plan\*" and the sixth is "References\*".

You have the option to enter any **Other Information for Consideration** and upload **Concept Supporting Documents**.

A screenshot of a web form showing two sections. The first section is "Other Information for consideration" with a large text area. The second section is "Concept Supporting Documents" with a counter showing "0" and a green circular button with a white plus sign, highlighted by a red arrow. Below this section are two tabs: "Description" and "Document". At the bottom of the section, it says "There are no records to display."

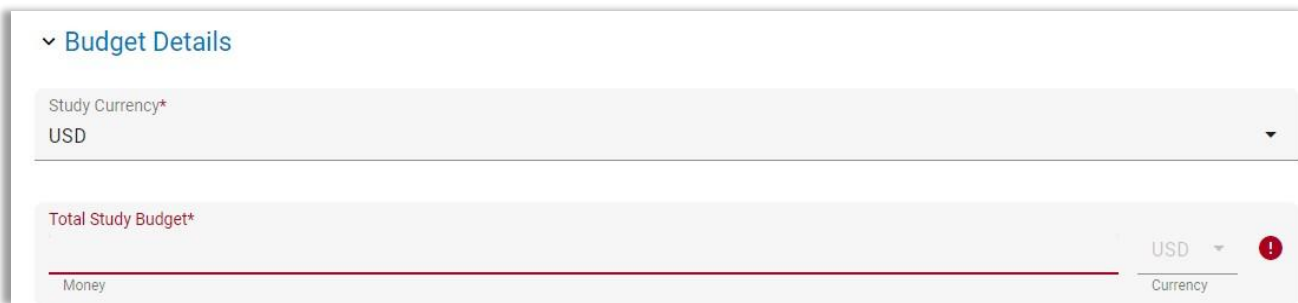


To upload the documents click on . The New Document page will open. Enter a **Description** and click  to upload the document. Repeat the steps for additional documents.



The 'New Document' form has a blue header with a close button. Below is a 'Details' section with two input fields: 'Description\*' and 'Document\*'. The 'Document\*' field contains a 'SELECT FILE...' button. A red arrow points to this button. At the bottom, a red error bar states 'You have 2 incomplete fields.' and a 'SAVE' button is on the right, with a red arrow pointing to it.

Finally enter the **Budget Details**. The **Study Currency** is prepopulated to USD. It is required that you enter a **Total Study Budget** and optional to enter the Budget Breakdown.



The 'Budget Details' form shows 'Study Currency\*' set to 'USD'. Below is the 'Total Study Budget\*' field, which is empty. To its right, 'USD' is shown with a dropdown arrow and a red error icon. At the bottom, 'Money' and 'Currency' are labeled.

To complete the **Budget Breakdown**, click on the , use the dropdown to select the **Cost Category**. Enter the **Description**, **Unit Cost/Hourly Rate** and **Unit Volume/# of Hours** then click **UPDATE**. Repeat the steps for all additional budget lines.



The 'Budget Breakdown' section has a title 'Budget Breakdown (Must encode at minimum Patient Care/Personnel Cost)\*'. It features a table with columns: 'Cost Category', 'Description', 'Unit Cost/Hourly Rate', and 'Unit Volume/# of Hours'. A red arrow points to the 'Cost Category' dropdown. Another red arrow points to the 'Description' field. A third red arrow points to the 'Unit Cost/Hourly Rate' field. A fourth red arrow points to the 'Unit Volume/# of Hours' field. A red error icon is in the top right. Below the table are 'UPDATE' and 'CANCEL' buttons.



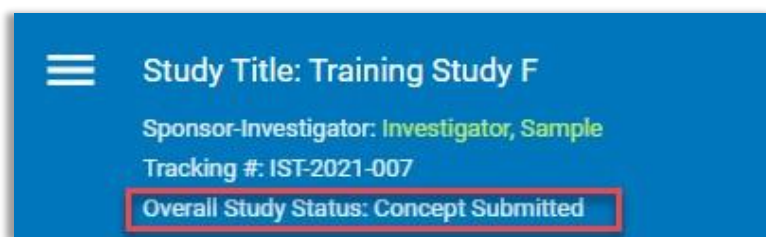
Select Yes or No for “**Will you be requesting additional support for this study from any other source?**”. If Yes, click on the  enter the **Source** and the **Amount**, click **UPDATE**. Repeat for all additional sources. Once done enter the **Amount Requested from Exelixis**.

A screenshot of a web form titled "Will you be requesting additional support for this study from any other source?". The form has a dropdown menu set to "Yes". Below this, a section titled "If funding from another source, please identify the other source(s) and the amount from other source(s):\*" contains a table. The table has two columns: "Source" and "Amount". A red arrow points to a green plus icon in the "Source" column. The "Amount" column has a dropdown menu set to "USD". Below the table, there are "UPDATE" and "CANCEL" buttons. A red arrow points to the "UPDATE" button. At the bottom of the form, there is a field for "Amount requested from Exelixis\*" with a "Money" label and a "Currency" dropdown set to "USD".

After you have completed all required fields click **SUBMIT** in the lower left-hand corner.



After you have submitted your concept, the Overall Study Status becomes Concept Submitted.



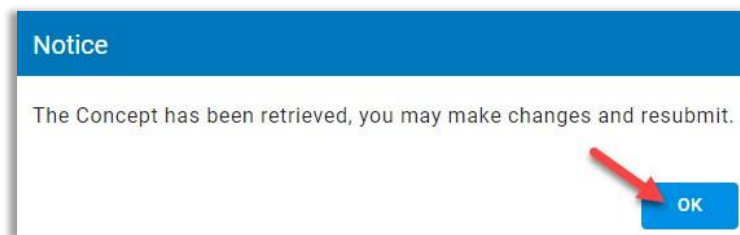


## Retrieving Concept for Edits

If you need to make any updates to your concept you are able to retrieve it for edits if the Overall Study Status is Concept Submitted. To edit your concept locate the study on the My Submitted Studies table, click on the vertical ellipsis to the right of the study and select **Retrieve for Edits**.

| My Submitted Studies |                  |                      |                   |                      |                    |                      |
|----------------------|------------------|----------------------|-------------------|----------------------|--------------------|----------------------|
| Tracking #           | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status |
| IST-2021-002         | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Concept Submitted    |
| IST-2021-003         | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | Concept Submitted    |
| IST-2021-004         | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   | Submitted            |

A **Notice** advising the concept has been retrieved pops up. Click **OK**



The Overall Study Status is now **Investigator Editing Concept**. Click on the row of the study.

| My Submitted Studies |                  |                      |                   |                      |                    |                              |
|----------------------|------------------|----------------------|-------------------|----------------------|--------------------|------------------------------|
| Tracking #           | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status         |
| IST-2021-002         | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Investigator Editing Concept |
| IST-2021-003         | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | Concept Submitted            |
| IST-2021-004         | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   | Concept Submitted            |
| IST-2021-005         | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Concept Submitted            |



The study page will open. Click **Update**, make the updates and click SUBMIT.

A screenshot of the EXELIXIS web application interface. The top header is blue and contains the study title "Study Title: Training Study F", sponsor-investigator "Investigator, Sample", tracking number "IST-2021-007", and overall status "Investigator Editing Concept". Navigation links for Home, Support, and Log off are on the right. Below the header is a tabbed interface with "OVERVIEW", "CONCEPT DETAILS", "PROTOCOL DETAILS", and "BUDGET DETAILS". The "OVERVIEW" tab is active. On the left is a sidebar with options: "Update" (highlighted with a red arrow), "Alert Settings", "Withdraw Study", and "Print / Print to PDF". The main content area shows a "Details" section with fields for "Created Date" (02-Sep-2021), "Request Date" (03-Sep-2021), and "Created By" (Investigator, Sample). It also includes a question "Are you the sponsor-investigator for the study?" with a "Yes" response.

Once the study is locked by Exelixis for review, you will no longer be able to make any updates unless the concept is returned to you for more information.



## Resubmitting after Request for More Information

When your concept is 'In Review' it can be determined that clarifications are requested in order to provide a decision. If a concept is returned to you for more information you will be informed via email and the requested clarifications will appear on the study for your reference. To view what clarifications are requested, click on the row of the study with an Overall Study Status of **Concept Request for More Information**

| My Submitted Studies |                  |                      |                   |                      |                    |                                    |   |
|----------------------|------------------|----------------------|-------------------|----------------------|--------------------|------------------------------------|---|
| Tracking #           | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status               |   |
| IST-2021-002         | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Active                       | ⋮ |
| IST-2021-003         | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | In Contracting                     | ⋮ |
| IST-2021-004         | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   | Full Protocol and Budget Requested | ⋮ |
| IST-2021-005         | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Concept Accepted, Site...          | ⋮ |
| IST-2021-006         | Training Study E | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Study Completed, Awaiting Final... | ⋮ |
| IST-2021-007         | Training Study F | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Concept Request for More...        | ⋮ |

The study page will open, click on the **CONCEPT REVIEW** tab. The **Pre-Review** or **Post Review Clarifications Requested** fields will display what updates are being requested. To submit your updates, click the **Update** button.

The edit study page will open, make the updates requested and click **SUBMIT**. The Overall Study Status is now **Concept Resubmitted**.

The resubmitted concept will be placed in review and the status will be communicated via email. Once the concept is accepted, you will be requested to add Site Information.



## Adding Site Details

To add site information from the homepage click on the row of the study with an Overall Study Status of **Concept Accepted, Site Information Required**.

| Tracking #   | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status                        |
|--------------|------------------|----------------------|-------------------|----------------------|--------------------|---------------------------------------------|
| IST-2021-002 | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Active                                |
| IST-2021-003 | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | In Contracting                              |
| IST-2021-004 | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   | Full Protocol and Budget Requested          |
| IST-2021-005 | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Concept Accepted, Site Information Required |
| IST-2021-006 | Training Study E | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Study Completed Awaiting Final...           |
| IST-2021-007 | Training Study F | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Concept Resubmitted                         |

The study page will open, click **Update**.

Study Title: Training Study D  
Sponsor-Investigator: Investigator, Sample  
Tracking #: IST-2021-005  
Overall Study Status: Concept Accepted, Site Information Required

OVERVIEW | CONCEPT DETAILS | CONCEPT REVIEW | PROTOCOL DETAILS | BUDGET DETAILS | CONTRACTING & REGULATORY DOCUMENTS

Update | Alert Settings | Withdraw Study | Print / Print to PDF

Details  
Created Date: 02-Sep-2021  
Request Date: 02-Sep-2021  
Created By: Investigator, Sample  
Assigned Admin(s): Admin, Sample  
Are you the sponsor-investigator for the study?  
Yes

Click on the **+** to add the first row of site information. Use free text to enter the **Site/Institution Name**. Click on the dropdown arrow to select the **Country** of the site and the site **Contact Type** (ie. Research Coordinator, Pharmacy Contact, Budgets & Contract Contact, etc.). Enter the **Address** to include city and state, enter the **Phone** and **Email** of the site contact. Click **UPDATE** to save that entry. Repeat the steps to add additional site detail. After you have added all the site information click **SELECT FILE...** to upload the **Primary Site / Institution W9**.



Site Details

Site Details\*

Site/Institution Name Country Contact Type Contact Name (First Last) Address (street #, city and state) Phone Email

UPDATE CANCEL

Primary Site / Institution W9\*

SELECT FILE...

Click **SAVE** in the lower left-hand corner.

The Overall Study Status is now **Site Information Submitted, Awaiting CDA**.

Study Title: Training Study D

Sponsor-Investigator: Investigator, Sample

Tracking #: IST-2021-005

**Overall Study Status: Site Information Submitted, Awaiting CDA**

Once the CDA is executed you will receive an email requesting you to submit the Full Protocol and Budget.



## Submitting Full Protocol/Budget

To submit your full protocol and budget, locate the study with an Overall Study Status of **Full Protocol and Budget Requested** on the My Submitted Studies table. Click on the row of the study.

| My Submitted Studies |                  |                      |                   |                      |                    |                                    |   |
|----------------------|------------------|----------------------|-------------------|----------------------|--------------------|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tracking #           | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status               |                                                                                                                                                                         |
| IST-2021-002         | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Active                       | ⋮                                                                                                                                                                       |
| IST-2021-003         | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | In Contracting                     | ⋮                                                                                                                                                                       |
| IST-2021-004         | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   | Full Protocol and Budget Requested | ⋮                                                                                                                                                                       |
| IST-2021-005         | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Concept Accepted, Site...          | ⋮                                                                                                                                                                       |
| IST-2021-006         | Training Study E | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Study Completed, Awaiting Final... | ⋮                                                                                                                                                                       |
| IST-2021-007         | Training Study F | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Concept Request for More...        | ⋮                                                                                                                                                                       |

Click **Update** to submit the Protocol and Budget details.

Study Title: Training Study C

Sponsor-Investigator: Investigator, Sample

Tracking #: IST-2021-004

Overall Study Status: Full Protocol and Budget Requested

[Home](#) [Support](#) [Log off](#)

OVERVIEW **CONCEPT DETAILS** CONCEPT REVIEW PROTOCOL DETAILS BUDGET DETAILS CONTRACTING & REGULATORY DOCUMENTS

 Update

 Alert Settings

 Withdraw Study

 Print / Print to PDF

Details

Created Date: 02-Sep-2021

Request Date: 02-Sep-2021

Created By: Investigator, Sample

Assigned Admin(s): Admin, Sample

Are you the sponsor-investigator for the study?  
Yes

At this time you are able to edit specific concept details that may have changed since concept submission and review. Scroll down to the **Protocol Details** section. Click  to upload the **Full Protocol (Word version required)**. Use free text to enter the **Duration of Study Treatment (Per Subject in months)** and **Number and Description of Each Treatment Arm/Group**.

Protocol Details

Full Protocol (Word version preferred)\*

Duration of Study Treatment (Per Subject in months) 

Number and Description of Each Treatment Arm/Group

You have the option to upload **Protocol Supporting Documents**.

Protocol Supporting Documents  

| <input type="checkbox"/> Description | Document |
|--------------------------------------|----------|
| There are no records to display.     |          |

To upload the documents click on . The New Document page will open. Enter a Description and click  to upload the document. Repeat the steps for all additional documents.

New Document

Details

Description\* 

Document\*  

 You have 2 incomplete fields.

 SAVE



Use the calendar icon to select a date for the required and optional **Study Timeline** fields.

Study Timelines

Planned Study Start/Study Activation\*  
dd-Mmm-yyyy ! 📅

Planned First Patient, First Visit\*  
dd-Mmm-yyyy ! 📅

Planned Last Patient, First Visit  
dd-Mmm-yyyy 📅

Planned Last Patient, Last Visit\*  
dd-Mmm-yyyy ! 📅

Planned Study Completion (End of data collection)\*  
dd-Mmm-yyyy ! 📅

Planned Final Study Report Submission\*  
dd-Mmm-yyyy ! 📅

Planned Manuscript or Publication Submission (if applicable)  
dd-Mmm-yyyy 📅

The Publication Plan field is optional, however to add your publication plan(s) click on the +

Publication Plan 0

| Type                             | Planned / Estimated Date of Submission | Meeting | Journal |
|----------------------------------|----------------------------------------|---------|---------|
| There are no records to display. |                                        |         |         |

The **New Publication Plan** page will open. Use free text to add a **Title**. Use the dropdown arrow to select the **Type** and click on the calendar icon to select the **Planned/Estimated Date of Submission**. You can add the Meeting and Journal and click SAVE in the lower right-hand corner.

× New Publication Plan

Details

Title\*

Type\*

Planned / Estimated Date of Submission\*  
dd-Mmm-yyyy

Meeting

Journal

▲ You have 3 incomplete fields.

SAVE

Upon saving the publication plan you will return to the edit study page. Scroll down and click [SELECT FILE...](#) to upload your **Detailed Budget**.

Detailed Budget\*

SELECT FILE...

When all required fields are completed, click **SUBMIT**.

SAVE DRAFT

SUBMIT

After you have submitted your protocol, the Overall Study Status becomes **Protocol/Budget Submitted**.

Study Title: Training Study C

Sponsor-Investigator: Investigator, Sample

Tracking #: IST-2021-004

Overall Study Status: Protocol/Budget Submitted



## Retrieving Protocol/Budget for Edits

If you need to make any updates to your protocol, you can retrieve it for edits when the Overall Study Status is Protocol/Budget Submitted. To edit your protocol, locate the study on the My Submitted Studies table, click on the vertical ellipsis to the right of the study with an Overall Study Status of Protocol/Budget Submitted, and select **Retrieve for Edits**.

| My Submitted Studies |                  |                      |                   |                      |                    |                           |                                                           |
|----------------------|------------------|----------------------|-------------------|----------------------|--------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tracking #           | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status      |                                                                                                                                                                                                                                 |
| IST-2021-002         | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Active              | ⋮                                                                                                                                                                                                                               |
| IST-2021-003         | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | In Contracting            | ⋮                                                                                                                                                                                                                               |
| IST-2021-004         | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   | Protocol/Budget Submitted | ⋮                                                                                                                                                                                                                               |
| IST-2021-005         | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Awaiting Final...         | <div> Retrieve For Edits</div> <div> Withdraw Study</div> |
| IST-2021-006         | Training Study E | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   |                           |                                                                                                                                                                                                                                 |
| IST-2021-007         | Training Study F | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Concept Resubmitted       | ⋮                                                                                                                                                                                                                               |

The **Notice** advising the protocol has been retrieved pops up. Click **OK**

**Notice**

The Protocol has been retrieved, you may make changes and resubmit.



The Overall Study Status is now **Investigator Editing Protocol**. Click on the row of the study.

| My Submitted Studies |                  |                      |                   |                      |                    |                                    |   |
|----------------------|------------------|----------------------|-------------------|----------------------|--------------------|------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tracking #           | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status               |                                                                                                                                                                             |
| IST-2021-002         | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Active                       | ⋮                                                                                                                                                                           |
| IST-2021-003         | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | In Contracting                     | ⋮                                                                                                                                                                           |
| IST-2021-004         | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   | Investigator Editing Protocol      | ⋮                                                                                                                                                                           |
| IST-2021-005         | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Site Information Submitted,...     | ⋮                                                                                                                                                                           |
| IST-2021-006         | Training Study E | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Study Completed, Awaiting Final... | ⋮                                                                                                                                                                           |
| IST-2021-007         | Training Study F | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Concept Resubmitted                | ⋮                                                                                                                                                                           |



The study page will open. Click **Update**, make the updates and click SUBMIT.

Study Title: Training Study C  
Sponsor-Investigator: Investigator, Sample  
Tracking #: IST-2021-004  
Overall Study Status: Investigator Editing Protocol

Update  
Alert Settings  
Withdraw Study  
Print / Print to PDF

Details  
Created Date: 02-Sep-2021  
Request Date: 02-Sep-2021  
Created By: Investigator, Sample  
Assigned Admin(s): Admin, Sample  
Are you the sponsor-investigator for the study?  
Yes

Once the study is locked by Exelixis for review, you will no longer be able to make any updates, unless the protocol is returned to you for more information. Refer to the **Resubmitting after Request for More Information** section on how to respond to Protocol Clarifications Requested.

When the protocol is approved and the Overall Study Status = **In Contracting** you will need to add the **IRB/EC Approval Date and Documentation, Regulatory Approval Date and Documentation** as well as the **IND # and NCT #**. Click the row of the study with the Overall Study Status of **In Contracting**.

| Tracking #   | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status               |
|--------------|------------------|----------------------|-------------------|----------------------|--------------------|------------------------------------|
| IST-2021-002 | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Active                       |
| IST-2021-003 | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | In Contracting                     |
| IST-2021-004 | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   | Investigator Editing Protocol      |
| IST-2021-005 | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Site Information Submitted,...     |
| IST-2021-006 | Training Study E | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Study Completed, Awaiting Final... |
| IST-2021-007 | Training Study F | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Concept Resubmitted                |

Click the **Update** button.

Study Title: Training Study B  
Sponsor-Investigator: Investigator, Sample  
Tracking #: IST-2021-003  
Overall Study Status: In Contracting

Update  
Alert Settings  
Withdraw Study  
Print / Print to PDF

Details  
Created Date: 02-Sep-2021  
Request Date: 02-Sep-2021  
Created By: Investigator, Sample  
Assigned Admin(s): Admin, Sample  
Are you the sponsor-investigator for the study?  
Yes



Scroll down to the **Key Dates** and **Documentation** sections to enter the information.

A screenshot of a web form with two main sections: "Key Dates" and "Documentation". The "Key Dates" section has two date input fields, each with a calendar icon and a red exclamation mark icon. Red arrows point to these icons. The "Documentation" section has two file upload buttons labeled "SELECT FILE..." with cloud icons, each with a red arrow pointing to it. Below these are two text input fields labeled "IND #" and "NCT#", which are enclosed in a red rectangular border.

Key Dates

IRB/EC Approval Date\*  
dd-Mmm-yyyy

Regulatory Approval Date\*  
dd-Mmm-yyyy

Documentation

EC / IRB Approval\*

SELECT FILE...

Regulatory Authority Approval/Exemption\*

SELECT FILE...

IND #

NCT#

No additional action is required until the study becomes Active. Once a study is Active you are able to do the following:

- Submit an Amendment
- Submit Progress Updates
- Submit Report/Manuscripts



## Submitting an Amendment

To submit an amendment click on the vertical ellipsis for the row where Overall Study Status = Study Active and select **+ Amendment**.

| My Submitted Studies |                  |                      |                   |                      |                    |                                                                                                                                                                |
|----------------------|------------------|----------------------|-------------------|----------------------|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tracking #           | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status                                                                                                                                           |
| IST-2021-002         | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Active                                                                                                                                                   |
| IST-2021-003         | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | <div><div>+ Amendment</div><div>+ Submit Progress Update</div><div>+ Submit Report / Manuscript</div><div>Terminate Study</div><div>Withdraw Study</div></div> |
| IST-2021-004         | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   |                                                                                                                                                                |
| IST-2021-005         | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   |                                                                                                                                                                |
| IST-2021-006         | Training Study E | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   |                                                                                                                                                                |
| IST-2021-007         | Training Study F | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Concept Resubmitted                                                                                                                                            |

The **Add Amendment** page opens. Enter the **Title** for the amendment. **Amendment Request Date** will auto populate with the current date. Use the dropdown arrow to select the **Type of Amendment**. What you select as Type of Amendment will determine what additional fields show to be completed.

← Add Amendment

Home Support Log off

Details

Details

Title\*

This field is required.

Amendment Request Date\*  
06-Sep-2021

Type of Amendment\*

This field is required.

If Type of Amendment = Protocol Only or Protocol and Budget you are able to upload the new protocol by clicking **REPLACE** on the **Amended Protocol** field.

Amended Protocol\*

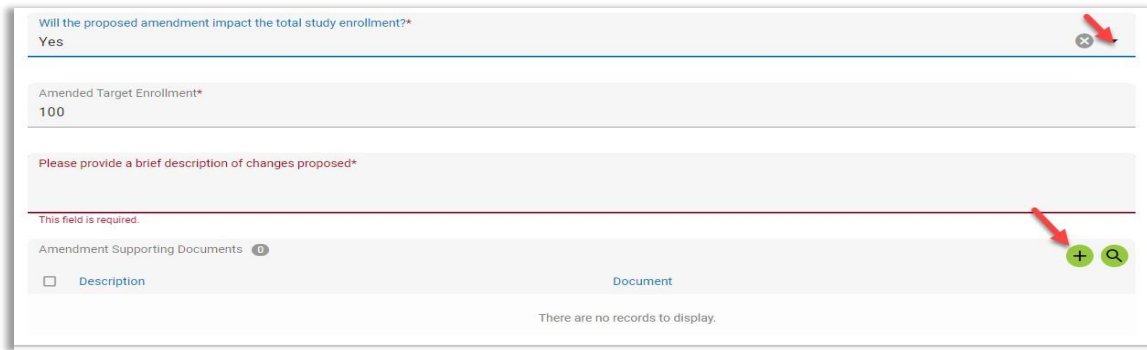
Sample Doc.docx

CLEAR

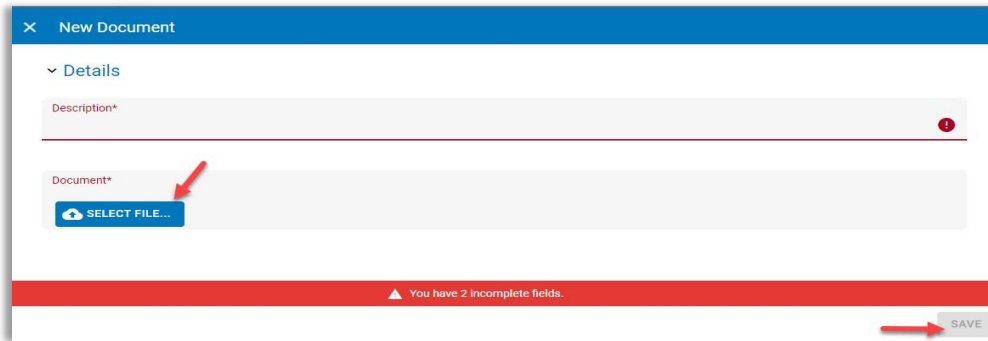
REPLACE



Use the dropdown arrow to select Yes or No for **Will the proposed amendment impact the total study enrollment?** If Yes, use numbers to enter the **Amended Target Enrollment**. Use free text for **Please provide a brief description of changes proposed**. If you have additional **Amendment Supporting Documents** click on the  to add them.



The New Document page will open. Enter a Description and click  to upload the document. Repeat the steps for additional documents.



If Type of Amendment = Budget Only or Protocol and Budget, use numbers to enter the **Amended Amount Requested from Exelixis**. You are able to upload the new budget by clicking  on the **Amended Budget** field.



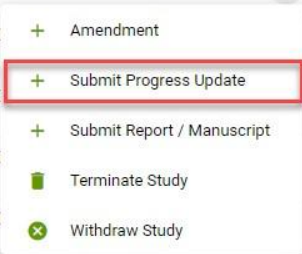
Click **SUBMIT** in the lower left-hand corner when all fields have been completed. Your amendment will be reviewed by Exelixis.



## Submitting Progress Updates

To submit Progress Updates click on the vertical ellipsis for the row where Overall Study Status = Study Active and select **+ Submit Progress Update**.

| My Submitted Studies |                  |                      |                   |                      |                    |                      |  |  |
|----------------------|------------------|----------------------|-------------------|----------------------|--------------------|----------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Tracking #           | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status |                                                                                     |                                                                                     |
| IST-2021-002         | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Active         |  |                                                                                     |
| IST-2021-003         | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   |                      |                                                                                     |                                                                                     |
| IST-2021-004         | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   |                      |                                                                                     |                                                                                     |
| IST-2021-005         | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   |                      |                                                                                     |                                                                                     |
| IST-2021-006         | Training Study E | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   |                      |                                                                                     |                                                                                     |
| IST-2021-007         | Training Study F | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Concept Resubmitted  |  |                                                                                     |



The **Add Progress Update** page will open. Using numbers, enter the **Patients Enrolled (Consented)**, **Screen Failures**, **Treated Patients** and **Active Patients**. Enter the number for each **Dose** and use free text to enter **Any comments related to the study (Responses, toxicities, enrollment concerns, etc.)**

*\*If this is the first progress update, the fields will be empty. If this is the second or later progress update the fields will be populated with the information from the previous progress update.*



Details

Date\*

06-Sep-2021



Enrollment

Patients Enrolled (Consented)\*

5



Screen Failures\*

0



Treated Patients\*

0



Active Patients\*

5

Dose (60mg qd)

Dose (40mg qd)

5

Dose (20mg qd)

Dose (20mg qod)

Any comments related to the study (Responses, toxicities, enrollment concerns, etc.)

Select Yes or No for **Any anticipated amendments?** If Yes, you are required to provide details regarding the anticipated amendments.

Amendments

Any anticipated amendments

Yes



Please provide details\*

This field is required.



Use the calendar icons to enter any dates that require updates in the **Timelines** section.

Timelines

Planned Study Start/Study Activation  
dd-Mmm-yyyy

Actual Study Start/Study Activation  
dd-Mmm-yyyy

Planned First Patient, First Visit  
dd-Mmm-yyyy

Actual First Patient, First Visit  
dd-Mmm-yyyy

Planned Last Patient, First Visit  
dd-Mmm-yyyy

Actual Last Patient, First Visit  
dd-Mmm-yyyy

Planned Last Patient, Last Visit  
dd-Mmm-yyyy

Actual Last Patient, Last Visit  
dd-Mmm-yyyy

Planned Study Completion (End of data collection)  
dd-Mmm-yyyy

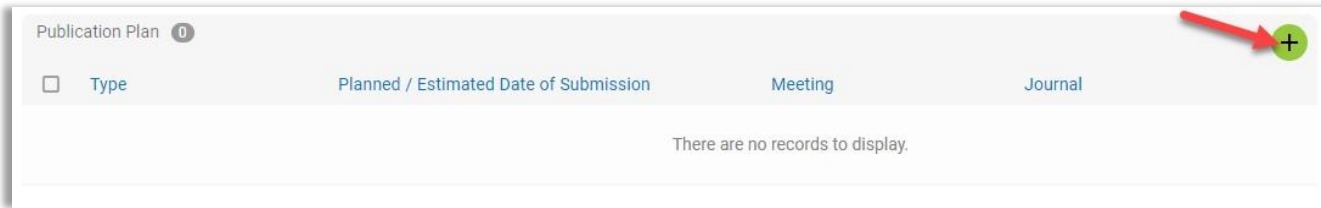
Actual Study Completion (End of data collection)  
dd-Mmm-yyyy

Actual Final Study Report Date  
dd-Mmm-yyyy

Planned Final Study Report Submission  
dd-Mmm-yyyy

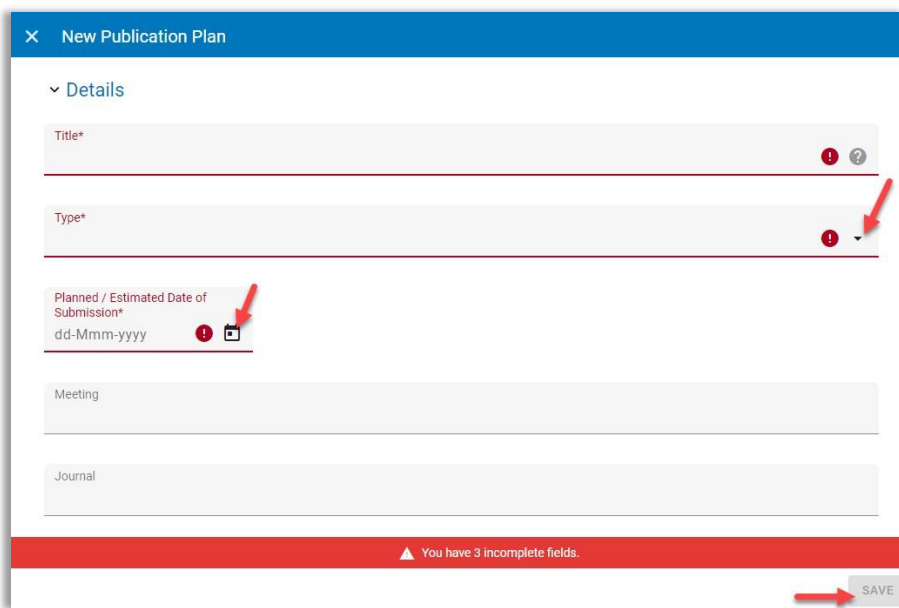


In the Publication Plans section, you are able to add any additional publication plans by clicking on the 



| Type                             | Planned / Estimated Date of Submission | Meeting | Journal |
|----------------------------------|----------------------------------------|---------|---------|
| There are no records to display. |                                        |         |         |

The **New Publication Plan** page will open. Use free text to add a **Title**. Use the dropdown arrow to select the **Type** and click on the calendar icon to select the **Planned/Estimated Date of Submission**. You can also add the anticipated Meeting and/or Journal and click **SAVE** in the lower right-hand corner.



**New Publication Plan**

Details

Title\*

Type\*

Planned / Estimated Date of Submission\*  
dd-Mmm-yyyy

Meeting

Journal

You have 3 incomplete fields.

SAVE

Lastly, if you have reached your next milestone, place a check in the box to the left of **Have you reached your next milestones?**



Enrollment

☐ Have you reached your next milestone?

Click **SAVE** in the lower left-hand corner.



## Submitting a Report/Manuscript

To submit a **Report/Manuscript** click on the vertical ellipsis for the row where Overall Study Status = Study Active and select **+ Submit Report / Manuscript**.

| My Submitted Studies |                  |                      |                   |                      |                    |                                                                                                                                                                |
|----------------------|------------------|----------------------|-------------------|----------------------|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tracking #           | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status                                                                                                                                           |
| IST-2021-002         | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Active                                                                                                                                                   |
| IST-2021-003         | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | <div><div>+ Amendment</div><div>+ Submit Progress Update</div><div>+ Submit Report / Manuscript</div><div>Terminate Study</div><div>Withdraw Study</div></div> |
| IST-2021-004         | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   |                                                                                                                                                                |
| IST-2021-005         | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   |                                                                                                                                                                |
| IST-2021-006         | Training Study E | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   |                                                                                                                                                                |
| IST-2021-007         | Training Study F | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   |                                                                                                                                                                |
|                      |                  |                      |                   |                      |                    | Concept Resubmitted                                                                                                                                            |

The **Add Report / Manuscript** page will open, use free text to enter the **Title**. Use the dropdown arrows to select the **Type** and **Version of Submission**. Click **SELECT FILE...** to upload the report /manuscript. Once all required fields are completed click **SUBMIT**.

← Add Report / Manuscript

Home Support Log off

Details

Details

Title\*  
Training Study A

Type of Submission\*  
1

Document\*  
SELECT FILE...

Version of Submission\*  
1

SAVE DRAFT

SUBMIT



## How to Closeout a Study

When you have reached the end of your study and you are ready to closeout, click on the update button, scroll down to the Closeout Details section and place a check in the box to the left of **Request Study Closeout Questionnaire**. Then click SAVE in the lower left hand corner.

Closeout Details

☐ Request Study Closeout Questionnaire

Exelixis will review the request and open the study closeout questionnaire for you to complete. You will receive an email when closeout information is requested.

Click on the study from the homepage with status of **Study Completed, Awaiting Final Documents**.

| My Submitted Studies |                  |                      |                   |                      |                    |                                    |   |
|----------------------|------------------|----------------------|-------------------|----------------------|--------------------|------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tracking #           | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status               |                                                                                                                                                                         |
| IST-2021-002         | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Active                       | ⋮                                                                                                                                                                       |
| IST-2021-003         | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | In Contracting                     | ⋮                                                                                                                                                                       |
| IST-2021-004         | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   | Investigator Editing Protocol      | ⋮                                                                                                                                                                       |
| IST-2021-005         | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Withdrawn                    | ⋮                                                                                                                                                                       |
| IST-2021-006         | Training Study E | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Study Completed, Awaiting Final... | ⋮                                                                                                                                                                       |
| IST-2021-007         | Training Study F | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Concept Resubmitted                | ⋮                                                                                                                                                                       |



Click **Update**

The **Closeout Details** section now shows 10 additional required fields. Use the dropdown arrows to select Yes, No or Not Applicable for each question. If you select Yes you are required to enter the **Action Date**. If you select No or Not Applicable you are required to enter a **Comment** explaining the answer.

Once all the questions have been answered, click **SAVE** to submit the closeout questionnaire to Exelixis.



## Terminating or Withdrawing a Study

If you wish to end your study before the anticipated start date, you may do so by withdrawing a study prior to a contract being executed. If a contract is executed you are able to request to terminate the study. You can withdraw a study from the homepage or from the study itself.

To withdraw from the homepage click on the vertical ellipsis and select **Withdraw Study**.

| My Submitted Studies |                  |                      |                   |                      |                    |                                    |                                                         |
|----------------------|------------------|----------------------|-------------------|----------------------|--------------------|------------------------------------|---------------------------------------------------------|
| Tracking #           | Study Title      | Sponsor-Investigator | Support Requested | Therapeutic Area(s)  | Total Study Budget | Overall Study Status               |                                                         |
| IST-2021-002         | Training Study A | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Active                       | ⋮                                                       |
| IST-2021-003         | Training Study B | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$100,000.00 USD   | In Contracting                     | ⋮                                                       |
| IST-2021-004         | Training Study C | Investigator, Sample | Drug and Funding  | Carcinoid Tumors     | \$100,000.00 USD   | Investigator Editing Protocol      | ⋮                                                       |
| IST-2021-005         | Training Study D | Investigator, Sample | Drug and Funding  | Adrenal Gland Tumors | \$100,000.00 USD   | Study Withdrawn                    | ⋮                                                       |
| IST-2021-006         | Training Study E | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Study Completed, Awaiting Final... | ⋮                                                       |
| IST-2021-007         | Training Study F | Investigator, Sample | Drug and Funding  | Breast Cancer        | \$150,000.00 USD   | Concept Resubmitted                | ⋮                                                       |
|                      |                  |                      |                   |                      |                    |                                    | <div>Retrieve For Edits</div> <div>Withdraw Study</div> |

To withdraw from the study itself, click the **Withdraw Study** button on the left hand side of the study details.

Study Title: Training Study F

Sponsor-Investigator: Investigator, Sample

Tracking #: IST-2021-007

Overall Study Status: Concept Resubmitted

OVERVIEW

Update

Alert Settings

Retrieve For Edits

Withdraw Study

Print / Print to PDF

Details

Created Date: 02-Sep-2021

Request Date: 03-Sep-2021

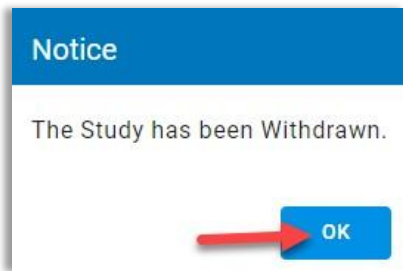
Created By: Investigator, Sample

Assigned Admin(s): Admin, Sample

Are you the sponsor-investigator for the study?  
Yes



Once you have clicked Withdraw Study you will get a Notice confirming the study has been withdrawn.



Click Ok, the Overall Study Status is now **Study Withdrawn**.

Once a contract is Fully Executed you must request to terminate the study. You are able to submit the termination request from the homepage or from the study itself, the same way you can withdraw. Upon selecting **Terminate Study** you will see a Notice, confirming the study termination has been requested. Click Ok.



Exelixis will review the study and determine if additional information is needed. You will be informed via email if additional documentation is needed or if your request for termination has been approved and the study will be terminated.



## Settings



If at any time you need to update your profile information such as your name, address, phone number or email, you are able to do so by clicking on the Settings tile.

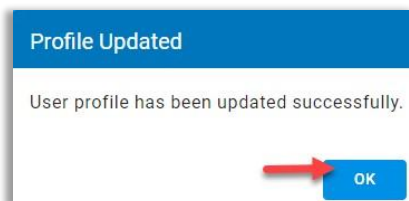
Click on the **My Profile** tile.



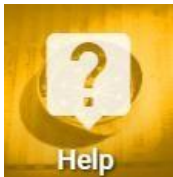
Update any information you need to be updated and click **SAVE**.

A screenshot of a web form titled "Edit HCP". The form has a blue header bar with a close button (X) and the title "Edit HCP". Below the header, there is a section titled "Contact Details" with a dropdown arrow. The form contains several input fields: "Salutation\*" with a dropdown menu showing "Dr."; "First Name\*" with the text "Sample"; "Middle Name/Middle Initial"; "Last Name\*" with the text "Investigator"; "Degree(s)" with a dropdown menu; "Local First Name"; and "Local Last Name". At the bottom right of the form, there is a blue button labeled "SAVE" with a red arrow pointing to it.

Profile Updated confirmation box will appear, click **OK** to return to the homepage.



## Help



The Help tile will have a copy of this guide with step by step instructions on how to submit a study as well as any other documentation Exelixis feels is useful for you as an investigator.

## Helpful Settings

Pop-up windows must be allowed for certain features on the site to work.

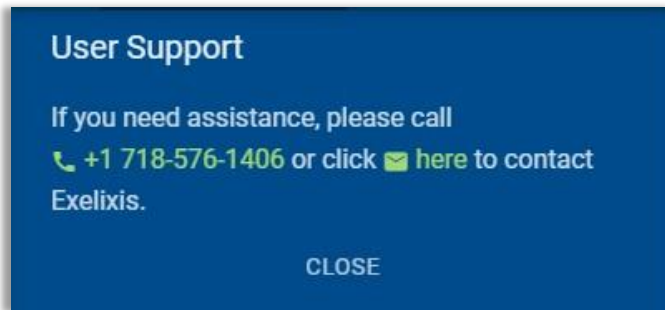
1. Open **MS Internet Explorer**.
  2. Select the 'Tools' tab.
  3. Scroll down to 'Pop-up Blocker.'
  4. Select 'Pop-up Blocker settings.'
  5. Type '\*.steeprocksinc.com' into the 'Address of website to allow:' field.
  6. Select 'Add' and 'Close.'
- 
1. Open **Firefox**.
  2. Select the 'Tools' tab.
  3. Select the 'Content' tab.
  4. Select 'Pop-ups' 'Exceptions' button across from the 'Block pop-ups windows' check box.
  5. Type '\*.steeprocksinc.com' into 'Address of website:' field.
  6. 'Save Changes.'
- 
1. Open **Chrome**.
  2. Select the Chrome menu ☰ button on the top right-hand side.
  3. 'Settings.'
  4. 'Show Advanced Settings.'
  5. Under 'Privacy,' select 'Content Settings.'
  6. Under 'Pop-ups,' select 'Manage Exceptions.'
  7. Type '\*.steeprocksinc.com' into the 'Hostname pattern' field.
  8. 'Done.'



1. Open **Safari**.
2. Select the 'Safari' tab.
3. Select 'Preferences 'and 'Websites.'
4. Under 'General,' select 'Pop-up Windows'
5. Under 'Currently Open Website,' select 'Allow'

## **Support**

For technical problems, please contact: [support@steeprockinc.com](mailto:support@steeprockinc.com) or call +1 718-576-1406.





## IST Activation and Completion Process

