

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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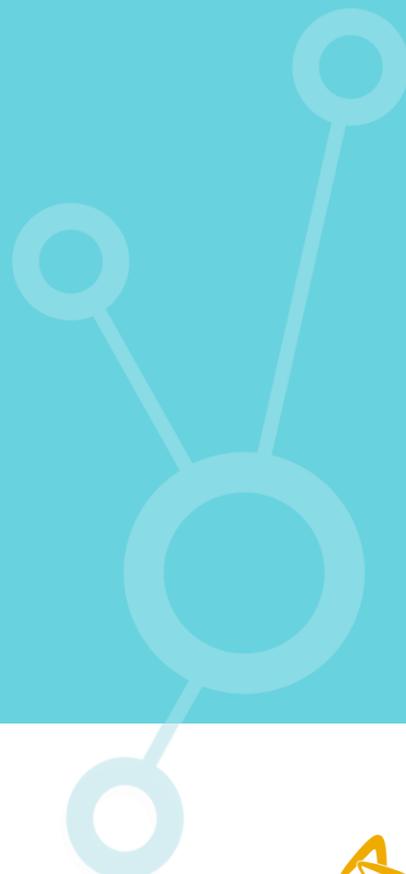
Training Materials





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

Welcome to Evidence Connect

This platform supports the submission, management and operations of requests from registered external partners. Once you complete the registration process, you may request and manage submissions for either of our external partner programs outlined below. Please note, submission does not guarantee acceptance of your proposal or request.

Externally sponsored scientific research

Externally sponsored research is research that is initiated and managed by a Non-Company Researcher who assumes the legal and regulatory responsibility for the conduct and management of the research as defined by applicable regulations and laws of the country involved.

Early access programmes

We recognise that there are circumstances where patients with serious or life-threatening diseases have exhausted all available therapeutic options and may not be eligible to enroll in one of our clinical trials. In such circumstances individual patients may be eligible for early access to an AstraZeneca or Medimmune investigational medicinal product through our Early Access programmes.

Privacy Notice: We value your privacy. By using this website, you confirm that you have read, understood and accept the [AstraZeneca \(the Company\) Privacy Policy](#).

System Login

User Name:

Password:

[Register for New Account](#)
[Forgot Password?](#)

Contact Us

Email: astaznec@connect.essros.com

User Registration

Right-Click to add text

Name Prefix *First Name *Email Address *Confirm Email

Middle Name *Last Name *Password *Confirm Password

Name Suffix Organization My preferred language is Time Zone

Address Line 1

I agree to the Terms and Conditions

Address Line 2

Country City

State/Province ZIP Code

Primary Phone Number





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

The screenshot displays the Evidence Connect website interface. On the left, the navigation menu includes 'Home', 'Externally Sponsored Research', and 'Early Access Programmes'. The main content area features a 'Welcome to Evidence Connect' message and sections for 'Externally sponsored scientific research' and 'Early access programmes'. On the right, the 'System Login' form is highlighted with a yellow border, showing fields for 'User Name' and 'Password', a 'Log In' button, and a 'Register for New Account' link. Below it is a 'Contact Us' section with an email address. To the right of the login form is the 'Forgot Password' form, also highlighted with a yellow border, which includes a text input for 'Login ID', a dropdown for 'Security Question 1', and a text input for 'Answer'. A 'Submit' button and a 'Cancel' button are located at the bottom right of the forgot password form.





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)

EVIDENCE CONNECT Externally Sponsored Research Portal

Dashboard > Visiontracker Clinical Applicant

Visiontracker Clinical Applicant Open View

Monday
22
OCT

Welcome
Testa
Investigata

2 Applications Available for Project Status Update
2 Applications to Complete
15 Total Applications

Last Login - 19 Oct 2... Start New Application

Recent

Tracking Number	Requestor	Primary Product/Compound	Status Group
ESR-18-000021	Investigata, Mista Testa	Pramlintide Acetate	Study Active
ESR-18-000019	Investigata, Mista Testa	Pramlintide Acetate	Study Active
TEMP-000033	Investigata, Mista Testa	Pramlintide Acetate	Incomplete
ESR-18-000020	Investigata, Mista Testa	Pramlintide Acetate	Submitted
ESR-18-000010	Investigata, Mista Testa	AMP-224	Under Review
ESR-18-000014	Investigata, Mista Testa	Pramlintide Acetate	Submitted
ESR-18-000015	Investigata, Mista Testa	Pramlintide Acetate	Start Amendment Approval
ESR-18-000017	Investigata, Mista Testa	AMP-224	Submitted
TEMP-000022	Investigata, Mista Testa	AMP-224	Incomplete
ESR-18-000016	Investigata, Mista Testa	AZD0328	Submitted

View All





Navigating the System

Navigation Overview

Navigation Icon → [Menu Icon]

Breadcrumbs → Externally Sponsored Research > Workbench

Context Bar → All My Applications: 130 of 130

Global Tools → [Help, Bookmarks, Notifications, Profile, Settings icons]

Context Menus → [Open, View, Actions dropdowns]

Task Cards → [List of application cards]

Gear Icons → [Settings icons on task cards]

ESR-2018-000121	[empty]	Clinical Research	Non-Interventional study Using Secondary Data Collection	Tracking Number
<input checked="" type="checkbox"/> Study Active 9/21 Clinical study test	Project Lead	Project Lead	Status Study Active	ESR-2018-000121
ESR-2018-000117	[empty]	*Study Title	9/21 Clinical study test	
<input checked="" type="checkbox"/> Treatment Complete Test	Project Lead	*T/A to be Studied	*Primary Product/...	Request Date
		Oncology	AMP-224	21 Sep 2018



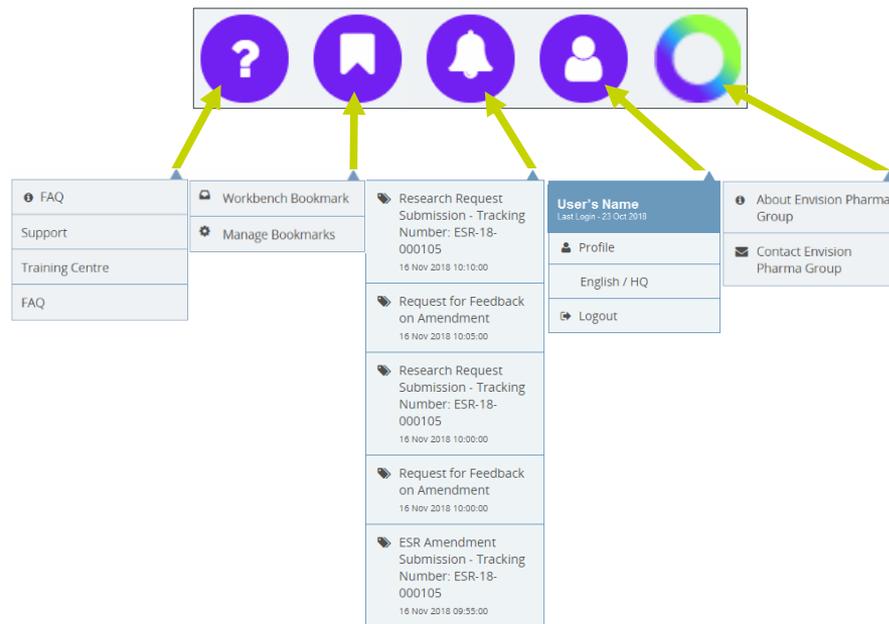


Navigating the System

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

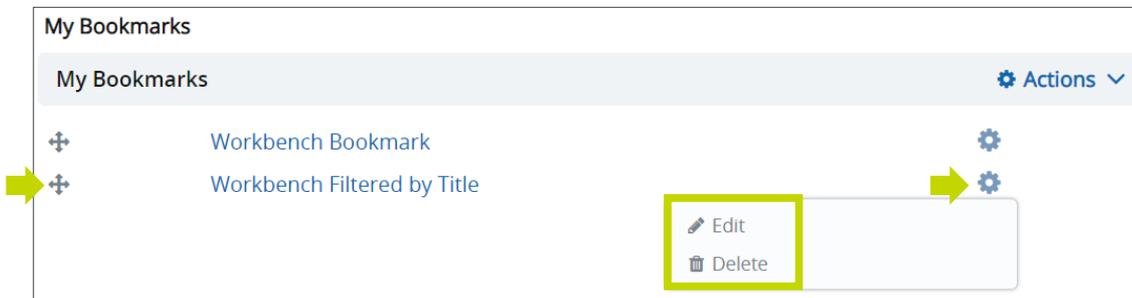
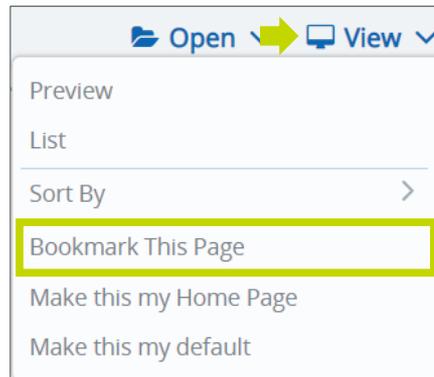
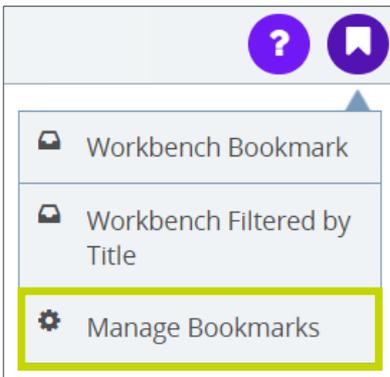




Navigating the System

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

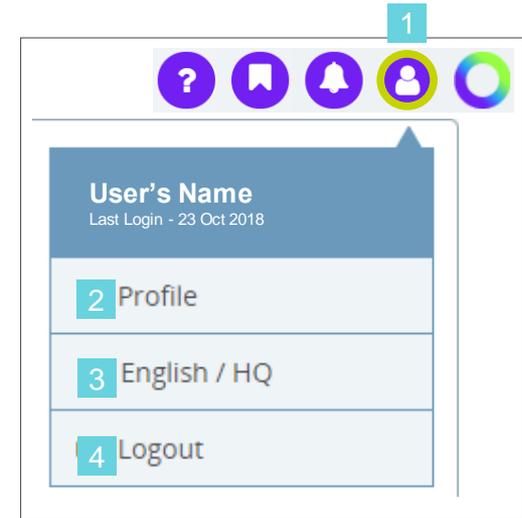




Navigating the System

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





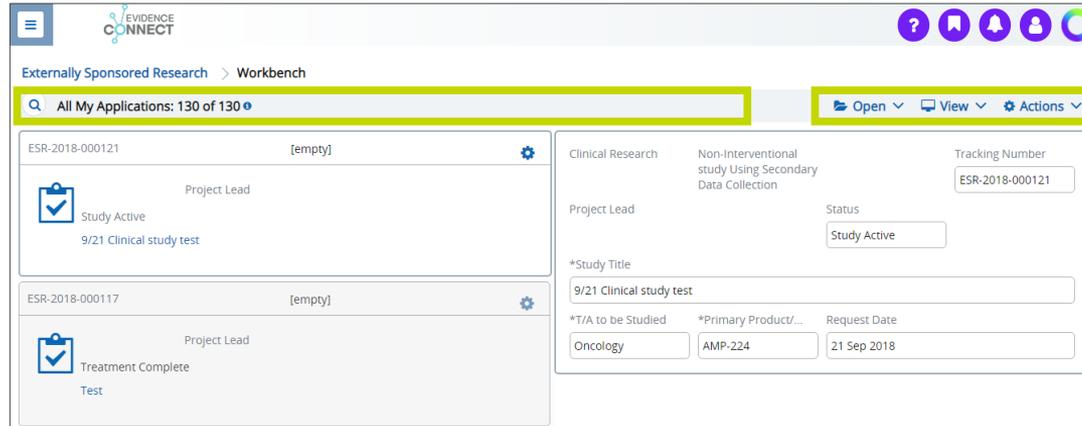
Navigating the System

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



The screenshot shows the Evidence Connect Workbench interface. At the top, there is a navigation bar with the Evidence Connect logo and user icons. Below this is a breadcrumb trail: "Externally Sponsored Research > Workbench". The Context Bar is highlighted with a yellow border and contains a search bar with the text "All My Applications: 130 of 130" and three dropdown menus: "Open", "View", and "Actions". Below the Context Bar, there are two application cards. The first card is for application ESR-2018-000121, with a status of "Study Active" and a project lead of "9/21 Clinical study test". The second card is for application ESR-2018-000117, with a status of "Treatment Complete" and a project lead of "Test". To the right of these cards is a detailed view for the selected application, showing fields for "Clinical Research", "Non-Interventional study Using Secondary Data Collection", "Tracking Number" (ESR-2018-000121), "Project Lead", "Status" (Study Active), "*Study Title" (9/21 Clinical study test), "*T/A to be Studied" (Oncology), "*Primary Product/..." (AMP-224), and "Request Date" (21 Sep 2018).

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

The screenshot displays the Evidence Connect Workbench interface. At the top, the 'EVIDENCE CONNECT' logo is visible. The navigation path is 'Externally Sponsored Research > Workbench', with 'Workbench' highlighted by a yellow box and a blue '1' callout. Below the navigation, a search bar shows 'All My Applications: 130 of 130'. To the right of the search bar are buttons for 'Open', 'View', and 'Actions', with a blue '2' callout and a yellow arrow pointing to the 'Open' button. The main area contains two task cards. The first card, for application ESR-2018-000121, is highlighted by a yellow box and a blue '3' callout with a yellow arrow. It shows a 'Study Active' status with a checkmark icon and the text '9/21 Clinical study test'. The second card, for application ESR-2018-000117, shows a 'Treatment Complete' status with a checkmark icon and the text 'Test'. To the right of the task cards is a detailed view of the selected study (ESR-2018-000121). This view includes fields for 'Clinical Research', 'Non-Interventional study Using Secondary Data Collection', 'Tracking Number' (ESR-2018-000121), 'Project Lead', 'Status' (Study Active), '*Study Title' (9/21 Clinical study test), '*T/A to be Studied' (Oncology), '*Primary Product/...' (AMP-224), and 'Request Date' (21 Sep 2018).





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

The screenshot displays the Evidence Connect Workbench interface. At the top, there is a navigation bar with the Evidence Connect logo, a hamburger menu, and several utility icons (help, bookmark, notifications, user profile, and refresh). Below the navigation bar, the breadcrumb path reads "Externally Sponsored Research > Workbench". A search bar shows "All My Applications: 130 of 130" with filters for "Open", "View", and "Actions".

The main content area is divided into two panels. The left panel shows a list of applications:

- Application ESR-2018-000121: [empty] (gear icon). Project Lead: Study Active. 9/21 Clinical study test.
- Application ESR-2018-000117: [empty] (gear icon). Project Lead: Treatment Complete. Test.

The right panel shows the detailed view for the selected application (ESR-2018-000121):

- Clinical Research: Non-Interventional study Using Secondary Data Collection. Tracking Number: ESR-2018-000121.
- Project Lead: Status: Study Active.
- *Study Title: 9/21 Clinical study test.
- *T/A to be Studied: Oncology. *Primary Product/...: AMP-224. Request Date: 21 Sep 2018.





Navigating the System

System Icons

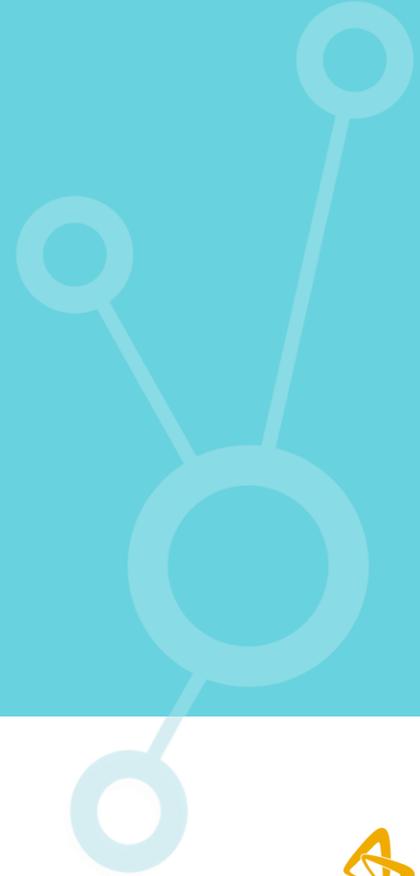
 Additional Info	 Approver	 Back	 Bookmarks	 Collapse	 Copy	 Dashboard	 Edit	 Excel Download
 Expand	 Help	 Hover Search	 iEnvision Logo	 Image Download	 List	 Meetings	 My Files	 Navigation
 Nearly Due	 No File	 Notifications	 Overdue	 PDF Preview	 People	 Print	 Products	 Profile
 Remove	 Reports	 Save	 Search	 Share	 Table	 Verbal Approval	 Views	 Workbench





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](#)





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

Friday
18
JAN

Welcome
Testa Investigata

73 Incomplete Applications
14 Additional Information Requested
4 Protocol Requested
8 Regulatory Information Requested
10 Amendments
22 Active

Last Login - 18 Jan 20 **1 Start New Application**

Application Type

2 Select Main Project Type

- Clinical Research**
Interventional Clinical Research (Phase I - IV) using authorised (marketed), unauthorised (Investigational Medicinal Products, IMP), or discontinued (no longer being developed by the Company) compounds.
- Observational Research**
Observational Research based on the use of Real World Evidence (RWE) -- the product of interventional or non-interventional research -- utilising data collected through observation of current clinical practice and/or patient reported experience.
- Non-Clinical Research**
Non-Clinical Research using in vitro, in vivo or ex-vivo research for compounds in Phase III development and authorised (marketed) compounds. Examples of non-clinical research includes but is not limited to Pharmacodynamic, Pharmacokinetic, Animal Research, Microbiologic, Human Biological Samples (for example, biomarker, diagnostic assay).





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

 Acknowledgement

1 AstraZeneca's willingness to provide support in accordance with this Agreement is based upon its review and acceptance of the Protocol as well the Sponsor and Principal Investigator having provided evidence satisfactory to AstraZeneca that adequate expertise and facilities will be available for the conduct and completion of the Externally Sponsored Research.

[Sponsor and Principal Investigator represents and warrants to AstraZeneca that] Principal Investigator and Study Site Staff are properly registered with appropriate registration bodies and are sufficiently qualified by training and experience for conduct of the Externally Sponsored Research.

I have read and agree to the contents of the [Collection Notice](#) and the [Terms and Conditions](#). *

I understand that completing this form expresses my interest in working with AstraZeneca and does not guarantee support for this Externally Sponsored Research. *

I authorize AstraZeneca to use the contact information provided with this submission to contact me by telephone, SMS, Fax, or email. *

I understand and agree that any required study drug packaging/labeling/distribution costs are my responsibility and these costs are to be included in the submitted budget as necessary.*

By ticking this box below, I confirm and agree to all 3 of the statements listed above.

2  *Acknowledged

3  [General Information](#) 



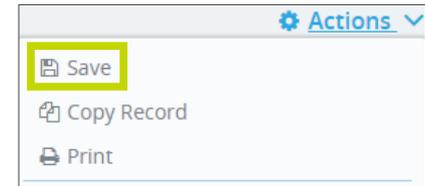


Starting a New Application

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

- ☑ Application
- ☑ General Informati...
- ▼ ☑ Personnel
 - ☑ Bonney, Dr Jackie*
 - ☑ Lazar, Dr Susan
- ▼ ☑ Sites
 - ☑ Academic Health Ce...
- ▼ ☑ Study Information
 - ☑ Project Outline
 - ☑ Scientific Summary
 - ☑ Requested Funding
 - ☑ Requested Product
- ☑ Publication Expecta...
- ☑ Attachments
- ☑ Acknowledgement
- Project Management





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

Acknowledgement

➔ General Information

Personnel

Primary Researcher

Sites

Primary Site

Study Information

Project Outline

Scientific Summary

Publication Expectati...

Attachments

General Information

*Study Title
Test 11.14

*Short Title *Primary Product/Compound
Test 11.14 PT010

*TIA to be Studied *Indication to be Studied If Other (Indication to be Studied)
Oncology Adjuvant Therapy

Other Combination Therapy
Test

*Have you contacted anyone at the company regarding this project?
Yes

*If yes, whom?
John Doe

Main Project Type
Clinical Research

*Type of Support
Funding and Product

*On Label?
Yes

*Number of Sites
122

➔ Personnel

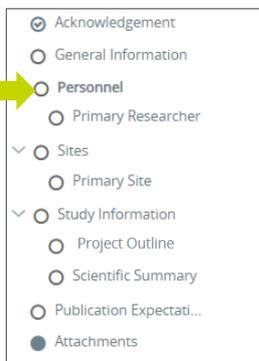




Starting a New Application

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



Personnel

Expand rows: 1 | to see detailed information.

Personnel Type	Name	Email	Institution Name	Country
Primary Researcher	Smith, Dr John		Evision Pharma	

Type any part of name or email - 3 characters min - or click the search icon.

Copy My Profile

Personnel Type: Primary Researcher

*Institution Name: Evision Pharma

*Address Line 1 (No PO box): 123 S Broad St

Address Line 2:

*Country: United States *City: Philadelphia

*State/Province: Pennsylvania *Postal Code: 19107

Research Request Person Licenses (US Only)

State	License Number	Expiration Date	
Pennsylvania	1543321	09 March 2023	✓ ✕
---- None ----			

*CV

Remove CV.docx

Replace File CV.docx

General Information

Sites





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

Acknowledgement

General Information

Personnel

Primary Researcher

Sites

Primary Site

Study Information

Project Outline

Scientific Summary

Publication Expectati...

Attachments

Sites

Expand rows [>] to see detailed information.

Site Type	Service Provider	Country	Contact
▼ Primary Site			
Type any part of name or email - 3 characters min - or click the search icon.			
Site Information		Contact Information	
Site Type Primary Site	*Institution Name --Required--	*Prefix --Required--	*First Name --Required--
*Address 1 (No PO Box) --Required--		*Primary Phone Number --Required--	*Last Name --Required--
Address 2		*Email Address --Required--	
*Country ... Select One ...	*City --Required--	*Degree ... Select One or More ...	If Other (Degree)
*State/Province --Required--	*Postal Code --Required--		

+ Add Site

Personnel

Project Outline





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

- Acknowledgement
- General Information
- Personnel
 - Primary Researcher
- Sites
 - Primary Site
- Study Information
 - Project Outline**
 - Scientific Summary
 - Publication Expectati...
- Attachments

Project Outline

*Study Design Characteristics	*Study Phase	*Are there Additional Countries for this Pr...	Additional Countries
Open-Label, Parallel	Real World Evidence	Yes	Argentina, Australia
*Does the Primary Researcher require receiving of Periodic SUSAR Line Listing?			
Yes			
*Total Number of Subjects Expected to Be...	*Number of Eligible Subjects Entering Tre...	*Total Number of Subjects Expected to En...	*Total Number of Subjects Expected to Co...
550	22	550	550
*Duration of Enrollment (in months)			
24			
*Contract Execution to FSI (in months)	*FSI to 50% Enrollment (in months)	*50% Enrollment to LSI (in months)	*LSI to LSLV (in months)
6	8	14	20
*LSLV to FSR (in months)			
22			
*Hypothesis		*Scientific Basis / Rationale	
<p>Sans Serif Normal B I U G A x² x, H. I E E E E E E E E E E</p> <p>Ne duo ipsum tacimatas, wisi cetero quaeque nam an, mea ut possit detrahit. Discere oporteat definitas ex ius, id argumentum deterruisset comprehensam nam. Sale voluptatum ne qui. Ad qui populo doctus deseruisse. Altera fastidii cum at, est quem justo volupbat te. Eam id animal voluptaria, vix ridens possim recusabo te. Omnes maluisse et no.</p>		<p>Sans Serif Normal B I U G A x² x, H. I E E E E E E E E E E</p> <p>Ne duo ipsum tacimatas, wisi cetero quaeque nam an, mea ut possit detrahit. Discere oporteat definitas ex ius, id argumentum deterruisset comprehensam nam. Sale voluptatum ne qui. Ad qui populo doctus deseruisse. Altera fastidii cum at, est quem justo volupbat te. Eam id animal voluptaria, vix ridens possim recusabo te. Omnes maluisse et no.</p>	

Sites Scientific Summary





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

- Acknowledgement
- General Information
- Personnel
 - Primary Researcher
- Sites
 - Primary Site
- Study Information
 - Project Outline
 - Scientific Summary**
 - Requested Funding
 - Requested Product
 - Publication Expectati...
- Attachments

Scientific Summary

***Primary Objective**

Sans Serif Normal B I U G A X² X₂
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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

- Acknowledgement
- General Information
- Personnel
 - Primary Researcher
- Sites
 - Primary Site
- Study Information
 - Project Outline
 - Scientific Summary
 - Requested Funding
 - Requested Product
 - Publication Expectati...
- Attachments

Requested Funding

1 Budget Template Instructions

Click on the link to download the template, and open the workbook in Microsoft Excel. All costs must be entered into either the Direct or Indirect table, and have one of the appropriate categories.

Enter all amounts in the currency you have specified. When complete, upload the template using the link. Values will be extracted from the template, and moved to the table.

[Download Budget Template](#) [Upload and Extract](#)

2

*Type	*Category	*Amt ()	Desc	+ Add Line
Direct Costs	Lab Test Fees	5,000.00		

3 Institutional Budget File

Attach file

*Are you requesting support from organizations other than AstraZeneca/MedImmune?
--- Select One ---

If Yes, please specify support

Budget Submission Instructions

Enter the local currency you wish to be paid in. Budget summary below displays direct and overhead subtotals calculated from your budget entries. Please enter the overhead percentage applied by your site. Total Study Costs will be reflected below. Please enter the amount you are requesting as part of this application for support.

*Requested Currency:
--- Select One ---

Budget Summary

Direct Costs	5,000.00
*Overhead %	---Required---
Total Direct Costs w/overhead	5,000.00
Total Indirect Costs	0.00
Total Study Costs	5,000.00
*Amount Requested ()	---Required---





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

The screenshot shows the 'Requested Funding' form with the following elements:

- 1** Download Budget Template button.
- 2** Upload and Extract button.
- 3** Funding table with columns: *Type, *Category, *Amt (\$), Desc. A row is visible: Direct Costs, Lab Test Fees, 5,000.00.
- 4** Requested Currency dropdown menu.
- 5** Institutional Budget File section with an Attach file button and a dropdown menu for support sources.

Budget Template Instructions: Click on the link to download the template, and open the workbook in Microsoft Excel. All costs must be entered into either the Direct or Indirect table, and have one of the appropriate categories.

Budget Submission Instructions: Enter the local currency you wish to be paid in. Budget summary below displays direct and overhead subtotals calculated from your budget entries. Please enter the overhead percentage applied by your site. Total Study Costs will be reflected below. Please enter the amount you are requesting as part of this application for support.

Budget Summary:

Direct Costs	5,000.00
*Overhead %	--Required--
Total Direct Costs w/overhead	5,000.00
Total Indirect Costs	0.00
Total Study Costs	5,000.00
*Amount Requested ()	--Required--

Institutional Budget File: Attach file

*Are you requesting support from organizations other than AstraZeneca/MedImmune? Select One ---

If Yes, please specify support: [Text box]





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

Requested Product

*Product/Comp...	*Dosage Formulation	*Dosage Strength	*Number of Subjects Receiving Product/Comp...	*Quantity	Quantity of Placebo Drug	Comments
AMP-224						

Are you requesting support from organizations other than Ast...
No





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

- Acknowledgement
- General Information
- Personnel
 - Primary Researcher
- Sites
 - Primary Site
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- Attachments

The screenshot shows the 'Publication Expectations' window with a table containing one entry: 'Journal/Congress' with columns for 'Publication Type' and 'Anticipation Publication Date'. A green arrow points to the '+ Add Journal/Congress' button.

Below is the 'Search Target Name' window. It has a search bar with 'Lan' entered. A green arrow points to the search bar, and another points to the 'Search' button. The results section shows a table of recommended targets:

The following targets are recommended.		
<input type="radio"/>	Lancet Global Hea...	The Lancet Global Health
<input type="radio"/>	Lancet Psychiatry	The Lancet Psychiatry
<input type="radio"/>	Lancet Haematol	The Lancet Haematology
<input type="radio"/>	Lancet HIV	The Lancet HIV
<input type="radio"/>	Lancet Gastroent...	The Lancet Gastroenterology & Hepatology

At the bottom of the search window, a green box highlights the text: 'If you did not find your target, please click here to add it manually.' A green arrow points to the 'Add' button.





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

Publication Expectation

[+ Add Journal/Congress](#)

Journal/Congress	Publication Type	Anticipated Publication Date
Journal of Clinical Oncology	Manuscript	31 Aug 2021

Requested Product

Attachments

The image shows a screenshot of a web application interface for adding a publication expectation. The main table has three columns: 'Journal/Congress', 'Publication Type', and 'Anticipated Publication Date'. The first row is highlighted in yellow and contains 'Journal of Clinical Oncology', 'Manuscript', and '31 Aug 2021'. A dropdown menu is open for the 'Manuscript' entry, showing options: '--- Select One ---', 'Secondary Manuscript', 'Abstract', 'Manuscript' (highlighted in blue), 'Poster', and 'Presentation'. To the right of the date field, there are three icons: a calendar, a checkmark, and an 'X'. Below the table, there are two sections: 'Requested Product' with a plus icon and 'Attachments' with a plus icon.





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 clicking 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

The screenshots illustrate the following steps:

- Navigation menu: **Attachments** is selected.
- Actions menu: **New Supporting Material** is selected.
- Post Attachment dialog: **Attachment Type** is set to **CV**.
- Attachments table: Shows a table with columns for Attachment Type, Posted By, and Posted Date. A gear icon is used to manage the attachment.

Attachment Type	Posted By	Posted Date	Actions
CV	Mista Testa Investigata	22 Oct 2018 09:48:10	Delete this Version Replace this Version View this Version





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

Dashboard > Visiontracker Clinical Applicant > General Information (Alia conclusionemque No Me)

ESR - Clinical Res... TEMP-000038 Investigata Incomplete 22 Oct 2018 Actions

- ☑ Acknowledgement
- ☑ General Information
- Personnel
 - ☑ Smith, Dr. Joe*
 - Bonney, Dr. Jackie
- Sites
 - EPG*
- ☑ Study Information
 - ☑ Project Outline
 - ☑ Scientific Summary
 - ☑ Requested Funding
 - ☑ Requested Product
 - ☑ Publication Expectati...
 - Attachments

General Information

*Study Title
Alia conclusionemque No Me

*Short Title: Alia *Primary Product/Compound: AMP-224

*T/A to be Studied: Cardiovascular *Indication to be Studied: ACS - Atrial Fibrillation If Other (Indication to be Stu...)

Other Combination Therapy

Submit Proposal

Submission Errors

There are errors on the pages ▲

- Institution Name Required
- Prefix Required

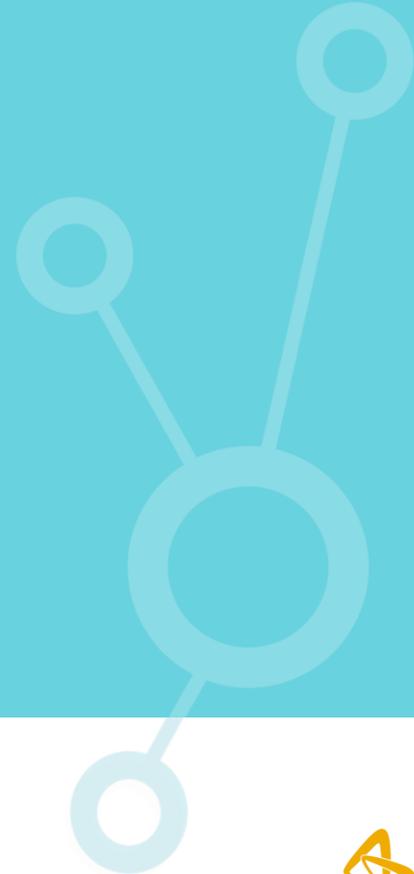
OK





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

Friday
18
JAN

Welcome
Testa Investigata

73 Incomplete Applications
14 Additional Information Requested
4 Protocol Requested
8 Regulatory Information Requested
10 Amendments
22 Active

Last Login - 18 Jan 2019... [Start New Application](#)

EVIDENCE CONNECT

Dashboard > Visiontracker Clinical Applicant > Scientific Summary (Alia conclusionemque No Me)

ESR - Clinical Res... ESR-18-000022 Investigata Additional Information Requested 22 Oct 2018

Scientific Summary

Additional Information Questions

Ne duo ipsum tacimates, wisi cetero quaeque nam an, mea ut possit detraxit. Discere oporteat definiebas ex ius, id argumentum deterruisset comprehensam nam. Sale voluptatum ne qui. Ad qui populo doctus deseruisse? Ad qui populo doctus deseruisse. Altera fastidii cum at, est quem justo volutpat te. Eam id animal voluptaria, vix ridens possim recusabo te. Omnes maluisset sit no?

Save
Addtl. Info Requested
Copy Record
Print
[Submit Additional Information](#)





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

Friday
18
JAN

Welcome
Testa Investigata

73 Incomplete Applications
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10 Amendments
22 Active

Last Login - 18 Jan 2019 ... [Start New Application](#)

Externally Sponsored Research Portal

Dashboard > Visiontracker Clinical Applicant > Protocol (Alia conclusionemque No Me)

ESR - Clinical Res... ESR-18-00022 Investigata Proposal Approved - Protocol Requested 22 Oct 2018 [Actions](#)

Protocol

Please attach a copy of the protocol that aligns with the previously submitted proposal.

*Protocol

Remove
Replace File
Protocol.docx

Scientific Summary Requested Funding

Submit Protocol





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](#)

Friday
18
JAN

Welcome
Testa Investigata

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22 Active

Last Login - 18 Jan 2019 ... [Start New Application](#)

- Acknowledgement
- General Information
- ▼ Sites
 - EPG*
- ▼ Study Information
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- Attachments
- ▼ Project Status Updates
 - Milestone Updates
 - Product Shipment
 - Regulatory Update
 - Publication Activity
- ▼ Personnel
 - Smith, Dr. Joe*
 - Bonney, Dr. Jackie
- Amendments





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

- ☑ Acknowledgement
- ☑ General Information
- ✓ ☑ Sites
- ☑ EPG*
- ✓ ☑ Study Information
- ☑ Project Outline
- ☑ Scientific Summary
- ☑ Protocol
- ☑ Requested Funding
- ☑ Requested Product
- Attachments
- ✓ ● **Project Status Updates**
- ➔ ● **Milestone Updates**
- Product Shipment
- Regulatory Update
- Publication Activity
- ✓ ☑ Personnel
- ☑ Smith, Dr. Joe*
- ☑ Bonney, Dr. Jackie
- Amendments

✓ Milestone Updates

Expand rows [>] to see detailed information.

Entry Date	Status
09 Jan 2019	Accepted

Progress Update

Milestone

Milestone	Current Plan Date	Updated Plan Date	Actual
Completion of Final Study Report/Draft Publication	09 Jan 2019	10 Jan 2019	<input type="checkbox"/>
OTHER 3	09 Jan 2019	18 Jan 2019	<input type="checkbox"/>
Completion of Project	10 Jan 2019	26 Jan 2019	<input type="checkbox"/>

*Are You Planning any Study Publications in the Next 12 Months?
Yes

†If Yes, Please Provide Likely Timing and Details of Likely Journal or ...
adfstud

+ Add No Change Milestone Update + Add Milestone Update

✓ Milestone Updates

Expand rows [>] to see detailed information.

Entry Date	Status
08 Feb 2019	Unsubmitted

Progress Update

Milestone

Milestone	Current Plan Date	Updated Plan Date	Actual
Completion of Final Study Report/Draft Publication	10 Jan 2019	<input type="text"/>	<input type="checkbox"/>
OTHER 3	18 Jan 2019	<input type="text"/>	<input type="checkbox"/>
Completion of Project	26 Jan 2019	<input type="text"/>	<input type="checkbox"/>

Are You Planning any Study Publications in the Next 12 Months?
... Select One ...

If Yes, Please Provide Likely Timing and Details of Likely Journal or C...

Actions

- Save
- Copy Record
- Print
- Provide Project Update
- Create Amendment





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

- ⊙ Acknowledgement
- ⊙ General Information
- ∨ ⊙ Sites
 - ⊙ organization*
- ∨ ⊙ Study Information
 - ⊙ Project Outline
 - ⊙ Scientific Summary
 - ⊙ Protocol
 - ⊙ Requested Product
- Attachments
- ∨ ● Project Status Updates
 - ⊙ Milestone Updates
 - ➔ ● **Product Shipment**
 - Regulatory Update
 - Publication Activity
- ∨ ⊙ Personnel
 - ⊙ lastName, prefix fir...
- ∨ ● Amendments
 - #1 - 19 Oct 2018

Product Shipment

Expand rows [>] to see detailed information.

Entry Date	Status	
31 Oct 2018	Accepted	
Entry Date	Decision Date	Status
31 Oct 2018	[empty]	Accepted

Product/Compound Dosage Formulation *Qty Dr... *Site *Shipment Type *Quantity of Shipment

AZD1236 Tablets 50 Institution Name Capsules 50

+ Add Product Request

Product Shipment

Expand rows [>] to see detailed information.

Entry Date	Status
22 Oct 2018	Unsubmitted

Entry Date Decision Date Status

22 Oct 2018 [empty] Unsubmitted

Product/Compound Dosage Formula... Qty Dr... Site Supply Source

AMP-224 Capsules 100 [empty] [empty]

Actions

- Save
- Copy Record
- Print
- Provide Project Update**
- Create Amendment





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

- ⊙ Acknowledgement
- ⊙ General Information
- ▼ Sites
 - ⊙ organization*
- ▼ Study Information
 - ⊙ Project Outline
 - ⊙ Scientific Summary
 - ⊙ Protocol
 - ⊙ Requested Product
 - Attachments
 - ▼ ● Project Status Updates
 - ⊙ Milestone Updates
 - Product Shipment
 - **Regulatory Update**
 - Publication Activity
 - ▼ ⊙ Personnel
 - ⊙ lastName, prefix fir...

Regulatory Update

Expand rows [>] to see detailed information.

Entry Date	IRB/EC Approval Date	IRB/EC Expiration Date	Regulatory Approval Date
▼ 22 Oct 2018			

IRB/EC Submission Date: 29 Aug 2018

IRB/EC Review Date: 01 Oct 2018

IRB/EC Approval Date: 20 Oct 2018

IRB/EC Expiration Date: 23 Oct 2025

IRB/EC Approval Document: Remove, Replace File, Approval.docx

Regulatory Approval Date:

Regulatory Authorization IND Number:

Clinical Trial Reg Num:

Registration Posted Date:

Regulatory Report (e.g., IND Annual Report): Attach file

Actions

- Save
- Copy Record
- Print
- Provide Project Update**
- Create Amendment





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

- ⊙ Acknowledgement
- ⊙ General Information
- ∨ ⊙ Sites
 - ⊙ organization*
- ∨ ⊙ Study Information
 - ⊙ Project Outline
 - ⊙ Scientific Summary
 - ⊙ Protocol
 - ⊙ Requested Product
- Attachments
- ∨ ● Project Status Updates
 - ⊙ Milestone Updates
 - Product Shipment
 - Regulatory Update
 - ➔ ● **Publication Activity**
 - ∨ ⊙ Personnel
 - ⊙ lastName, prefix fir...

Publication Activity

Planned Publications

[+ Add Journal/Congress](#)

Journal/Congress	Publication Type	Anticipated Publication Date	
New Medicine	Manuscript	22 Oct 2018	
Health Affairs	Secondary Manuscript	12 Oct 2021	

Actual Publications

Expand rows [>] to see detailed information. [+ Add Journal/Congress](#)

Entry Date	Journal/Congress	Publication Type	Publication Date
∨ 22 Oct 2018	International Academy for Biomedical ...		

Journal/Congress	Publication Title	Publication Type
International Academy for Biomedical and Drug Research - No Longer Published	<input type="text" value="Simul singularis eos in"/>	<input type="text" value="--- Select One ---"/>
Publication Review Needed By Date	Publication Acceptance Date	Publication Date
<input type="text"/>	<input type="text"/>	<input type="text"/>

Publication

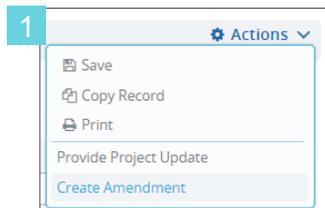
[Attach file](#)





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



2

Amendments

Expand rows (1) to see detailed information.

Amendment Number	Status	Additional Amount Requested
▼ #1 - 22 Oct 2018	New	

Description of change

Ut eum detrahit dissentias, esse consequuntur ea est. Mea ne dicat utroque dolores, ut duis albuicus pri. Debitis appellatur mei Id. Simul singularis eos in.

Reason: Modification Of Study Objectives

Other Reason: [empty]

IRB/EC Approval Date: [empty]

Additional Amount Requested: [empty]

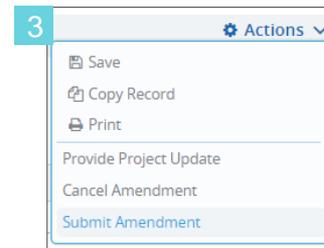
Revised Protocol: [Remove] [Replace File Protocol.docx]

Revised Budget: [Attach file]

Revised IRB/EC Approval Letter: [Attach file]

*Status: New

Decision Date: [empty]





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

- Acknowledgement
- General Information
- Personnel
 - Primary Researcher
- Sites
 - Primary Site
- Study Information
 - Project Outline
 - Scientific Summary
 - Requested Funding
 - Requested Product
 - Publication Expectati...
- Attachments



Actions

- Save
- New Supporting Material
- Download Attachments
- Copy Record
- Print

Post Attachment

Attach file

Attachment Type
--- Select One ---

--- Select One ---

Cancel

- Budget
- CV
- Closure Documentation
- Comments to Researcher
- Confidentiality Agreement

Attachments

Below is a summary of all documents included as part of the application. Use this section to upload any additional information that would assist us in making our support decision.
Please use the Actions menu at the top right to upload supporting materials and submit your proposal.

Attachments (2)			
Personnel			
Bonney, Dr. Jackie			
CV	Posted By Mista Testa Investigata	Posted Date 22 Oct 2018 09:48:10	
Smith, Dr. Joe			
Supporting Materials			





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

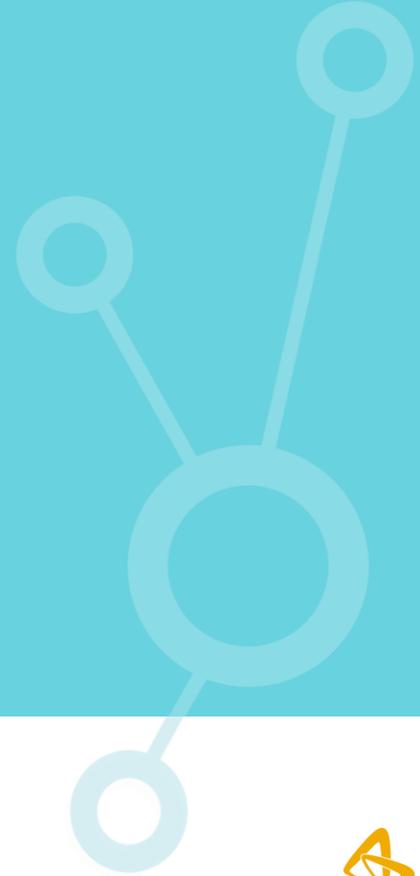
The screenshot shows the Evidence Connect web interface. At the top left is the Evidence Connect logo. The breadcrumb navigation reads: Search > Externally Sponsored Research > General Information. The main record header displays: ESR - Clinical Research: ESR-12-34567-ABC_123, Requestor: John Doe, and Request Date: 30 Apr 2014. The status 'Status: Project Closed' is highlighted with a yellow box. Below the header, there are tabs for 'Application' and 'General Information', with 'General Information' currently selected. Utility icons for help, bookmarks, notifications, and user profile are visible in the top right corner.





Training Materials

- [Evidence Connect Training Centre](#)
- [Videos](#)

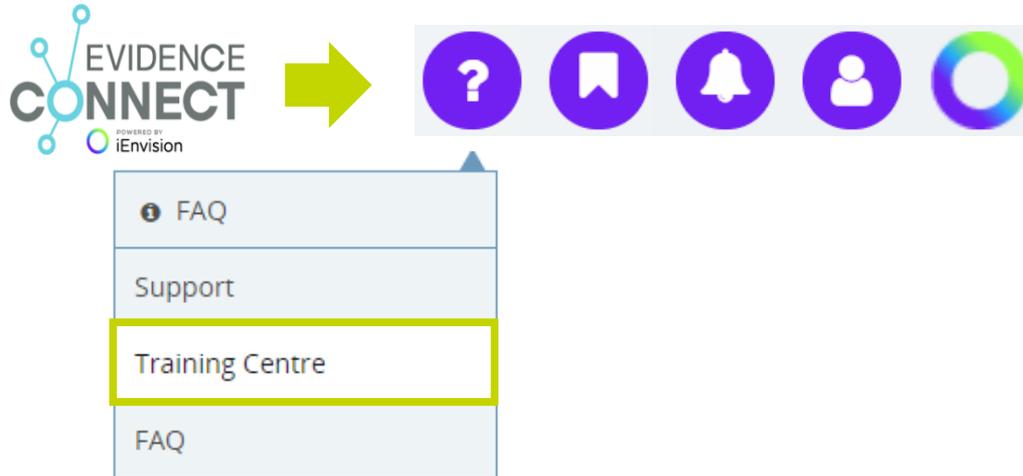




Training Materials

Evidence Connect Training Centre

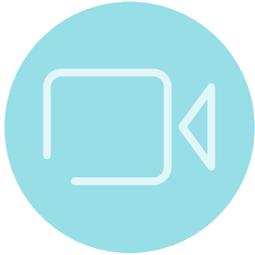
- The Evidence Connect Training Centre can be accessed by clicking the  icon at the top right-hand-side of the screen





Training Materials

Videos



Navigation Evidence Connect

Submitting a New Application

Project Status Updates

Project Close Out

