# AstraZeneca

# Evidence Connect Platform Externally Sponsored Research User Guide

March 2019

# How to Use This Guide

- This guide is divided into short sections for ease of use
- There are hyperlinks throughout this guide to aid with navigation
- Click the  icon in the lower left corner to return to the table of contents
- When logged into Evidence Connect, you can access the Evidence Connect Training Centre by clicking the ? icon located at the top right-hand-side of the screen
- If you need technical support using Evidence Connect, contact us at:
  - Email: AZEVIDENCECONNECTSUPPORT@astrazeneca.com

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Click an Icon to Navigate to a Specific Section

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# Navigating the System

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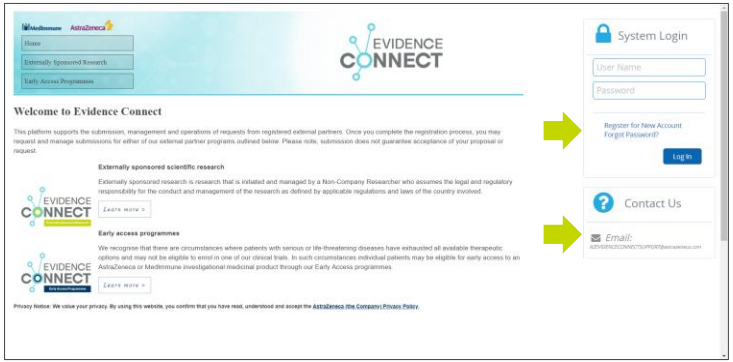
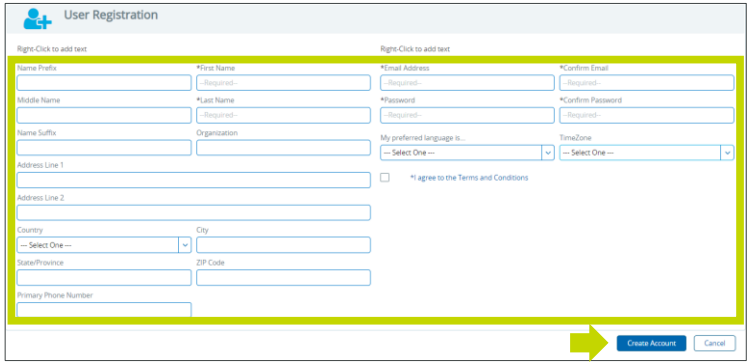
# Navigating the System

## Register for a New Account

- Register for an account by clicking **Register for New Account**
- Should you experience technical difficulties, contact Technical Support by using the email address or phone number listed under Contact Us

*If you were registered previously in ESSROS, your account will be migrated to Evidence Connect. You will receive an email requesting that you reset your password. Once reset, you will be able to sign into Evidence Connect*



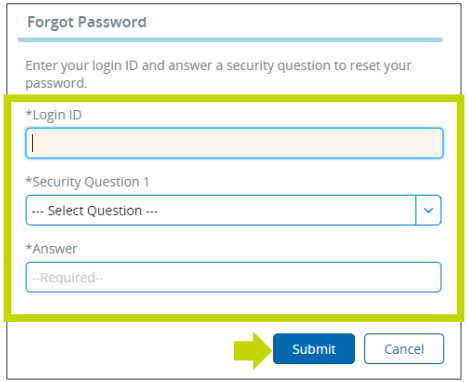
# Navigating the System

## Login

- Once registered, you will receive an email containing your username and password
- Log in by entering your account details on the right-hand-side of the landing page

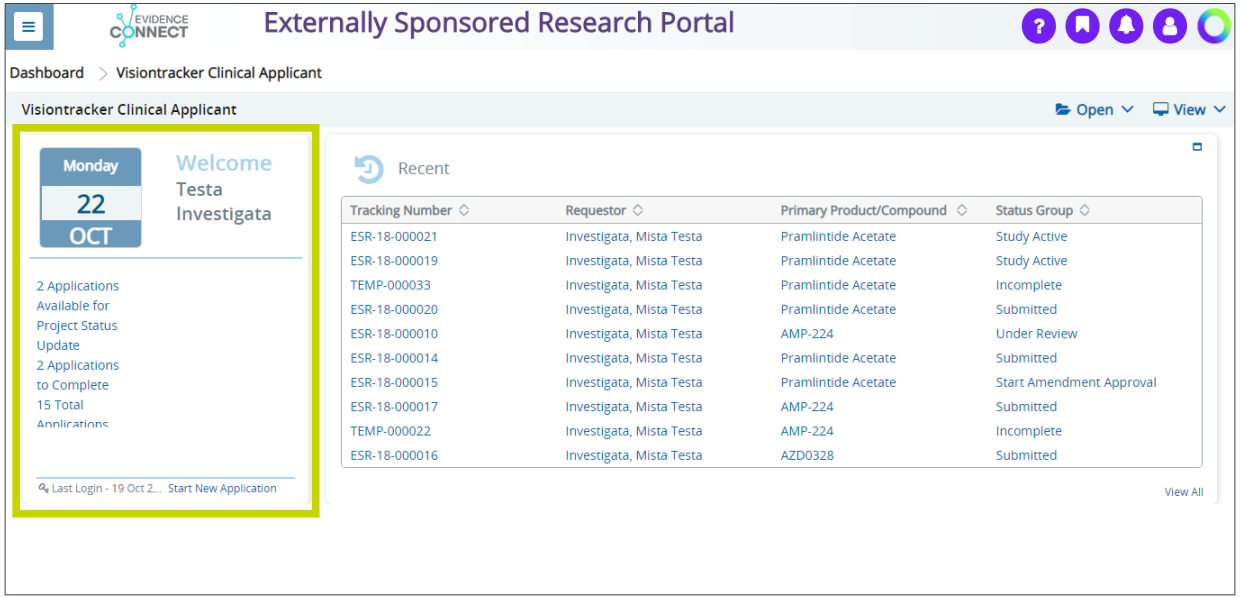
### Forgot Password?

- Click **Forgot Password?** and complete all fields; click Submit to receive an email with password reset details

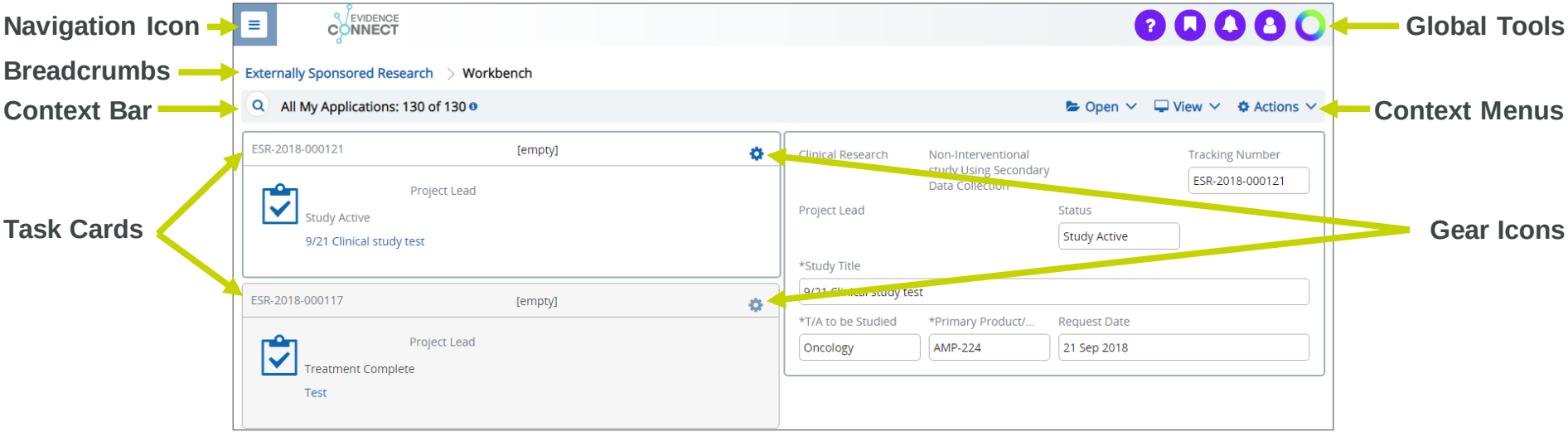
# Navigating the System
## Dashboard

- Once logged in, you will arrive at your **Dashboard**
- This contains a preconfigured set of widgets that enable you to see information about your applications
- The Dashboard Welcome Widget contains your current applications grouped by task (please note that this will be empty on your first login)



# Navigating the System

## Navigation Overview



# Navigating the System

## Global Tools

Global Tools always appear at the top of each active screen

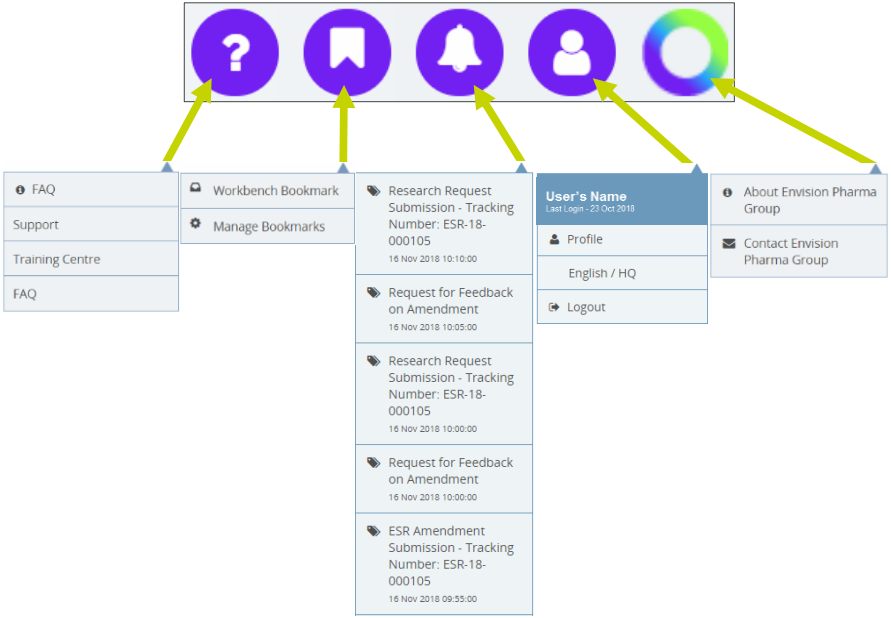
**Help:** view FAQ, access Support and the Evidence Connect Training Centre

**Bookmarks:** bookmark any Dashboard, Workbench, or Portfolio View

**Notifications:** view your notifications and files

**Profile:** update your contact information and log out of the system

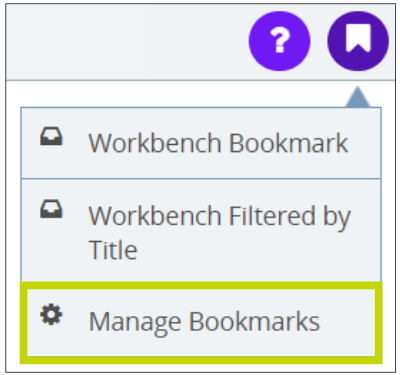
**iEnvision icon:** view information about Envision Pharma Group

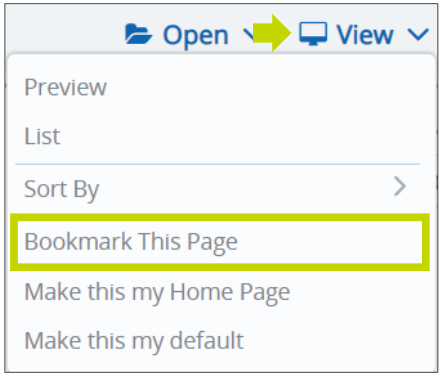


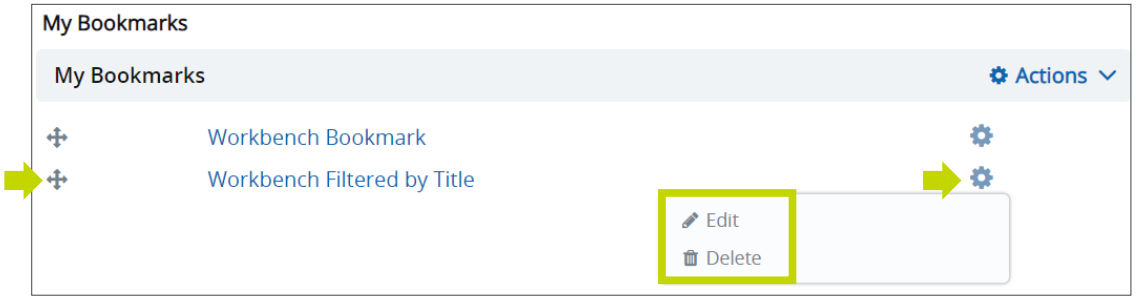
# Navigating the System

## Global Tools: Bookmarks

- You can bookmark any Dashboard or Workbench by clicking **Bookmark This Page** in the View menu
- You may have up to 20 bookmarks
- Clicking **Manage Bookmarks** allows you to remove, rearrange, and rename bookmarks



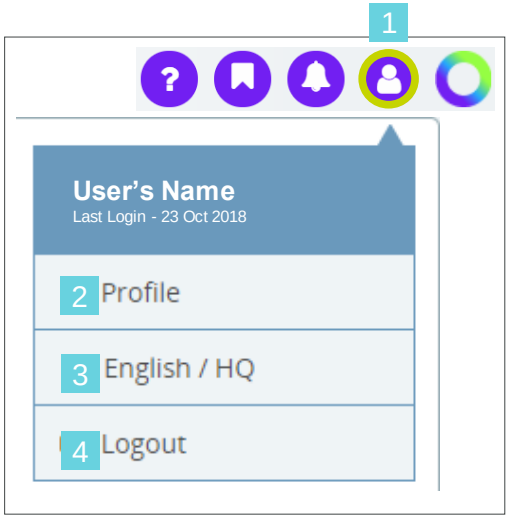



# Navigating the System

## Global Tools: Profile

1. To update your profile, click the Profile icon at the top right-hand-side of the screen
2. Profile allows you to:
   - Manage your contact information
   - Change your password
   - Change your security question(s)
3. Your current country/language are displayed
4. Log out of the system by selecting the Logout option



# Navigating the System

## Breadcrumbs

- Breadcrumbs show your location within the Evidence Connect platform and the path by which you arrived
- Your current location is shown in black. You can navigate back within the path by clicking the blue breadcrumb links
- You may also use your browser's "back" button to return to a previous screen

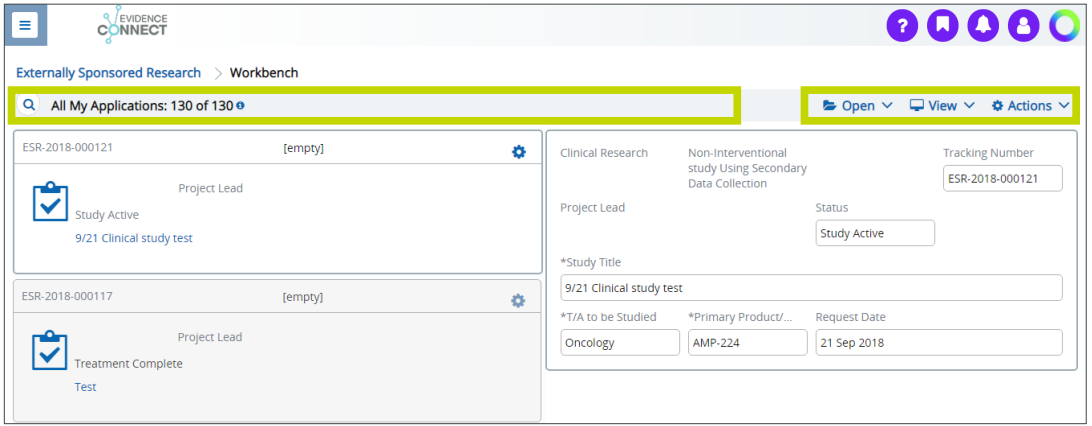
# Navigating the System

## Context Bar

- The Context Bar is located below the breadcrumb area. It provides information about the record, or set of records, on display
- The example below shows the Context Bar for your Workbench and its functionality

**Context Bar**

Opens and closes the facet panel, allowing you to search projects on your Workbench




**Context Menus**

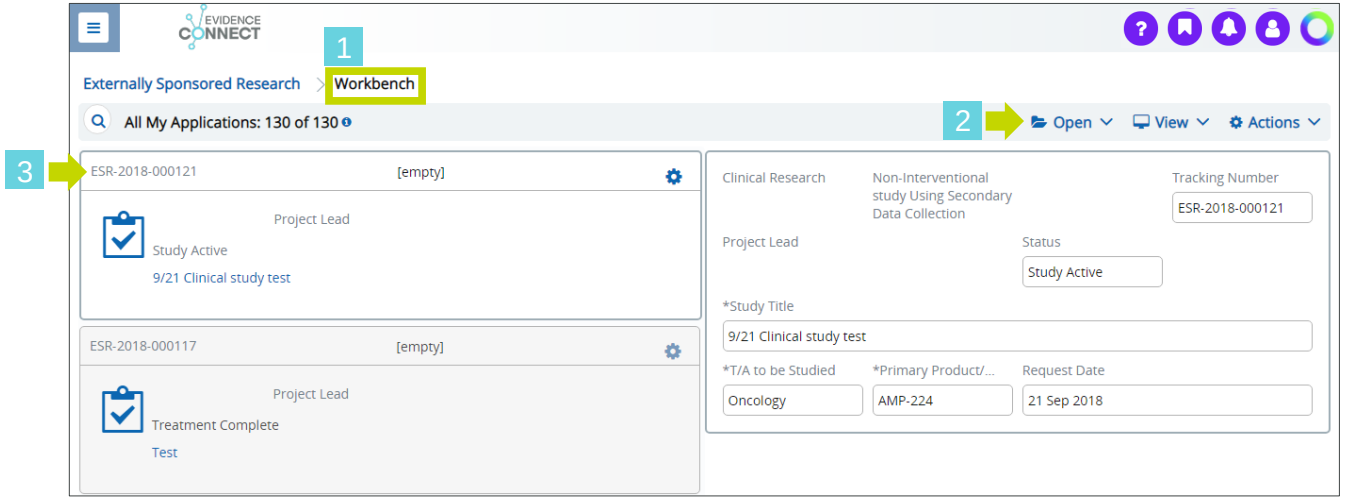
Open — Opens record sets and task groups

View — Toggles between different views

Actions — Lists available actions based on your selection

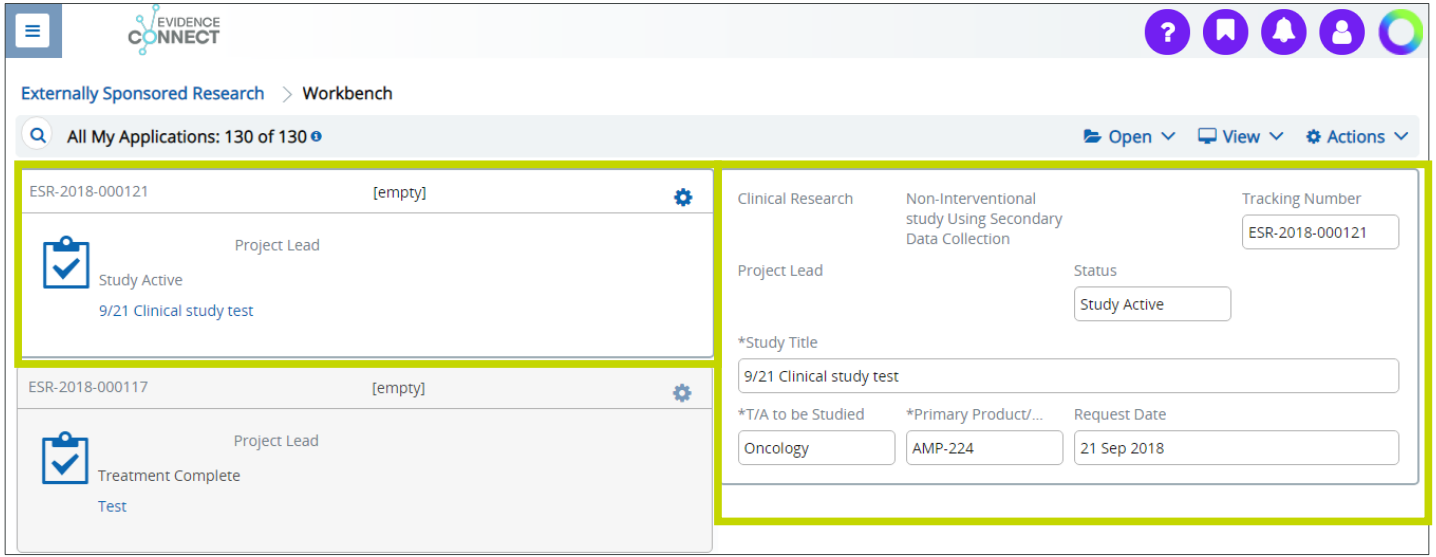
# Navigating the System
## Workbench

1. Your Workbench displays records related to your tasks
2. Groups of records to which you have access are organized into task groups within the Open menu
3. Each record is represented on the Workbench by a task card



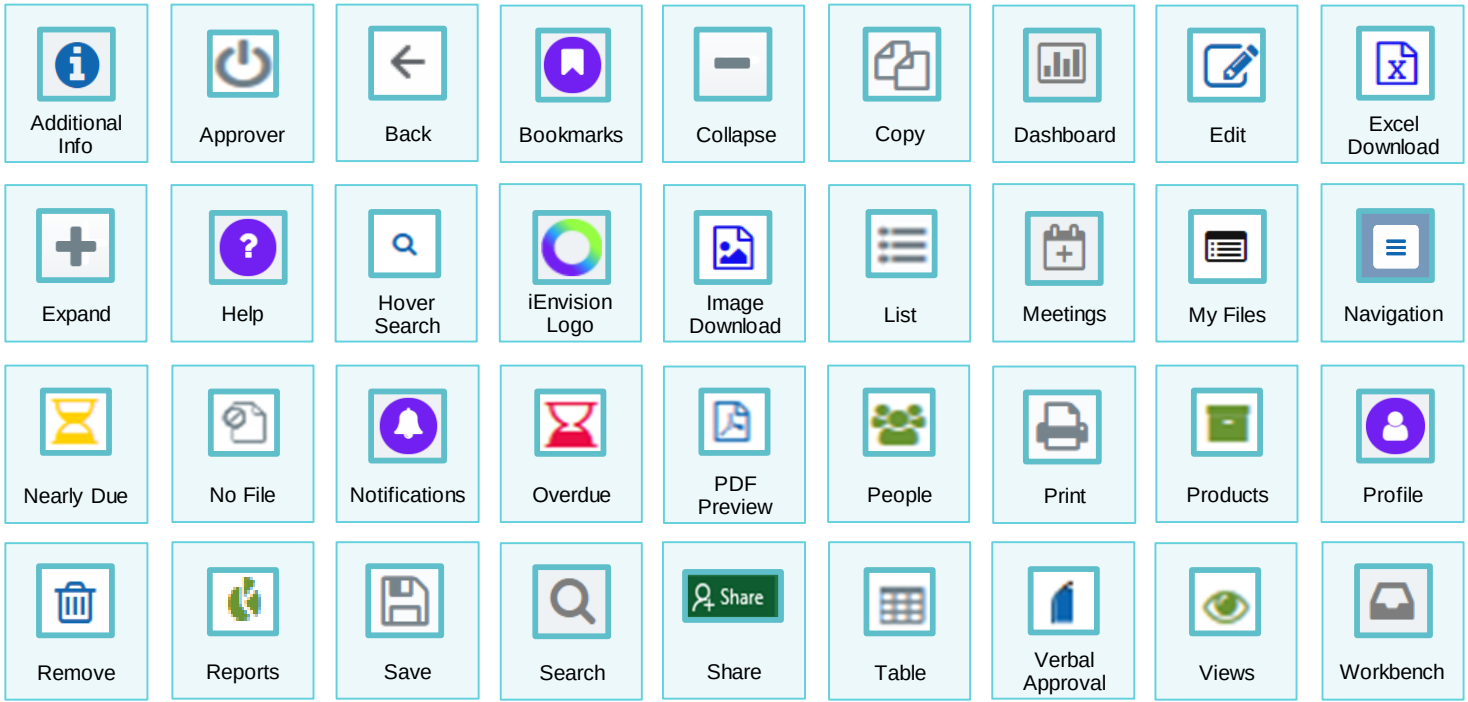
# Navigating the System
## Workbench Preview

- Workbench Preview displays a list of task cards on the left-hand-side of the screen
- When a task card is selected, additional information for that specific project appears in the preview panel on the right-hand-side of the screen



# Navigating the System

## System Icons



# Starting a New Application

- Main Project Type
- Acknowledgement
- Table of Contents
- General Information
- Personnel
- Sites
- Project Outline
- Scientific Summary
- Requested Funding
- Requested Product
- Publication Expectations
- Attachments
- Submission

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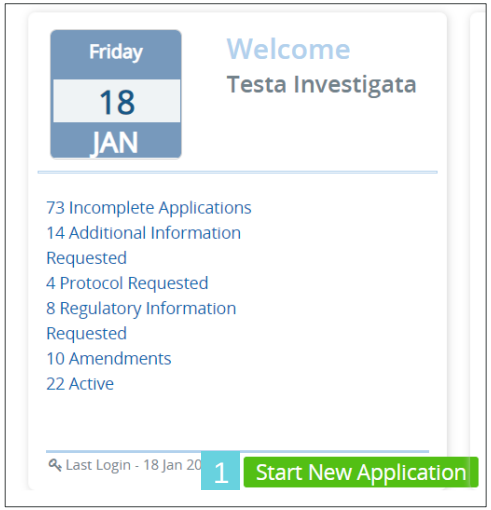
# Starting a New Application

## Main Project Type

1. To start a new application, click **Start New Application** on your Dashboard
2. You will then be prompted to **Select Main Project Type** from the options provided





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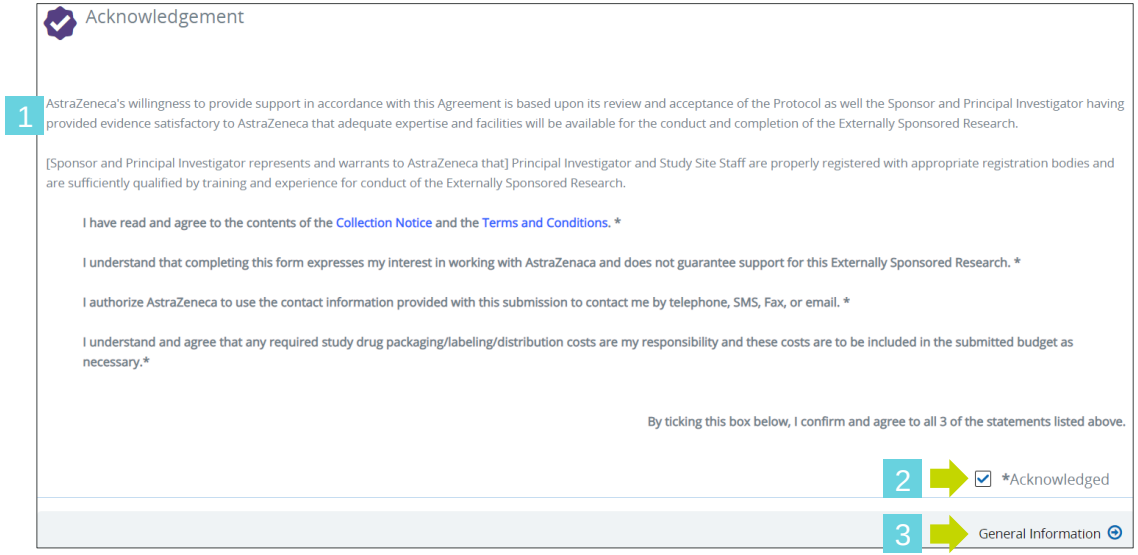
# Starting a New Application

## Acknowledgement

Once the main project type has been chosen, you will be prompted to read AstraZeneca's Acknowledgement statement

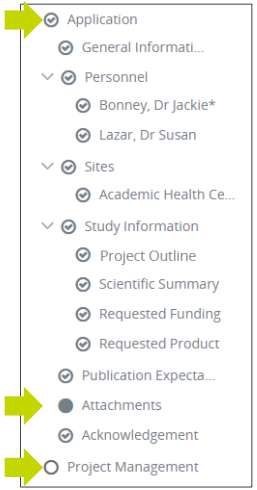
1. Please read these terms and conditions carefully. You must agree to all terms and conditions before you proceed
2. Once you have read the terms and conditions, check the **Acknowledged** box at the bottom of the screen to acknowledge your acceptance
3. Click **General Information** to proceed

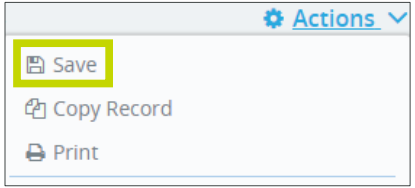


# Starting a New Application

## Table of Contents

- As you progress through the application process, you will see a table of contents on the left-hand-side
- Check marks will appear in the table of contents, denoting successful completion of the node
- The table of contents symbols are as follow:
  - **Empty circle:** Indicates that there are required fields in that node (based on status) that have not yet been completed
  - **Shaded circle:** Indicates that there are no required fields in that node
  - **Check mark in circle:** Indicates that there are required fields in that node (based on status) that have been completed
- As you move from node to node, Evidence Connect will save automatically
- You can also manually save at any time by using the Actions menu

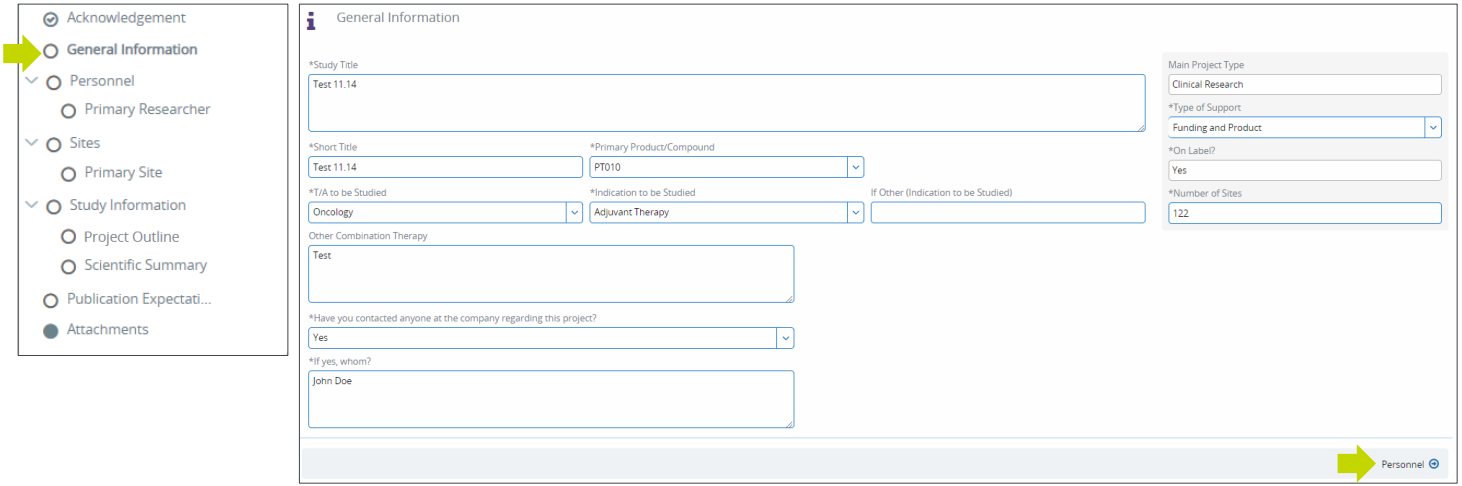


# Starting a New Application

## General Information

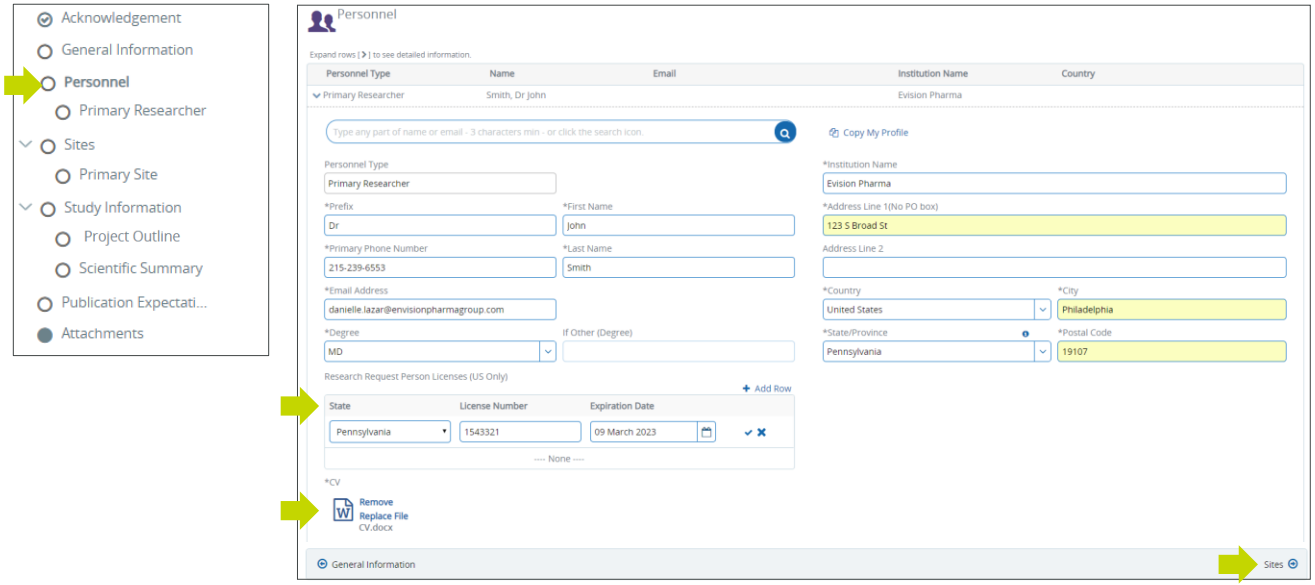
- General Information is the first node to be completed in the application process. Please note that mandatory fields are indicated with an asterisk (*) and must be completed in order to progress the application
- Once all mandatory fields have been completed, click **Personnel** to continue



# Starting a New Application

## Personnel

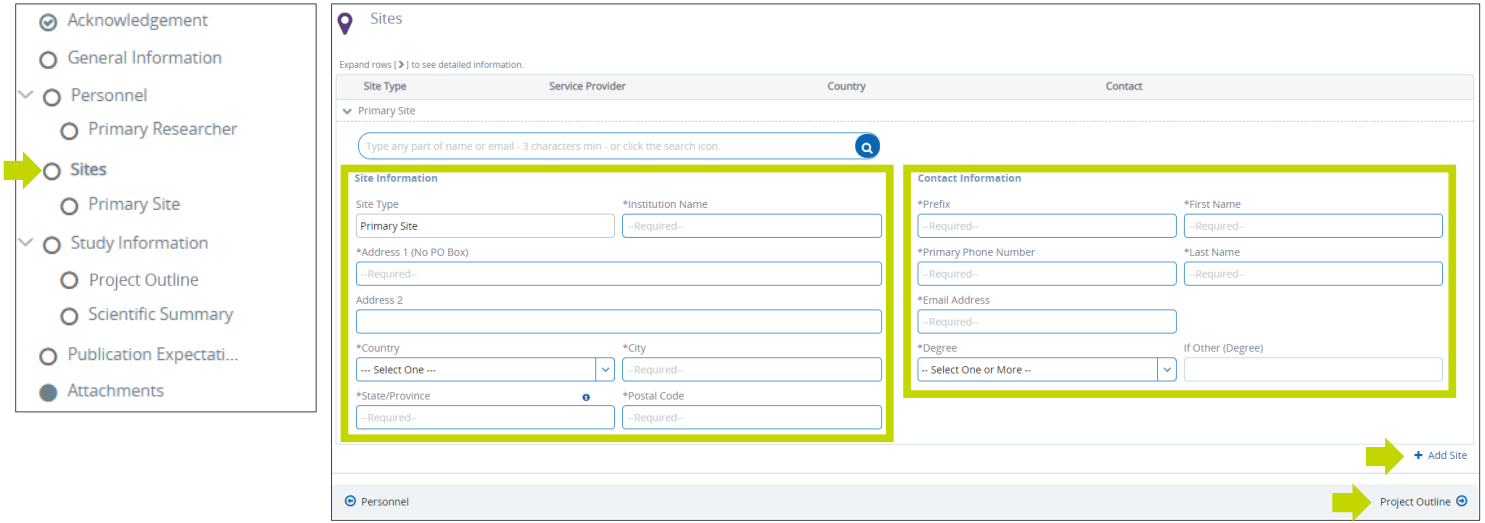
- The next step is to enter information about the Primary Researcher in the Personnel node
- For US-based Researchers, their license information must be entered into the **Research Request Person Licenses (US Only)** table
- Upload the Researcher's CV at the bottom of the screen
- Once all mandatory fields have been completed, click **Sites** to continue



# Starting a New Application

## Sites

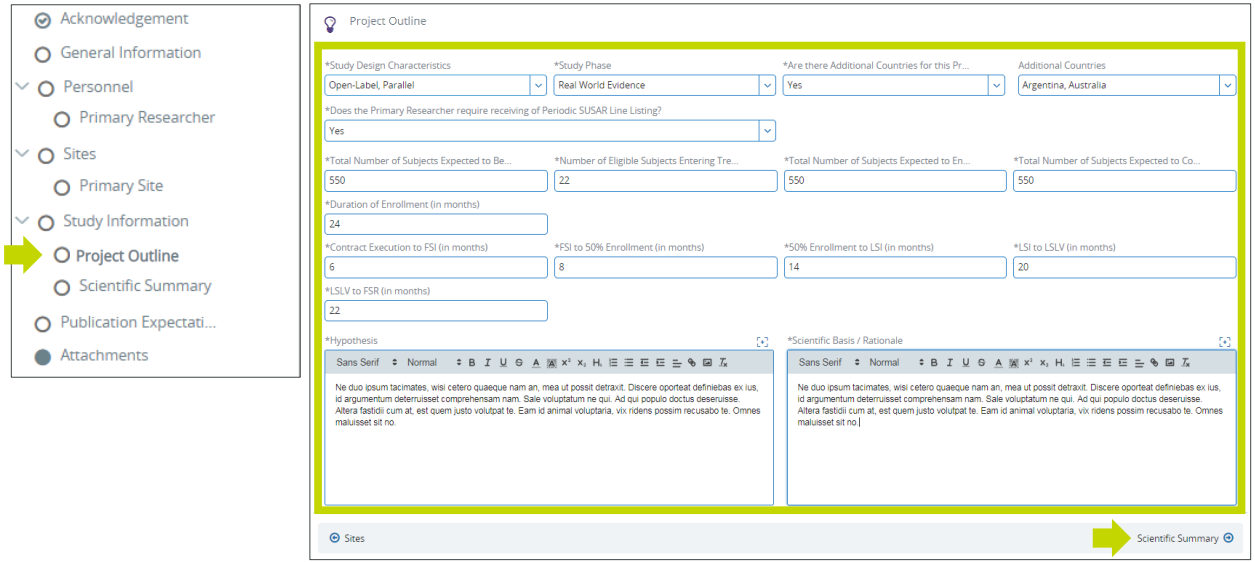
- In the Sites node, you will be required to fill in the details of your Primary Site
- Additional sites can be added by clicking **Add Site** at the bottom right-hand-side of the screen
- Once all mandatory fields have been completed, click **Project Outline** to continue



# Starting a New Application

## Project Outline

- On the Project Outline node, fill in the appropriate information. Required fields are indicated with an asterisk (*)
- Use the drop-down menus to enter study details
- For **Hypothesis** and **Scientific Basis/Rationale**, add text directly into the free text box
- Once the Project Outline node has been completed, click **Scientific Summary** to continue

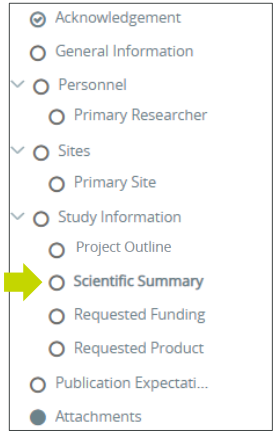


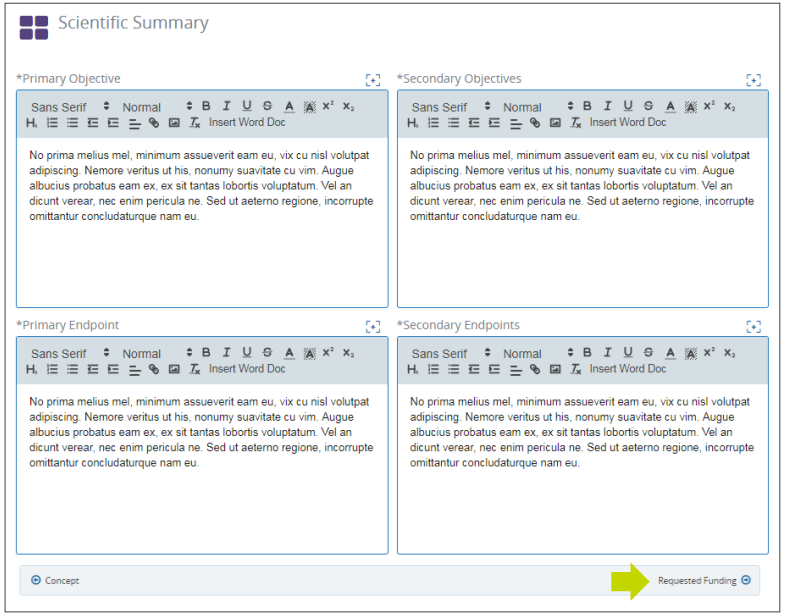
# Starting a New Application

## Scientific Summary

In the Scientific Summary section, you must provide the following study details:

- **Primary Objective**
- **Secondary Objectives**
- **Primary Endpoint**
- **Secondary Endpoints**
- **Inclusion Criteria**
- **Exclusion Criteria**
- **Population**
- **Sample Size Justification/Statistical Power**
- **Treatment Regimen**
- **References**



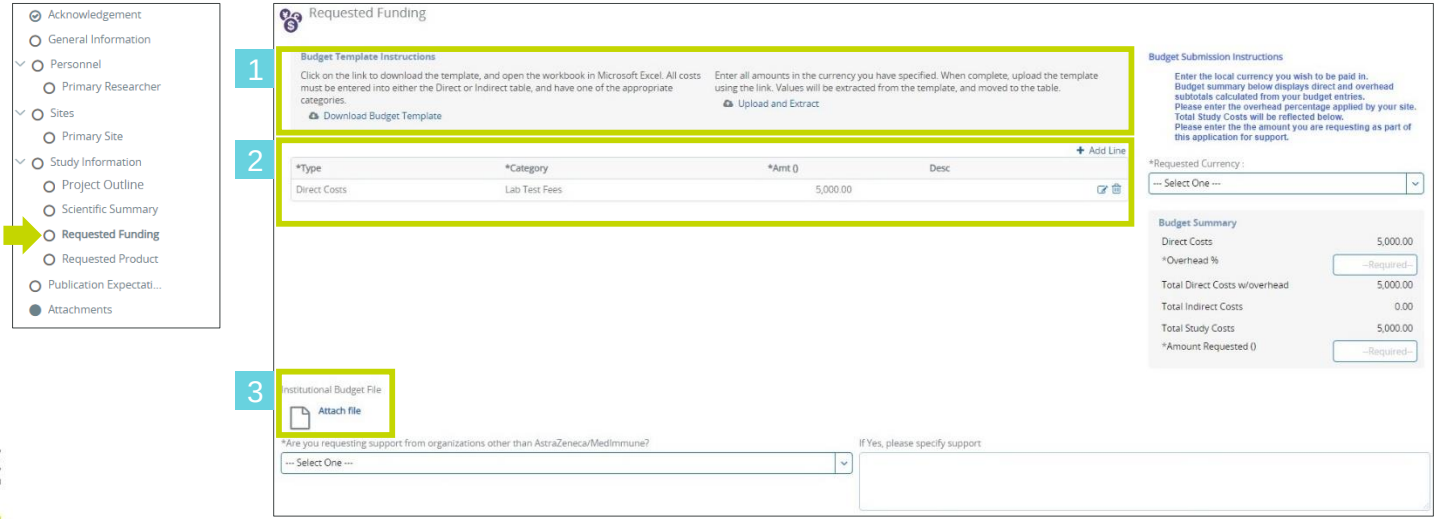




You can enter information directly into the free text box provided

Once the Scientific Summary node has been completed, click **Requested Funding** to continue

# Starting a New Application
## Requested Funding

- Complete the Requested Funding node when you are ready to submit
- You must upload budget information using one of the following three options:
  1. Using the Budget Template
  2. Entering the information manually into the funding table
  3. Uploading an institutional budget using the Attach file link at the bottom of the screen

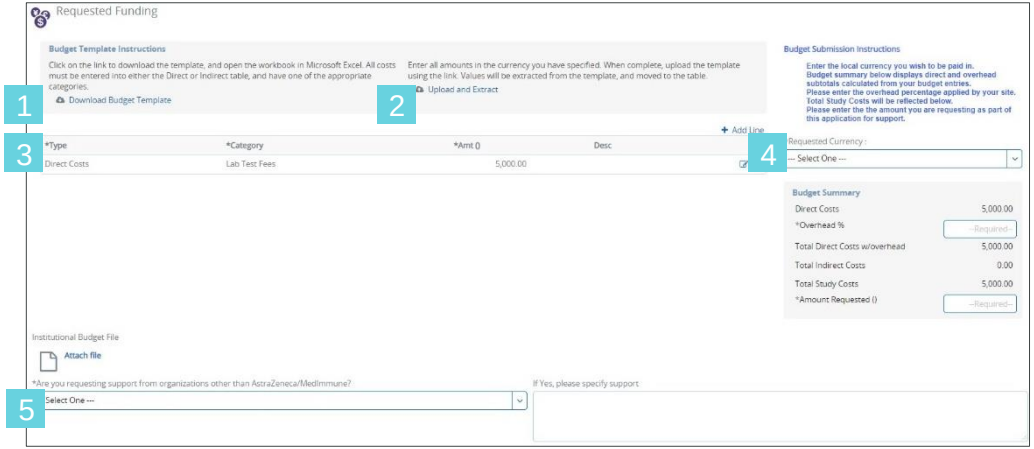


# Starting a New Application

## Requested Funding (continued)

If you choose to use the Budget Template:

1. Click **Download Budget Template** to download an Excel budget template in which you can enter both direct and indirect costs
2. Once completed, save the template to your computer and click **Upload and Extract** to import the data into Evidence Connect
3. All values entered will be extracted and copied to the funding table; you can edit this manually, if necessary
4. Next, select the currency in which you wish to be paid, then enter the overhead percentage and the amount requested
5. Remember to indicate whether you are requesting support from other sources. If Yes, list additional sources of support in the text box provided

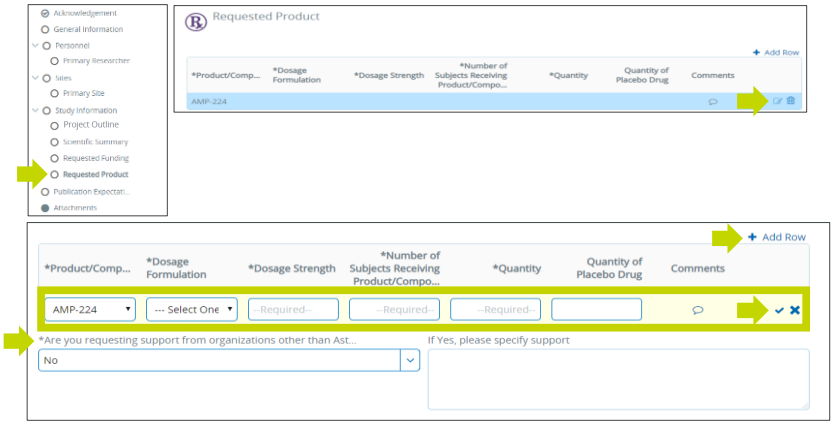


# Starting a New Application

## Requested Product

### Add Requested Product(s)

- The Product/Compound selected on the General Information node will appear in the Requested Product table; click the edit icon to enter the details
  - Select **Dosage Formulation** from the drop-down menu
  - Enter **Dosage Strength**
  - Enter **Number of Subjects Receiving Product/Compound**
  - Enter **Quantity**
  - Enter **Quantity of Placebo Drug** (if applicable)
  - Click the check mark to add the product information to the Requested Product table
- To add additional products, click Add Row
- Use the drop-down menu at the bottom of the screen to indicate if additional support is being sought for the project. There is a free text box where details can be entered



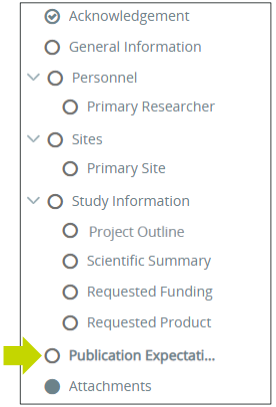
# Starting a New Application

## Publication Expectations

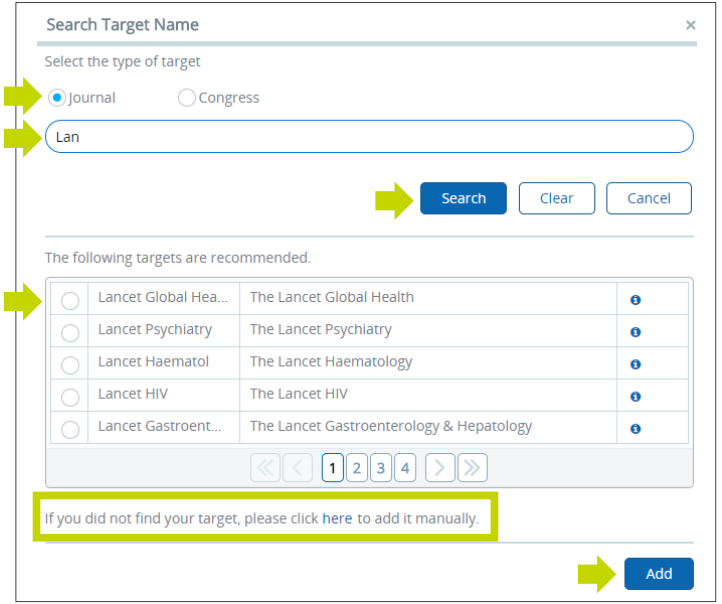
Enter details about any planned publications on the Publication Expectations node

Adding a Journal/Congress:

- Click **Add Journal/Congress** to open the Search Target Name window
- Enter the name or first few letters of the journal or congress you wish to add and click **Search**
- Select your target from the list and click **Add**
- If your target does not appear, use the link at the bottom of the window to enter the information manually
- If the publication or congress is not yet decided, enter TBD



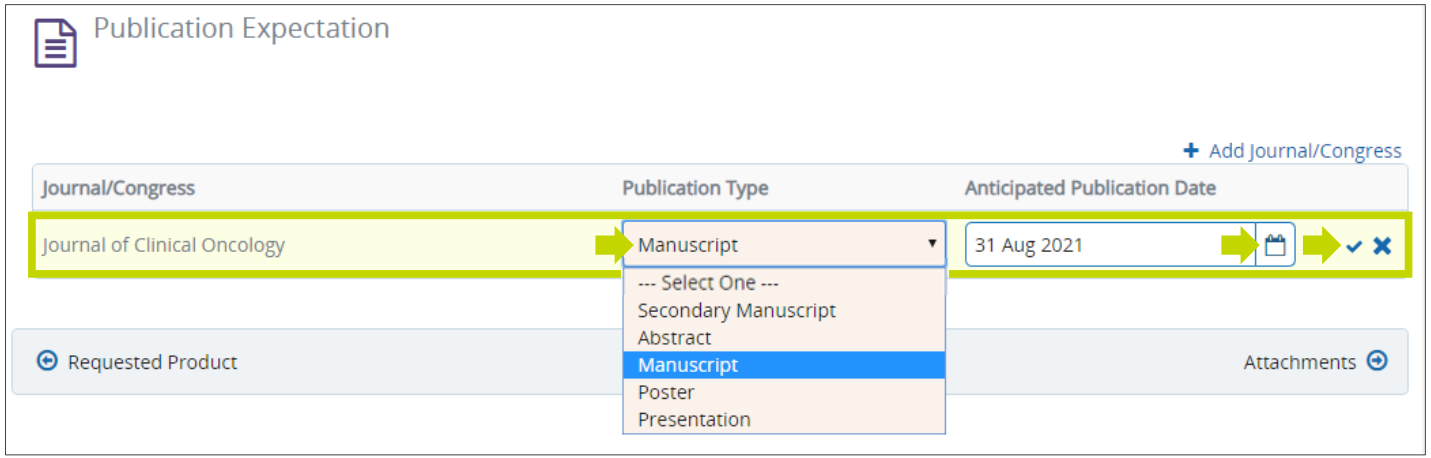




# Starting a New Application

## Publication Expectations (continued)

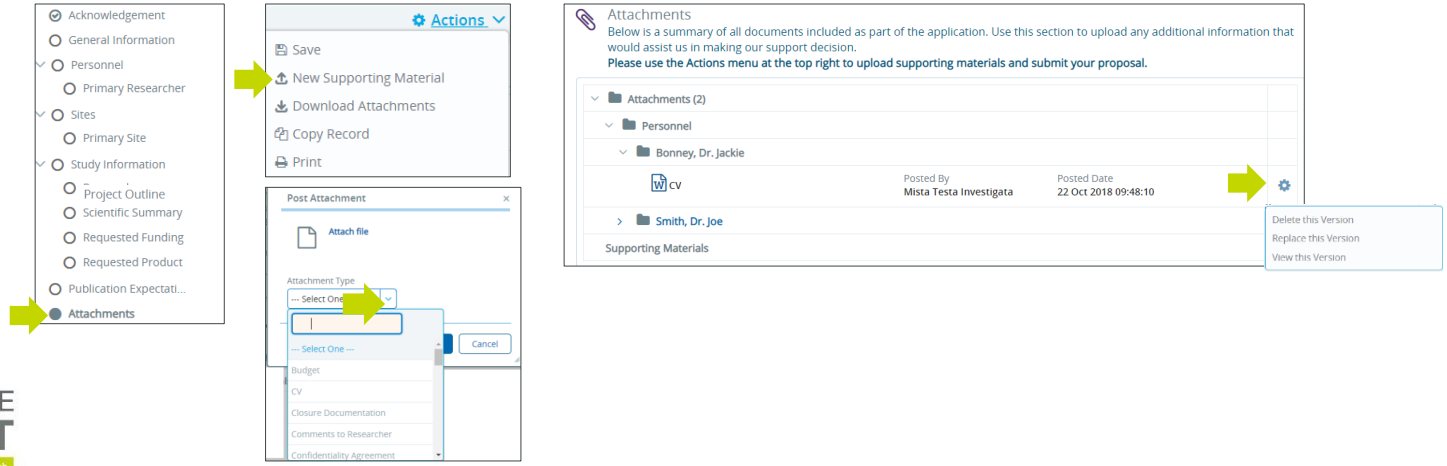
- The new publication will now appear in the Journal/Congress table
  - Select the **Publication Type** from the drop-down menu
  - Add the **Anticipated Publication Date**
  - Click the check mark to save
- Repeat to add additional publications



# Starting a New Application

## Attachments

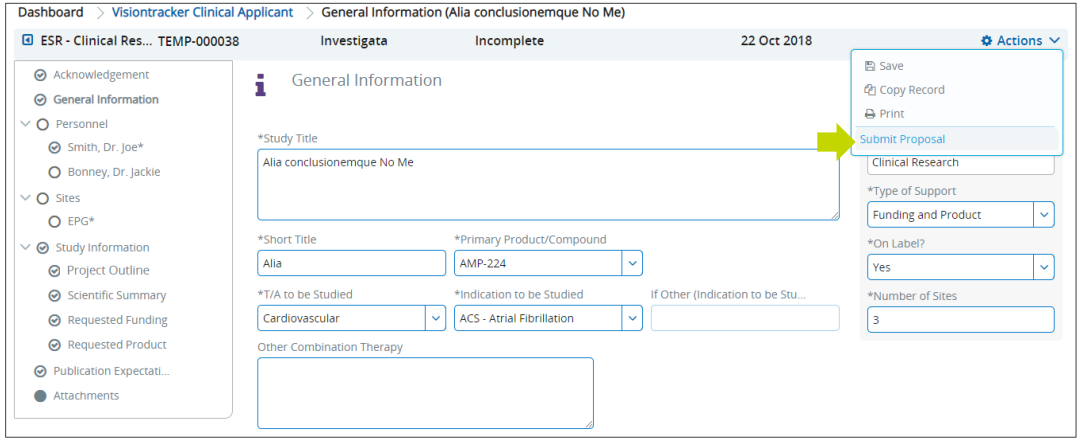
- Use the Attachments node to store project documentation such as study reports, invoices, and Institutional Review Board information. Upload a new document by selecting **New Supporting Material** from the Actions menu
- Select the **Attachment Type** from the drop-down menu, choose the file from your computer, and click **Post**
- By clocking the gear icon next to an existing attachment, you can: Delete the current version, Replace the current version, or View the current version
- The system will save all document versions for auditing purposes

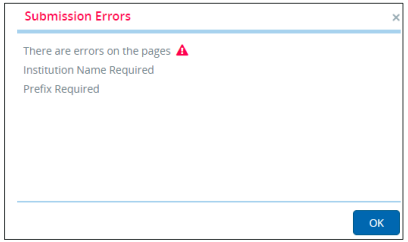


# Starting a New Application

## Submission

- Once all required information has been entered, select **Submit Proposal** from the Actions menu
- If you attempt to submit with required data missing, a new window will open that lists the fields requiring information and an exclamation mark will appear in the table of contents next to the node or nodes that require additional data
- Upon submission, you will no longer be able to edit your application. You will receive a notification confirming the submission, and the application status will change to Submitted



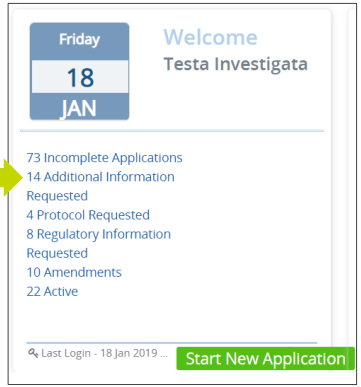
# Post-Submission

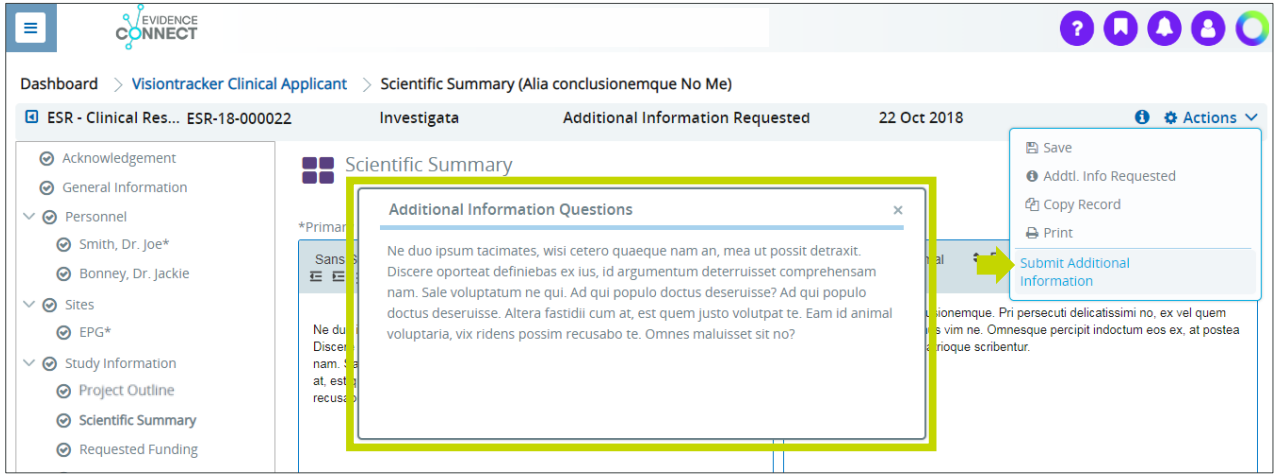
- Request for Additional Information
- Submit Protocol
- Project Status Updates
- Milestone Updates
- Product Shipment
- Regulatory Update
- Publication Activity
- Amendments
- Additional Documentation
- Project Closed Status

# Post-Submission

## Request for Additional Information

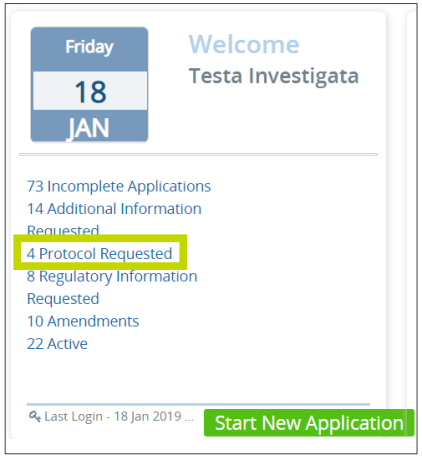
- During the review process, you may be asked to provide additional information regarding your application
  - You will receive a notification asking you to log in and provide additional information
  - The new task will be listed on your Dashboard Welcome Widget
  - Open the application and the **Additional Information Questions** window will appear
- The application is now open for editing; make any necessary changes and then select **Submit Additional Information** from the Actions menu



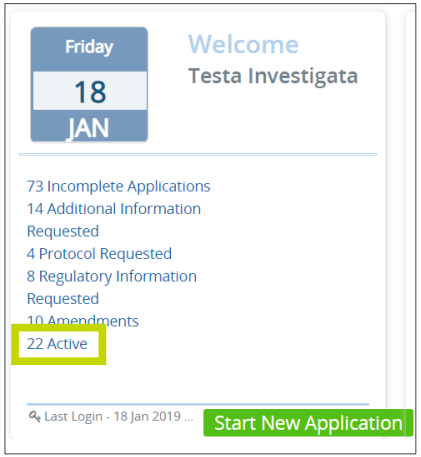
# Post-Submission
## Submit Protocol

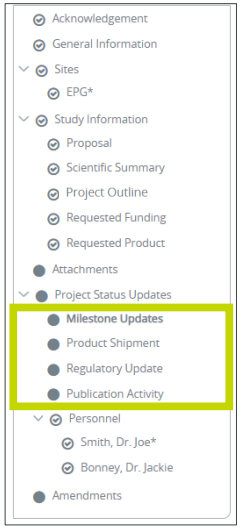
- You will receive a notification when the proposal has been approved. This communication will contain additional instructions asking you to log in to the system and submit a protocol and any other applicable study documents
- The new task will appear on your Dashboard Welcome Widget
- The application will open to the new Protocol node. Upload the protocol and any other additional documentation, then select **Submit Protocol** from the Actions menu




# Post-Submission
## Project Status Updates

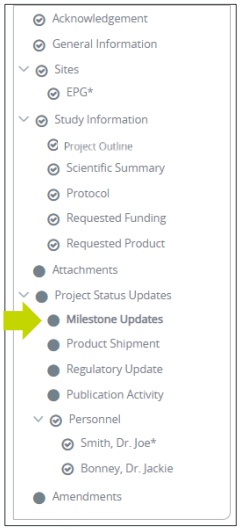
- Once the study is active, you will be required to submit **Project Status Updates** as outlined in your Research Agreement
  - Each new task will be listed on your Dashboard Welcome Widget
- There are a number of additional nodes now active in the application
  - Select the type of Project Status Update you would like to provide:
    - Milestone Updates
    - Product Shipment
    - Regulatory Update
    - Publication Activity

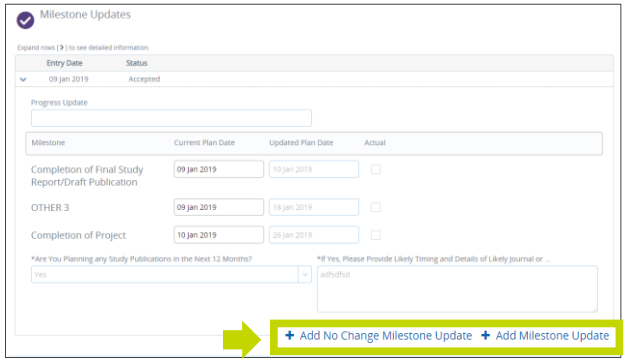


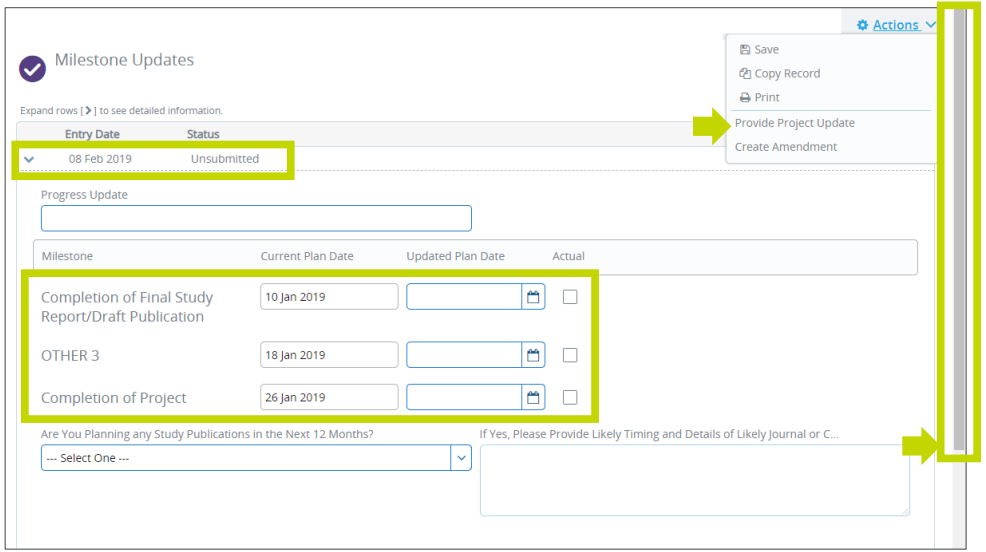



# Post-Submission
## Milestone Updates

- From the Milestone Updates node, click **Add Milestone Update**. Update the enrollment and milestone numbers, and answer the questions at the bottom of the screen. Select **Provide Project Update** from the Actions menu to submit

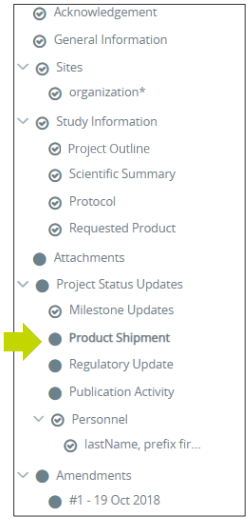


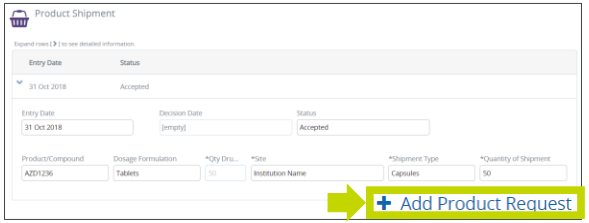



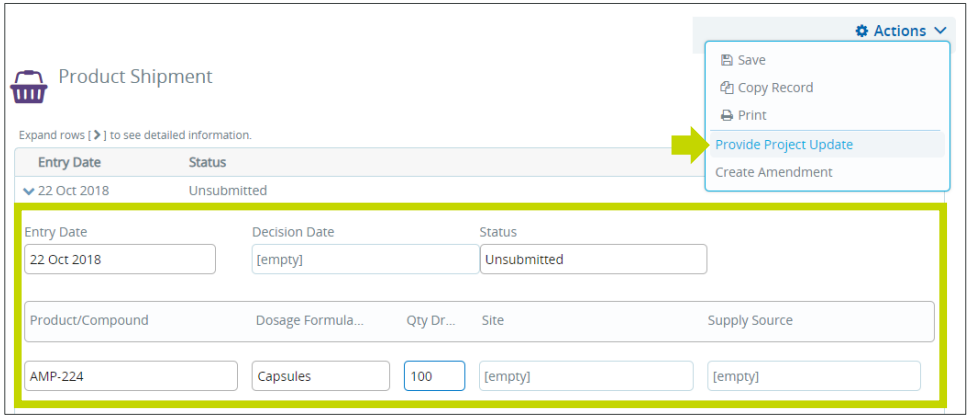



# Post-Submission
## Product Shipment

- Enter new requests in the Product Shipment node; all approved products will be listed. Select **Provide Project Update** from the Actions menu to submit

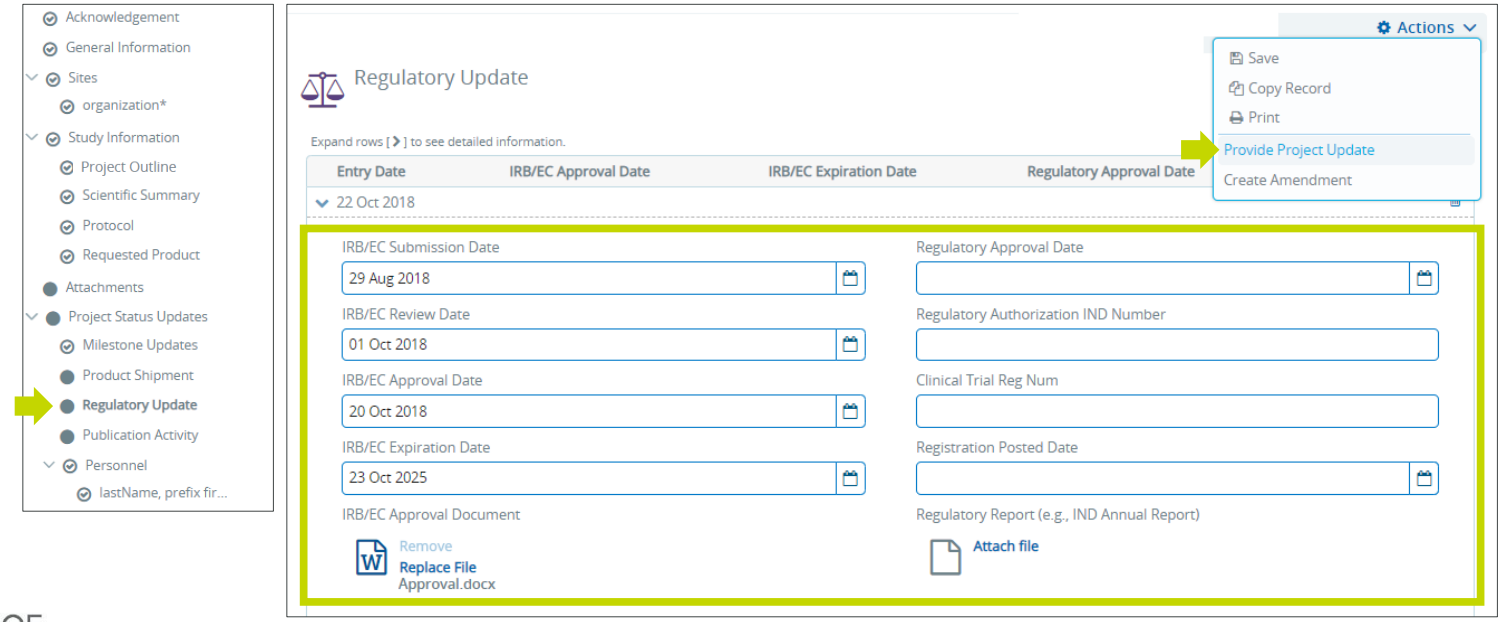


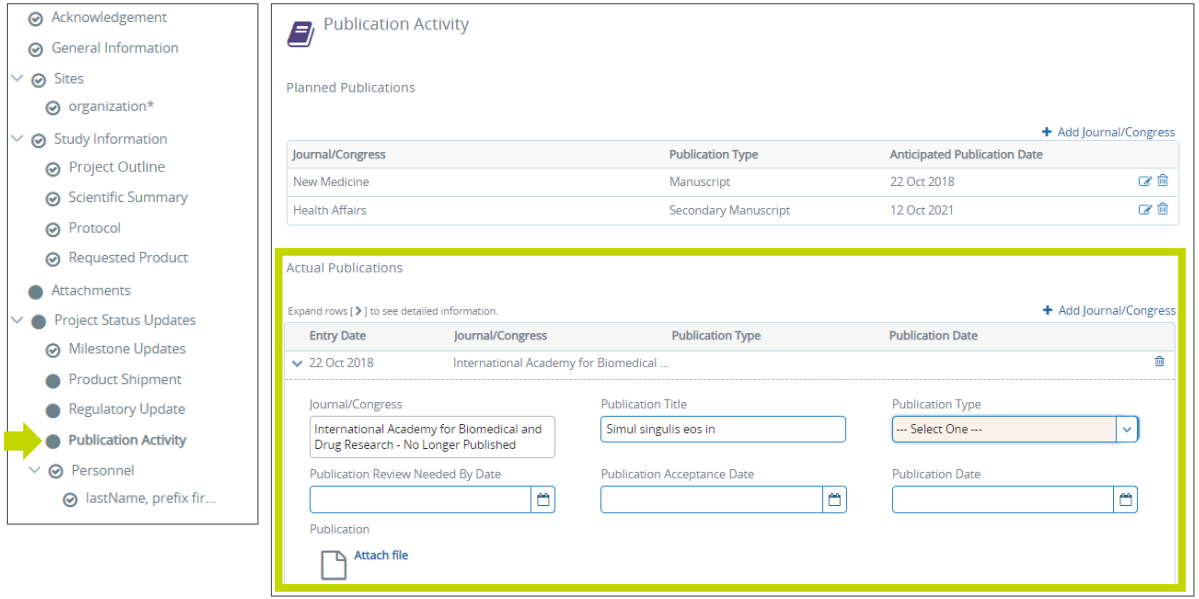
# Post-Submission
## Regulatory Update

- Click the Regulatory Update node to add required regulatory documentation. Enter key data and upload documents. Select **Provide Project Update** from the Actions menu to submit



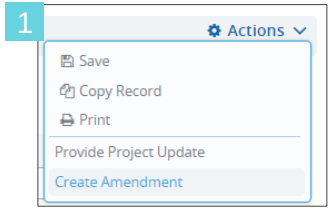
# Post-Submission
## Publication Activity

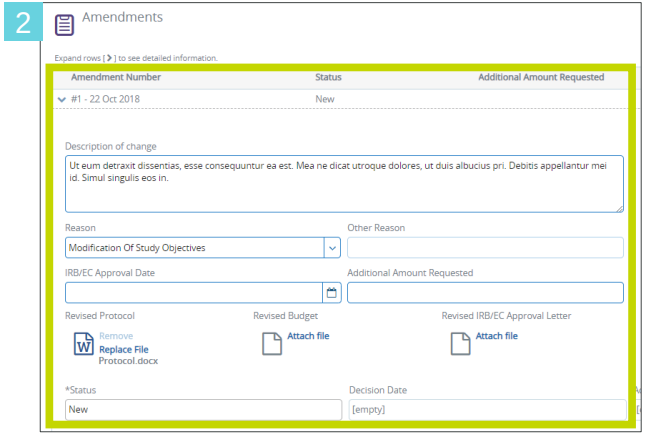
- The Publication Activity node contains both planned and actual publications. You will see that the data entered in the Publication Expectations node is also listed here
  - To enter the actual publication(s), click **Add Journal/Congress** to open the Search Target window, enter the name, and select the publication

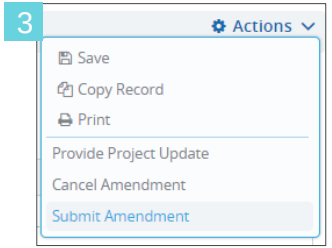


# Post-Submission
## Amendments

- If any changes to the protocol or budget are needed once the study is active, you will need to create an amendment
  1. Select **Create Amendment** from the Actions menu
  2. Enter the description of the change in the free text box and select the reason for the change from the drop-down menu. Upload any protocol or budget amendments, as well as any supporting materials
  3. After all pertinent information has been entered, click **Submit Amendment** from the Actions menu
- A confirmation notification will appear when the amendment has been submitted successfully

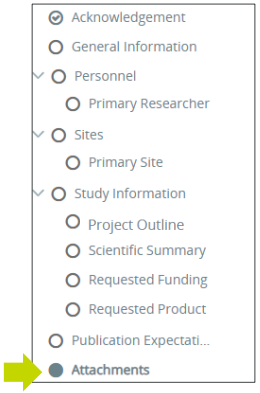


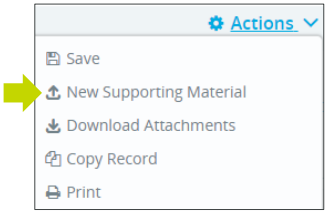



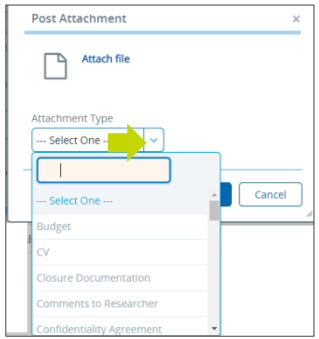



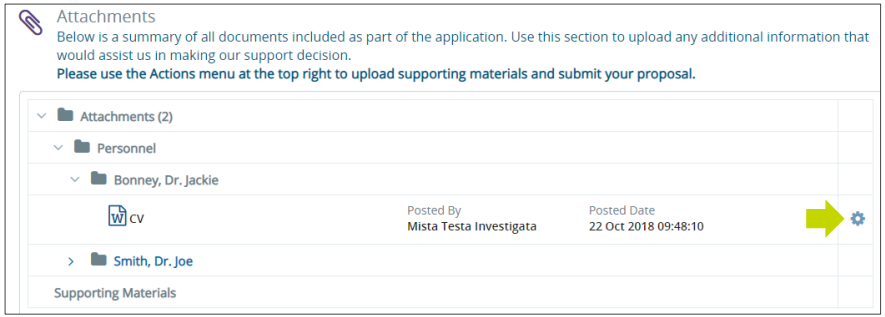
# Post-Submission
## Additional Documentation

- As stated in the Research Agreement, once the study has been completed you are required to provide additional documentation. This may include final study reports, closure reports, drug destruction documents and/or data sets
- Upload these documents on the Attachments node



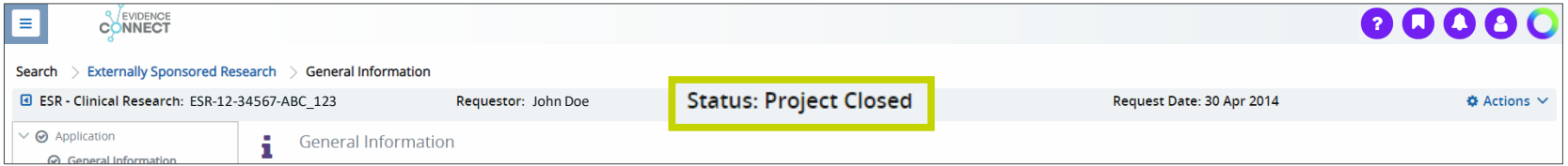



# Post-Submission

## Project Closed Status

- When all final information is uploaded into the system, the Local Coordinator will update the status to Project Closed
- The project is no longer active, but can always be viewed for reference



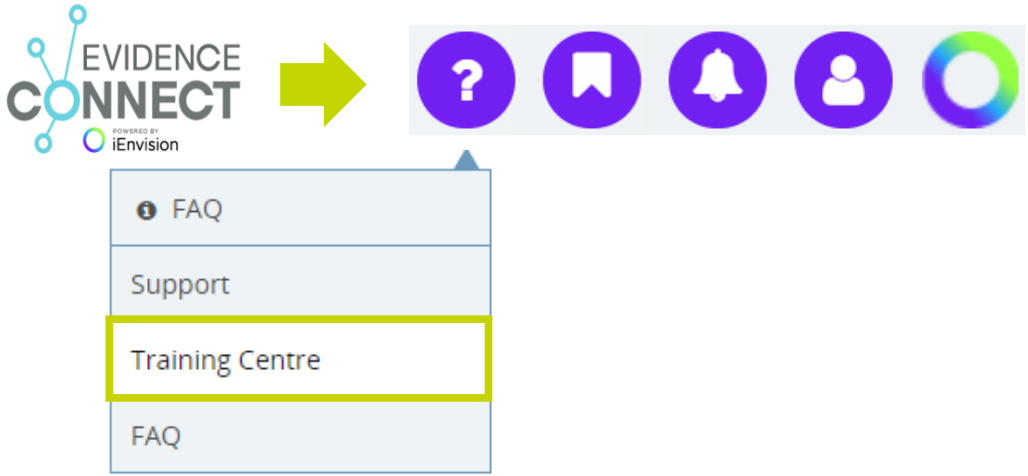
# Training Materials

- Evidence Connect Training Centre
- Videos

# Training Materials

## Evidence Connect Training Centre

- The Evidence Connect Training Centre can be accessed by clicking the ? icon at the top right-hand-side of the screen



# Training Materials

## Videos



- Navigation Evidence Connect
- Submitting a New Application
- Project Status Updates
- Project Close Out