

How to create and manage an ESR study in VCV

This guide for the Investigator explains how to create and manage a new ESR (Externally Sponsored Research) study in VCV.



How to use this guide

1

Click **Accept**



A pop-up box appears.

Tips and reminders

Numbered mulberry-coloured boxes describe the actions the user should carry out in sequence to complete the task.

Mulberry-coloured arrows identify odd-numbered actions, gold arrows identify even-numbered actions.

Grey boxes describe functionalities and explain what the user will see as they navigate the system.

Gold boxes contain tips and reminders to help the user navigate the system more efficiently.



Introduction

To **create a new ESR study proposal**, go to the **VCV homepage**, navigate to the **ESR Info tab**, select **Externally Sponsored Research** from the drop-down menu and click **+Create**

- **Open each section** for the newly created **study proposal** and **fill in mandatory fields** by using the pencil icon to edit the fields.
Note that **mandatory fields are yellow and/or marked with asterisks**. Then click **Save**.

It is essential to upload the **PI CV** – Primary Investigator Curriculum Vitae – and **Budget** in the **Related Documents** section before submitting the study proposal for review by AstraZeneca.
→ see Appendix **How to upload a document**.

It is also essential to provide information about your **Planned Publication** before submitting the study proposal for review by AstraZeneca.

- Once an ESR study proposal has been created and submitted to AstraZeneca, it undergoes **Proposal Review**.
- Depending on the Verdict of the Proposal Review, the Investigator may receive a task: **Additional Information Requested**.
- Once Proposal Review is completed, the **Protocol** must be submitted.
- Depending on the Verdict of the **Protocol QC (Quality Check) and Review**, the Investigator may receive a task: **Additional Information Requested**.
- Once the study is underway, it will be necessary for the Investigator to provide **Project Status Updates**.
- The Investigator may need to create an **Amendment**.
- When the study is Closing, the Investigator will need to provide **Final Deliverables**.

The steps for each of these tasks are included in this **How To guide**.



Contents

and how to navigate
these guidelines

- Links are clickable in **slideshow mode**
- Use the **Return to Contents** link within each section divider to return to the **Contents** page at any time

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How to create and submit
an ESR study proposal

2

How to submit Additional
Information Requested
for a proposal QC/Review

3

How to submit a study
Protocol

4

How to submit Additional
Information Requested
for a Protocol QC/Review

5

How to create and submit
a Project Status Update
(PSU)

6

How to create
an Amendment

7

How to provide Final
Deliverables

8

How to view an audit trail

9

How to upload a document

10

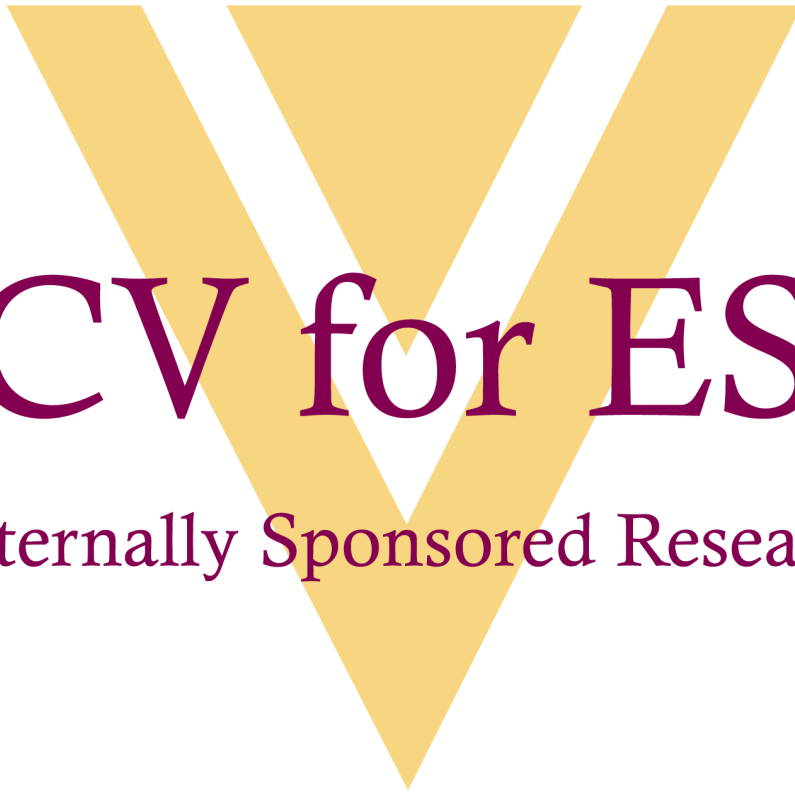
Any questions?



1

How to create and submit an ESR study proposal

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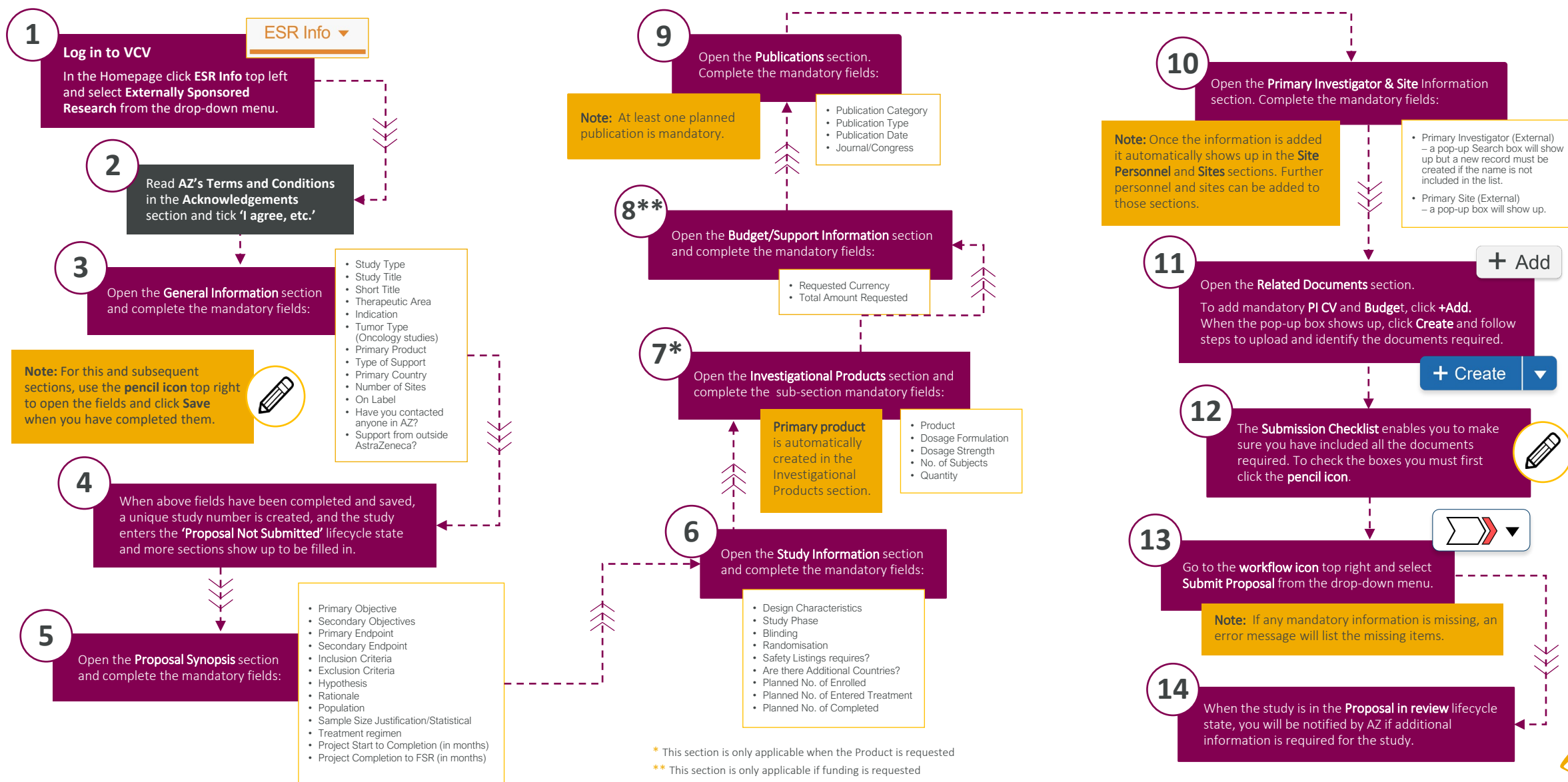


VCV for ESR

Externally Sponsored Research



Overview – How to create and submit an ESR study proposal

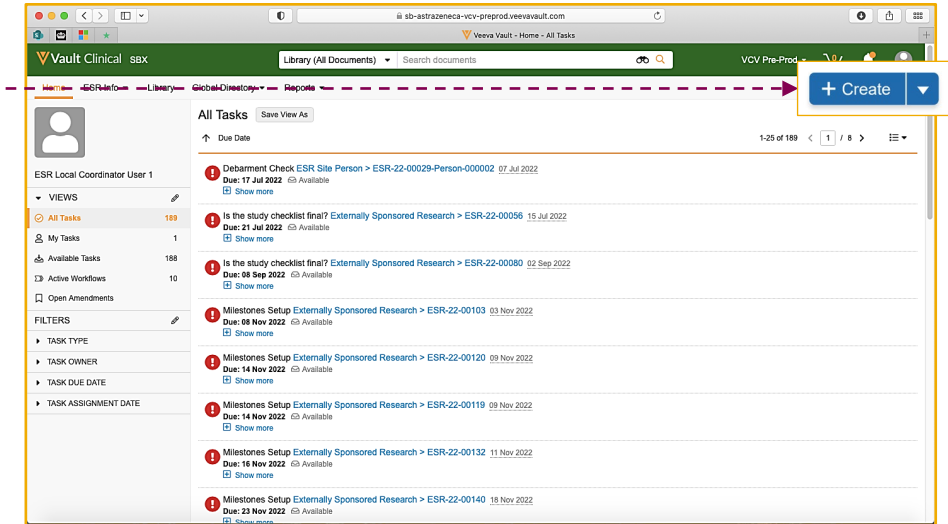


VCV Walkthrough - How to create and submit an ESR study proposal

Create a study proposal

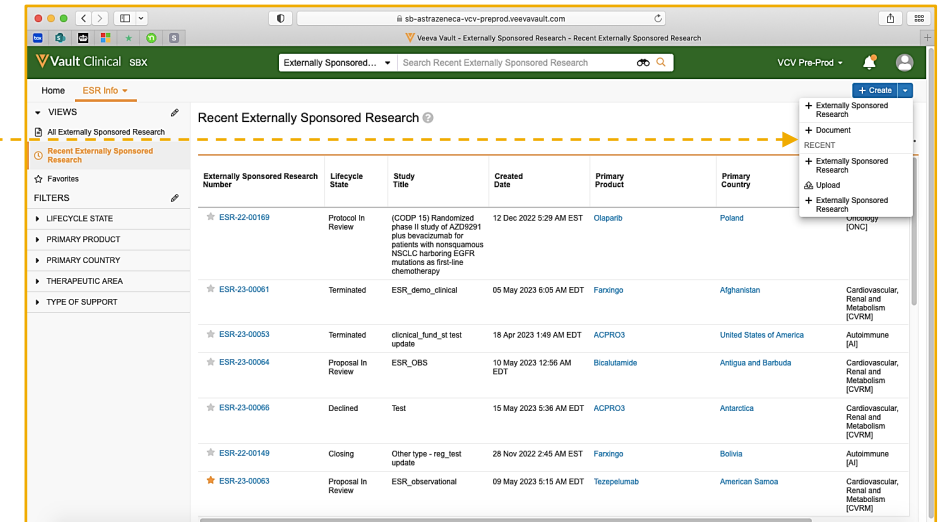
1

To create a new ESR study proposal, go to the VCV Homepage and click +Create



2

From the drop-down menu, select +Externally Sponsored Research



VCV Walkthrough - How to create and submit an ESR study proposal

Acknowledgement/General Information sections

3

Ensure you have read and understood the information in the **Acknowledgement** section, then click 'I agree with the statements above'

4

Then click **Save** top right

5

For the **General Information** section, fill in the mandatory fields and click **Save**

Further sections will be visible.
Some sections are dependent on some of the fields, e.g., Type of support.

Mandatory fields are yellow and/or marked with asterisks. They show up in **red** if the user does not fill them before clicking **Save**.
Where a field is underlined with dots, clicking the dots will bring up instructions for filling in the field.

The screenshot shows the 'Create Externally Sponsored Research' form in the VCV Pre-Prod environment. The 'Acknowledgement' section is active, displaying a paragraph of text regarding AstraZeneca's support and a checkbox labeled 'I agree with the statements above'. A 'Save' button is located in the top right corner of the form.

The screenshot shows the 'General Information' section of the 'Create Externally Sponsored Research' form. It contains several mandatory fields highlighted in yellow, including Study Type, Study Title, Short Title, Therapeutic Area, Indication, Primary Product, Study Status, Amendment In Review, Type of Support, Primary Country, Number of Sites, On Label, Have you contacted anyone in AZ?, Support from outside AstraZeneca?, and Product Areas of Interest. A 'Save' button is visible in the top right corner.



VCV Walkthrough - How to create and submit an ESR study proposal

Proposal not submitted

Proposal shows with study number ESR-YY-XXXXX as **Proposal Not Submitted**, and further sections will be visible and require completion.

The screenshot displays the Veeva Vault Clinical SBX interface. The top navigation bar includes 'Vault Clinical SBX', a search bar, and user information. The main header shows 'Externally Sponsored Research' and a search bar. The breadcrumb trail indicates 'Externally Sponsored Research'. The main content area displays 'Externally Sponsored Research: ESR-23-00017' with a status of 'Proposal Not Submitted'. The left sidebar contains a list of navigation links: General Information, Proposal Synopsis, Study Information, Investigational Products (1), Budget / Support Information, Publications (0), Primary Resource Management (0), Primary Investigator & Site Information, Site Personnel (0), Sites (0), Related Documents (0), Submission Checklist, Workflow Timeline, and Sharing Settings. The main content area is divided into sections: Acknowledgement, Collection Notice*, Terms and Conditions*, and Instructions. The Acknowledgement section contains a paragraph about AstraZeneca's willingness to provide support. The Collection Notice* section has a link to 'Click for more information'. The Terms and Conditions* section has a link to 'Click for more information'. The Instructions section contains text about saving and submitting proposals. A checkbox labeled 'I agree with the statements above.' is checked. The bottom of the page shows a list of sections: General Information, Proposal Synopsis, and Study Information.



VCV Walkthrough - How to create and submit an ESR study proposal

Proposal Synopsis section

6

Open the **Proposal Synopsis** section

7

Click on **pencil icon** top right

8

Mandatory fields appear marked with asterisks – fill and click **Save**

The screenshot shows the 'Externally Sponsored Research: ESR-23-00017' page in Veeva Vault Clinical. The 'Proposal Synopsis' section is expanded, showing a summary of the proposal. A pencil icon in the top right corner indicates the option to edit the section.

Field	Value
Primary Objective*	Contract Execution to FSI (in months)*
Secondary Objectives*	FSI to 50% Enrollment (in months)*
Primary Endpoint*	50% Enrollment to LSI (in months)*
Secondary Endpoint*	LSI to LSLV (in months)*
Inclusion Criteria*	LSLV to FSR (in months)*
Exclusion Criteria*	
Hypothesis*	
Rationale*	
Population*	
Sample Size Justification / Statistical*	
Treatment Regimen*	

The screenshot shows the 'Externally Sponsored Research: ESR-23-00017' page in Veeva Vault Clinical. The 'Proposal Synopsis' section is expanded, and the fields are now input fields. A 'Save' button is visible in the top right corner.

Field	Value
Primary Objective*	Primary Objective
Secondary Objectives*	Secondary Objectives
Primary Endpoint*	Primary Endpoint
Secondary Endpoint*	Secondary Endpoint
Inclusion Criteria*	Inclusion Criteria
Exclusion Criteria*	Exclusion Criteria
Hypothesis*	Hypothesis



VCV Walkthrough - How to create and submit an ESR study proposal

Study Information section

9

Open the **Study Information** section

10

Click on the **pencil icon** top right

11

Mandatory fields appear marked with asterisks – fill and click **Save**

The screenshot shows the VCV Clinical interface for ESR-23-00020. The 'Study Information' section is expanded, showing fields for Design Characteristics*, Study Phase*, Blinding*, Randomisation*, Safety Listings Required?*, and Are there Additional Countries?*. The 'Planned No. of Enrolled*', 'Actual No. of Enrolled', 'Planned No. of Entered Treatment*', 'Actual No. of Entered Treatment', 'Planned No. of Completed*', and 'Actual No. of Completed' fields are also visible. A pencil icon is located in the top right corner of the section.

The screenshot shows the VCV Clinical interface for ESR-23-00017. The 'Study Information' section is expanded, showing fields for Design Characteristics* (Placebo Controlled X), Study Phase* (Phase I), Blinding* (Double Blind), Randomisation* (Randomised), Safety Listings Required?* (Yes/No), and Are there Additional Countries?* (Yes/No). The 'Planned No. of Enrolled*', 'Actual No. of Enrolled', 'Planned No. of Entered Treatment*', 'Actual No. of Entered Treatment', 'Planned No. of Completed*', and 'Actual No. of Completed' fields are also visible. A 'Save' button is located in the top right corner of the section.

VCV Walkthrough - How to create and submit an ESR study proposal

Investigational Products section

12

Open the **Investigational Products** section

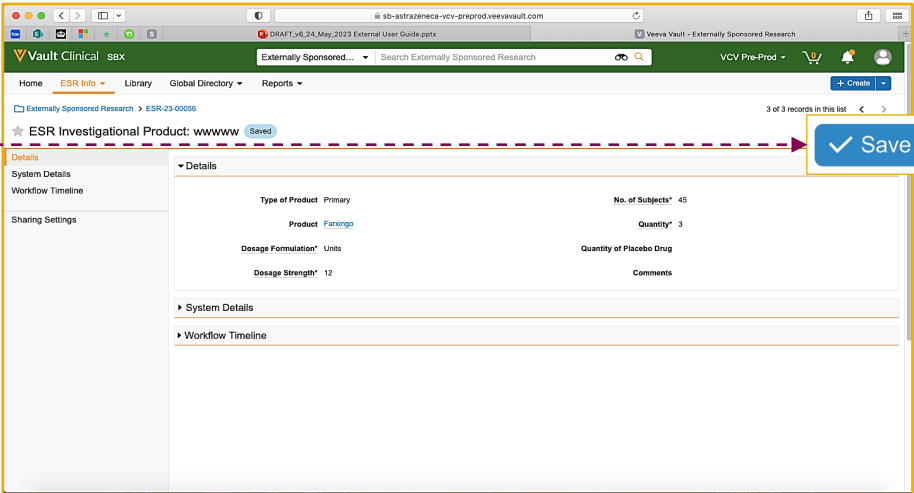
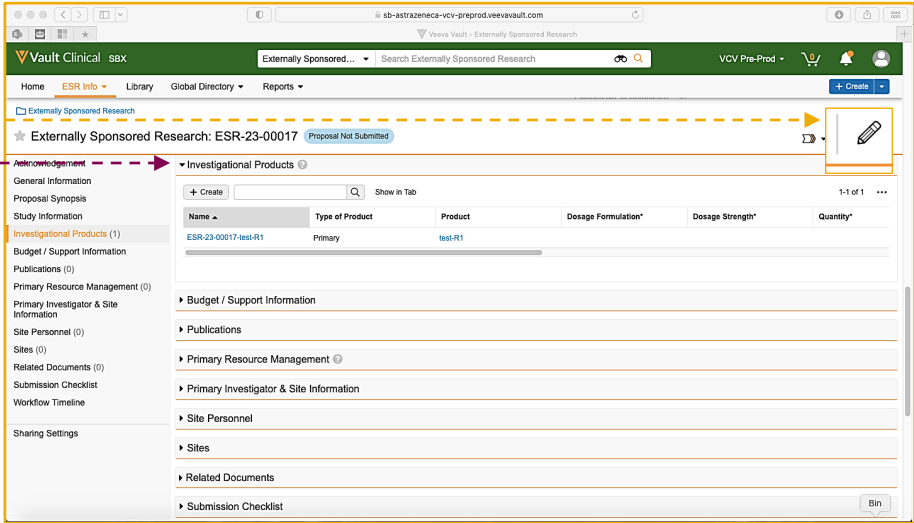
13

The primary product is automatically created – click and open it to review and complete the required fields

14

Click **Save**

Blue objects in VCV are clickable and can be opened.



VCV Walkthrough - How to create and submit an ESR study proposal

Investigational Products section

15

To add secondary products, open the **Investigational Products** section

16

Click **+Create**

17

Sub-sections appear with mandatory fields marked with asterisks – fill and click **Save**

Clicking on the yellow field will bring up a pick list, e.g., Product, headed by the item most recently selected for the field.
Alternatively, clicking the **binoculars icon** will bring up a Search box from which the user can select a Product and click **Save** before returning to the sub-section.

VCV Clinical sbx

Externally Sponsored... Search Externally Sponsored Research VCV Pre-Prod

Home ESR Info Library Global Directory Reports

Externally Sponsored Research

Externally Sponsored Research: ESR-23-00017 Proposal Not Submitted

Investigational Products

+ Create

Type of Product	Product	Dosage Formulation*	Dosage Strength*	Quantity*
Primary	test-R1			

Budget / Support Information

Publications

Primary Resource Management

Primary Investigator & Site Information

Site Personnel

Sites

Related Documents

Submission Checklist

Sharing Settings

VCV Clinical sbx

Externally Sponsored... Search Externally Sponsored Research VCV Pre-Prod

Home ESR Info Library Global Directory Reports

Externally Sponsored Research

Externally Sponsored Research: ESR-23-00017

Create ESR Investigational Product

Cancel Save

Details

System Details

Type of Product: Secondary

Product*

Dosage Formulation*

Dosage Strength*

No. of Subjects*

Quantity*

Quantity of Placebo Drug

Comments

System Details

Externally Sponsored Research: ESR-23-00017

Name*

Created By

Created Date

Last Modified By

Last Modified Date

VCV Walkthrough - How to create and submit an ESR study proposal

Investigational Products section

The added **investigational product** shows in the **Investigational Products** section.

The screenshot displays the Veeva Vault Clinical interface for study ESR-23-00017. The left sidebar contains a navigation menu with the following items: Acknowledgement, General Information, Proposal Synopsis, Study Information, **Investigational Products (2)**, Budget / Support Information, Publications (0), Primary Resource Management (0), Primary Investigator & Site Information, Site Personnel (0), Sites (0), Related Documents (0), Submission Checklist, Workflow Timeline, and Sharing Settings. The main content area is titled 'Externally Sponsored Research: ESR-23-00017' with a 'Proposal Not Submitted' status. It features a table for 'Investigational Products' with columns: Name, Type of Product, Product, Dosage Formulation*, Dosage Strength*, and Quantity*. The table lists two products: 'ESR-23-00017-test-R1' (Primary, test-R1) and 'Investigational Product ...' (Secondary, AZD7594, Tablets, 250 mg). Below the table are expandable sections for Budget / Support Information, Publications, Primary Resource Management, Primary Investigator & Site Information, Site Personnel, Sites, Related Documents, and Submission Checklist.

Name	Type of Product	Product	Dosage Formulation*	Dosage Strength*	Quantity*
ESR-23-00017-test-R1	Primary	test-R1			
Investigational Product ...	Secondary	AZD7594	Tablets	250 mg	

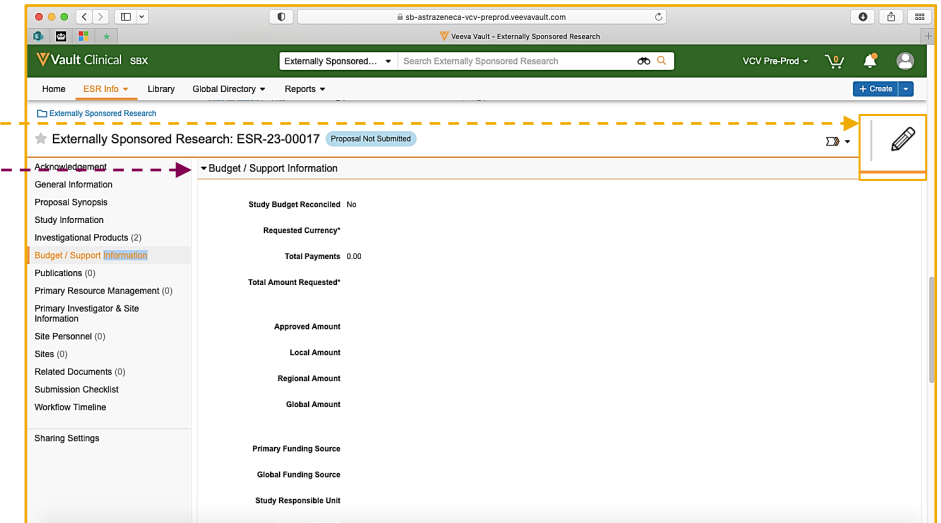


VCV Walkthrough - How to create and submit an ESR study proposal

Budget/Support Information section

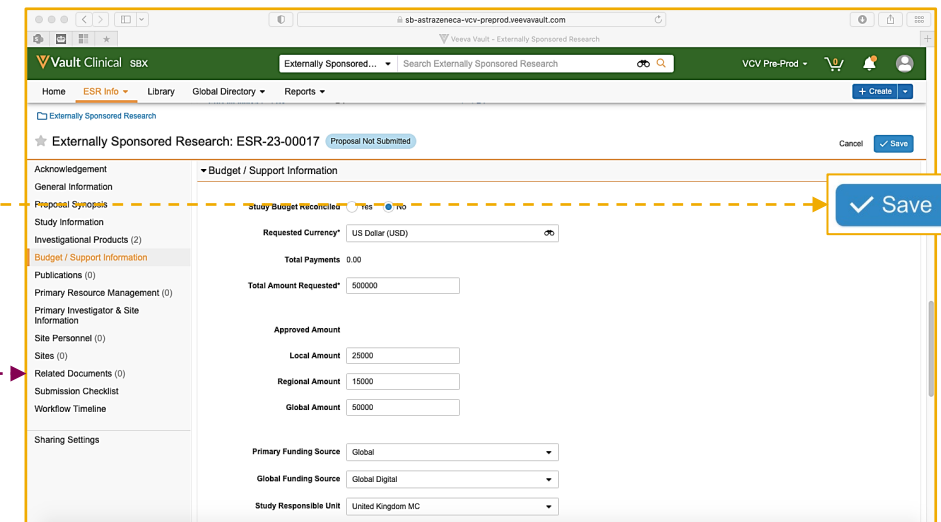
18

Open the **Budget/Support Information** section and click the **pencil icon** top right to edit the mandatory fields



19

Complete the mandatory fields and click **Save**



20

For the Budget field, add a **Budget** document via the **Related Documents** section (see [Appendix → How to upload a document](#))

VCV Walkthrough - How to create and submit an ESR study proposal

Publications section

21

Open the **Publications** section

22

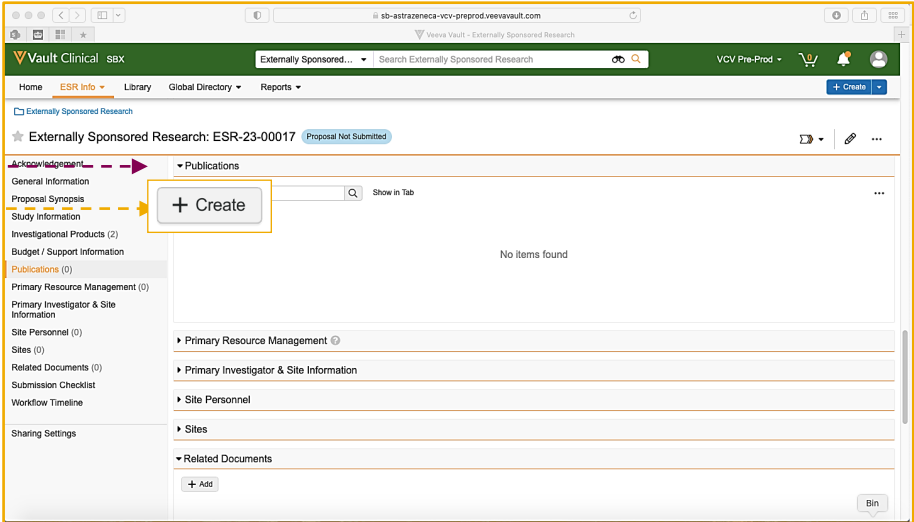
Click **+Create**

23

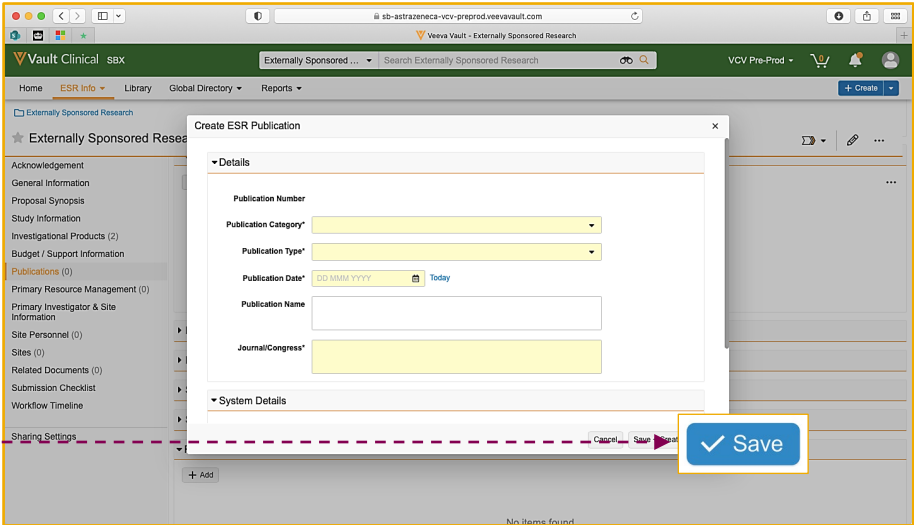
Fill in the mandatory fields and click **Save**

Publication appears in the **Publications** section.

Publication Number	Publication Category	Publication Type	Publication Date	Publication Name
ESR-23-00017-PUB-000001	Planned	Poster	31 Mar 2023	



A pop-up window appears:
Create ESR Publication.



VCV Walkthrough - How to create and submit an ESR study proposal

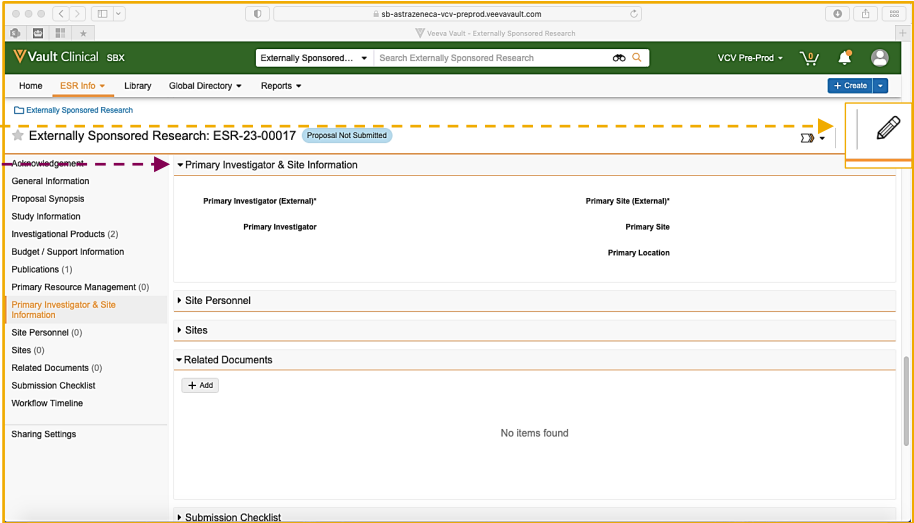
Primary Investigator & Site Information section

24

Open the **Primary Investigator & Site Information** section

25

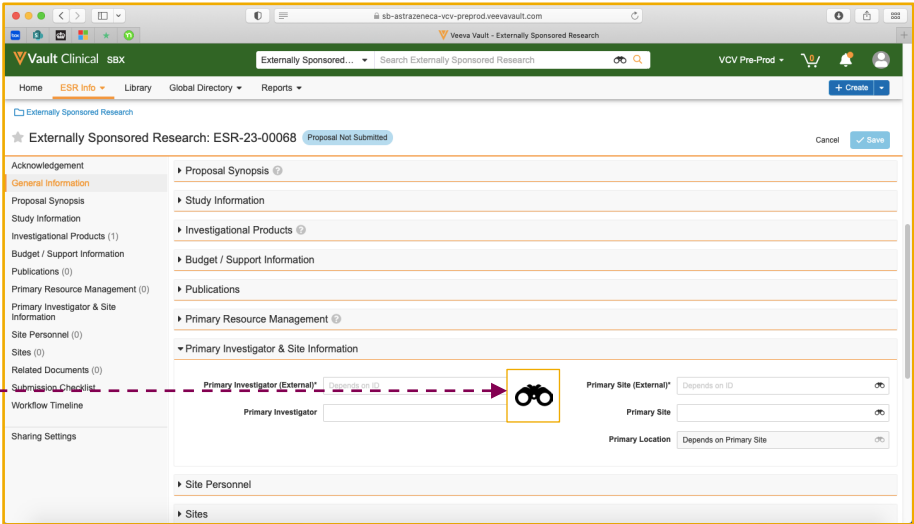
Click on the **pencil icon** top right



Binoculars search icons appear in fields.

26

Click the **binoculars icon** for **Primary Investigator (External)**



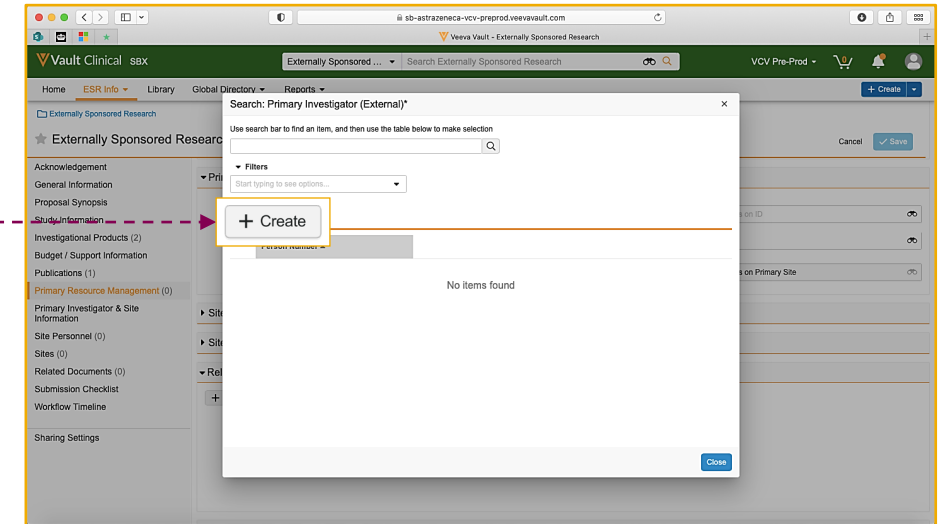
VCV Walkthrough - How to create and submit an ESR study proposal

Primary Investigator & Site Information section

27

Use Search bar to select
Primary Investigator or click **+Create**

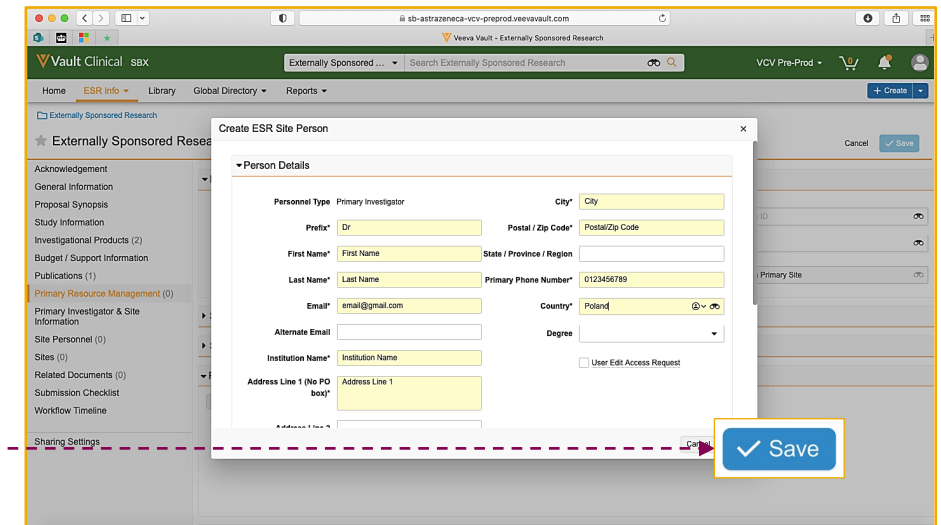
A pop-up window appears:
Search: Primary Investigator (External).



28

Fill in the mandatory yellow fields
and click **Save**

If **+Create** is selected, a further pop-up
window appears: **Create ESR Site Person.**



VCV Walkthrough - How to create and submit an ESR study proposal

Primary Investigator & Site Information section

29

Click the binoculars icon for Primary Site (External)

The screenshot shows the 'Externally Sponsored Research' page for ESR-23-00017. The 'Primary Investigator & Site Information' section is expanded, showing fields for 'Primary Investigator (External)*' (ESR-23-00017-Person-000001) and 'Primary Site (External)*' (Depends on ID). A binoculars icon is visible next to the 'Primary Site' field, which is highlighted by a dashed line from the instruction box.

A pop-up box appears:
Search: Primary Site (External).

30

Use the Search bar to select Site or click +Create

The screenshot shows a search pop-up box titled 'Search: Primary Site (External)*'. It includes a search bar with the text 'Use search bar to find an item, and then use the table below to make selection'. Below the search bar are 'Filters' and a '+ Create' button. The pop-up box is overlaid on the main interface, which shows the 'Primary Investigator & Site Information' section.

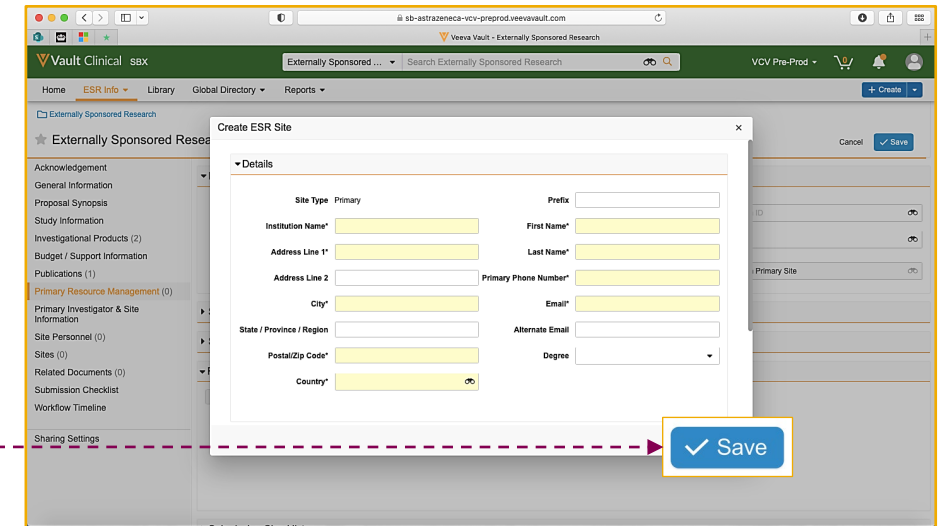
VCV Walkthrough - How to create and submit an ESR study proposal

Primary Investigator & Site Information section

If **+Create** is selected, a further pop-up window appears: **Create ESR Site**.

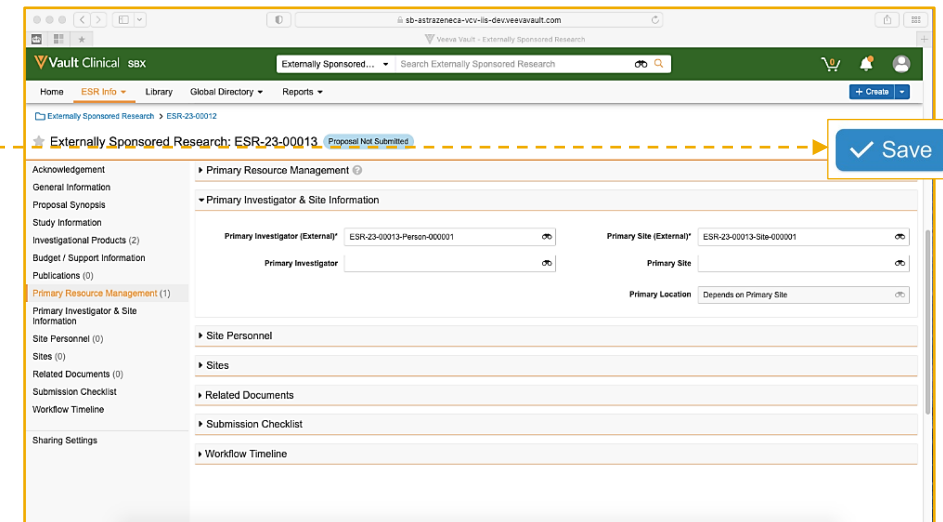
31

Fill in the mandatory yellow fields and click **Save**



32

Click **Save**



The **Primary Investigator (External)** and **Primary Site (External)** appear in the **Primary Investigator & Site Information** section.

VCV Walkthrough - How to create and submit an ESR study proposal

Site Personnel and Sites sections

Added **Person** with **Number** shows up in the **Site Personnel** section.

Externally Sponsored Research: ESR-23-00081

Review Log

Primary Resource Management

Primary Investigator & Site Information

Site Personnel

Sites

Site Number	Employer Identification Number	Site Type	Lifecycle State	Institution Name	Country
ESR-23-00081-Site-000001		Primary	Locked	Hosp	Poland

Added **Site** with **Number** shows up in the **Sites** section.

Externally Sponsored Research: ESR-23-00017

Primary Investigator & Site Information

Site Personnel

Sites

Site Number	Employer Identification Number	Site Type	Lifecycle State	Institution Name	Country
ESR-23-00017-Site-000001		Primary	Saved	Institution Name	Poland

VCV Walkthrough - How to create and submit an ESR study proposal

Site Personnel section

Further personnel may be added to the **Site Personnel** section at any time.

The screenshot shows the Veeva Vault Clinical interface for 'Externally Sponsored Research: ESR-23-00017'. The left sidebar contains a navigation menu with items like Acknowledgement, General Information, Proposal Synopsis, Study Information, Budget / Support Information, Publications (1), Primary Resource Management (0), Primary Investigator & Site Information, Site Personnel (1), Sites (1), Related Documents (0), Submission Checklist, Workflow Timeline, and Sharing Settings. The main content area shows the 'Site Personnel' section with a '+ Create' button and a table with columns: legacy_object_id, Personnel Type, Lifecycle State, and First Name. A table row is visible with 'ESR-23-00017-Person-000001' and 'Primary Investigator'.

33

To add further personnel, go to the **Site Personnel** section and click **+Create**

A pop-up box appears:
Create ESR Site Person.

34

Fill in the mandatory yellow fields and click **Save**

The screenshot shows the 'Create ESR Site Person' pop-up box. It contains a 'Person Details' section with the following fields: Personnel Type* (dropdown), City* (text), Prefix* (text), Postal / Zip Code* (text), First Name* (text), State / Province / Region (text), Last Name* (text), Primary Phone Number* (text), Email* (text), Country* (dropdown), Alternate Email (text), Degree (dropdown), Institution Name* (text), and Address Line 1 (No PO box)* (text). There is a checkbox for 'User Edit Access Request'. At the bottom right, there are 'Cancel', 'Save + Create', and a large blue 'Save' button.

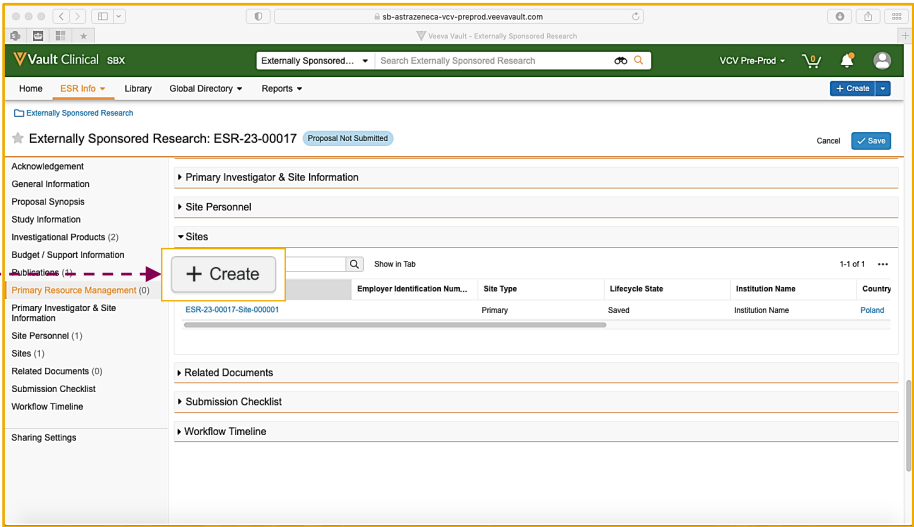
VCV Walkthrough - How to create and submit an ESR study proposal

Sites section

Further personnel may be added to the **Sites** section at any time.

35

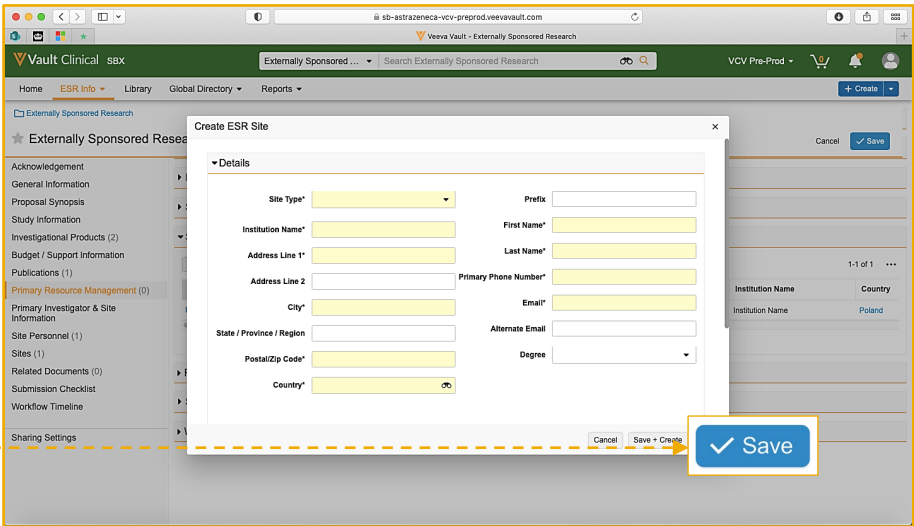
To add further sites, go to the **Sites** section and click **+Create**



A pop-up box appears:
Create ESR Site.

36

Fill in the mandatory yellow fields and click **Save**



VCV Walkthrough - How to create and submit an ESR study proposal

Site Personnel and Sites sections

Added personnel shows in the **Site Personnel** section.

▼ Site Personnel	
+ Create	Q Show in Tab
Person Number ▲	Personnel Type
ESR-23-00012-Person-000001	Primary Investigator
ESR-23-00012-Person-000002	Co-Investigator

Added site shows in the **Sites** section.

▼ Sites	
+ Create	Q Show in Tab
Site Number	Site Type ▲
ESR-23-00012-Site-000001	Primary
ESR-23-00012-Site-000002	Secondary

VCV Walkthrough - How to create and submit an ESR study proposal

Related Documents section

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To upload a document, e.g., PI CV, open the Related Documents section and click +Add

See also Appendix → [How to upload a document.](#)

The screenshot displays the Veeva Vault Clinical interface for 'Externally Sponsored Research: ESR-23-00017'. The left sidebar contains a list of sections: Acknowledgement, General Information, Proposal Synopsis, Study Information, Investigational Products (2), Budget / Support Information, Publications (1), Primary Resource Management (0), Primary Investigator & Site Information, Site Personnel (1), Sites (1), Related Documents (0), Submission Checklist, Workflow Timeline, and Sharing Settings. The 'Related Documents' section is highlighted with a red box, and a red arrow points to the '+ Add' button. The main content area shows 'No items found' under the 'Related Documents' section, with 'Submission Checklist' and 'Workflow Timeline' sections below it.

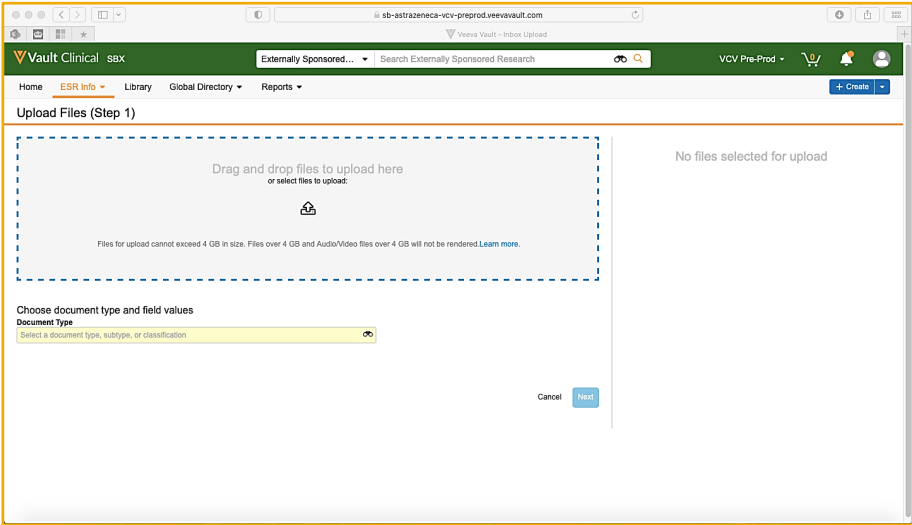
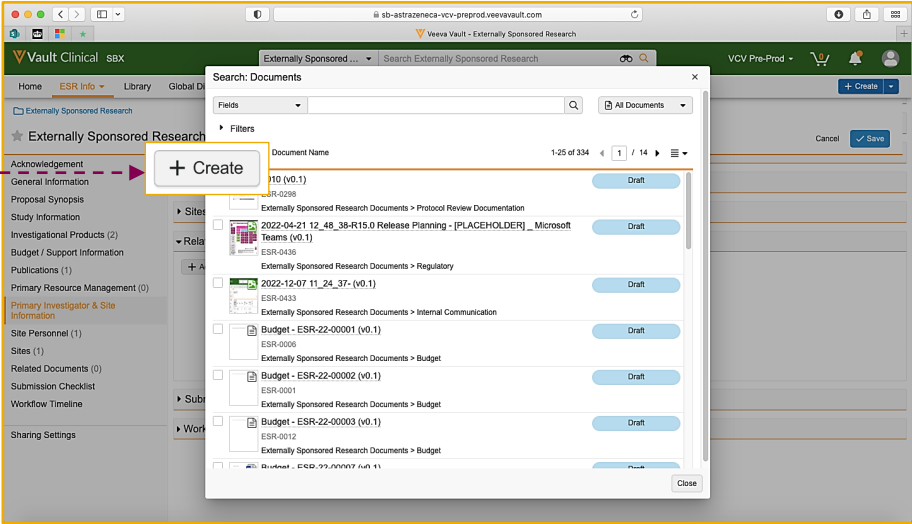
VCV Walkthrough - How to create and submit an ESR study proposal

Related Documents section

A pop-up window appears:
Search: Documents.

38 Select a document from the list then click **Close**, or click **+Create**

If **Create** is selected, a new field appears: **Upload Files (Step 1).**



VCV Walkthrough - How to create and submit an ESR study proposal

Related Documents section

39

Follow instructions to **upload files**

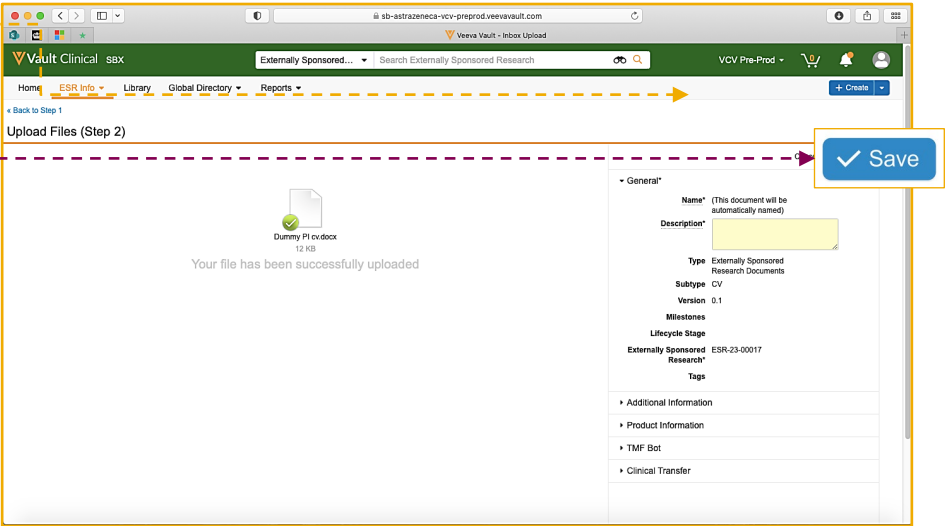
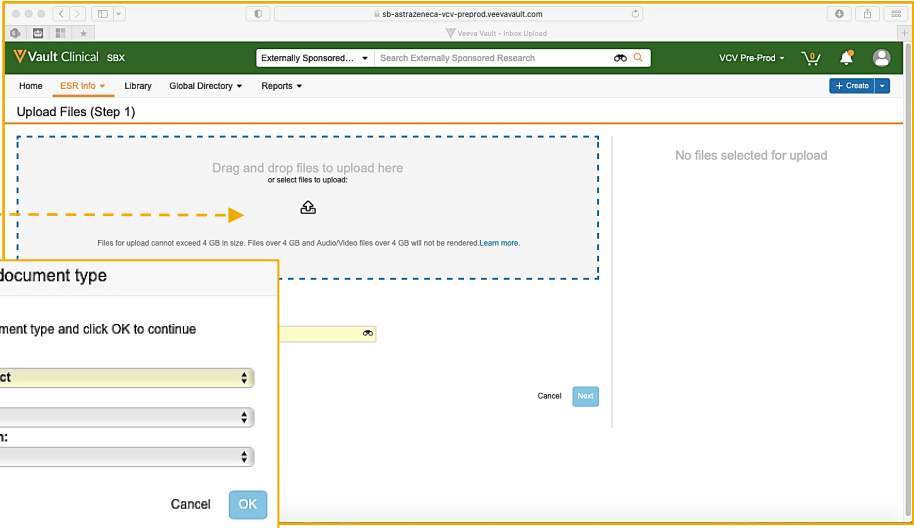
40

Choose document **type** and **subtype** from the drop-down menu and click **OK**, then click **Next**

Field appears: **Upload Files (Step 2)**.

41

Fill in mandatory yellow fields and click **Save**



VCV Walkthrough - How to create and submit an ESR study proposal

Related Documents section

The uploaded document shows in the **Related Documents** section.

sb-astrazeneca-vcv-lis-dev.veevavault.com

Veeva Vault - Externally Sponsored Research

Vault Clinical

sbx

Externally Sponsored...

Search Externally Sponsored Research

Home

ESR Info

Library

Global Directory

Reports

+ Create

Externally Sponsored Research

1 of 17 records in this list

★ Externally Sponsored Research: ESR-22-00285

Closing

Acknowledgement

General Information

Proposal Synopsis

Study Information

Investigational Products (1)

Product Shipments (0)

Budget / Support Information

Payments (0)

Milestones (3)

Contracts

Project Status Updates (1)

Classification

Performance Assessments (0)

Regulatory Identifiers

Publications (1)

Amendments (0)

Review Log (6)

Primary Resource Management (3)

Primary Investigator & Site Information

Site Personnel (1)

Site Personnel

Sites

Communication Log

Related Documents

+ Add

Show in Tab

1-3 of 3

Name	Subtype	Description	Status	Created By	Created Date
Protocol-ESR-22-00079	Initial Protocol	proto	Draft	External User 6	28 Oct 2022 2:1
PI CV-	CV	grzqrz	Draft	External User 6	26 Oct 2022 11:
Budget - ESR-000235	Budget	der	Draft	Internal User 6	05 May 2022 6:

Submission Checklist

Workflow Timeline

28

VCV Walkthrough - How to create and submit an ESR study proposal

Submission Checklist section

42

Open the **Submission Checklist** section, and if you have uploaded/provided the documents required, click the **pencil icon**, then **check the boxes** and click **Save**

Before the study proposal is submitted for review, it is essential to:

- Upload **PI CV**
- Provide at least one **Planned Publication**
- Upload **Budget** (if funding is requested)

See Appendix → [How to upload a document](#).

The screenshot displays the 'Externally Sponsored Research: ESR-23-00013' form in the Vault Clinical system. The left sidebar contains a navigation menu with sections like Acknowledgement, General Information, Proposal Synopsis, Study Information, Investigational Products (2), Budget / Support Information, Publications (0), Primary Resource Management (1), Primary Investigator & Site Information, Site Personnel (1), **Sites (1)**, Related Documents (0), Submission Checklist, Workflow Timeline, and Sharing Settings. The main content area shows details for the selected site, ESR-23-00013-Site-000001, including Site Type (Primary), Institution Name (Inst name), Country (Poland), and First Name (F Name). Below this, the 'Submission Checklist' section is expanded, showing three checkboxes: 'I have uploaded PI CV*', 'I have provided Planned Publication*', and 'I have uploaded Budget, if applicable*'. A 'Save' button is visible in the top right corner of the form area.



VCV Walkthrough - How to create and submit an ESR study proposal

Submit proposal

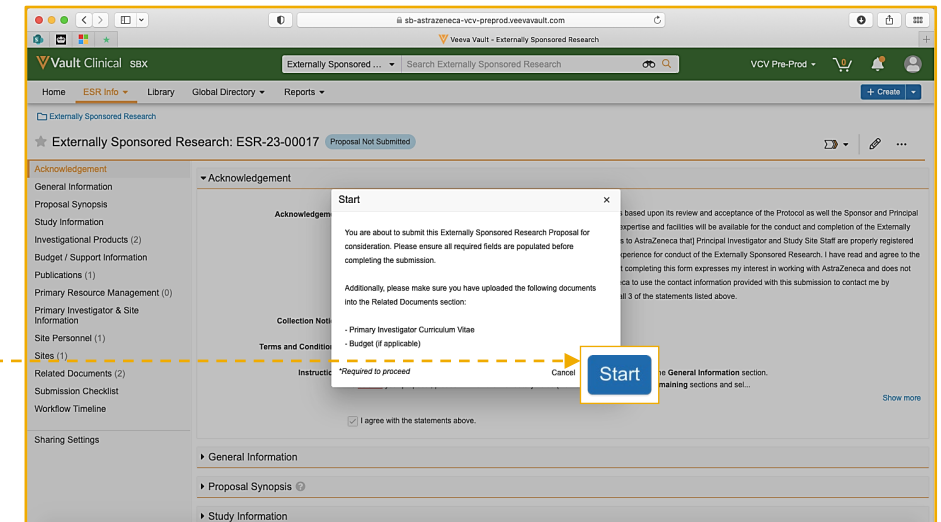
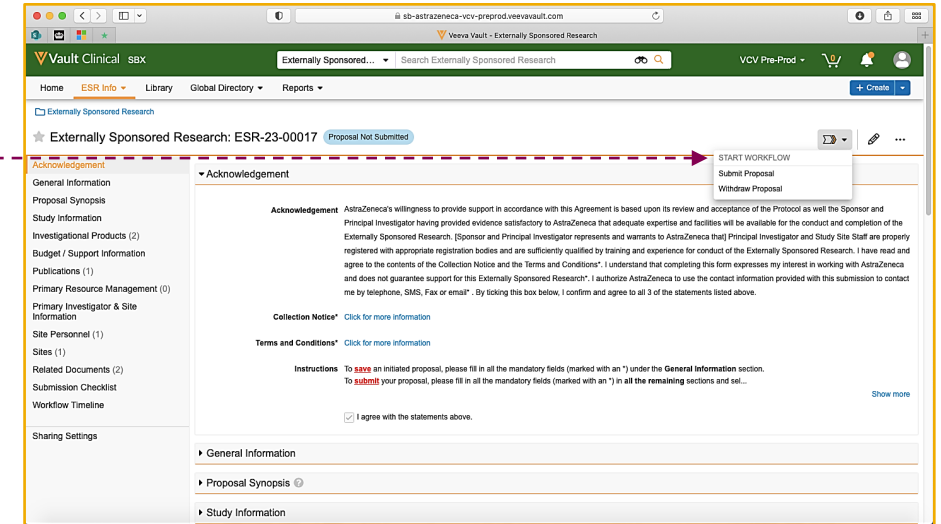
43

Go to the workflow icon top right and select **Submit Proposal** from the dropdown menu

Allow >1 minute for system to process the submission.

44

Follow the instructions and click **Start**



VCV Walkthrough - How to create and submit an ESR study proposal

Submit proposal

Pop-up windows will appear identifying any unfilled mandatory fields and explaining how to fill them.

When the submission has been successfully completed, the study shows as **Proposal in Review**.

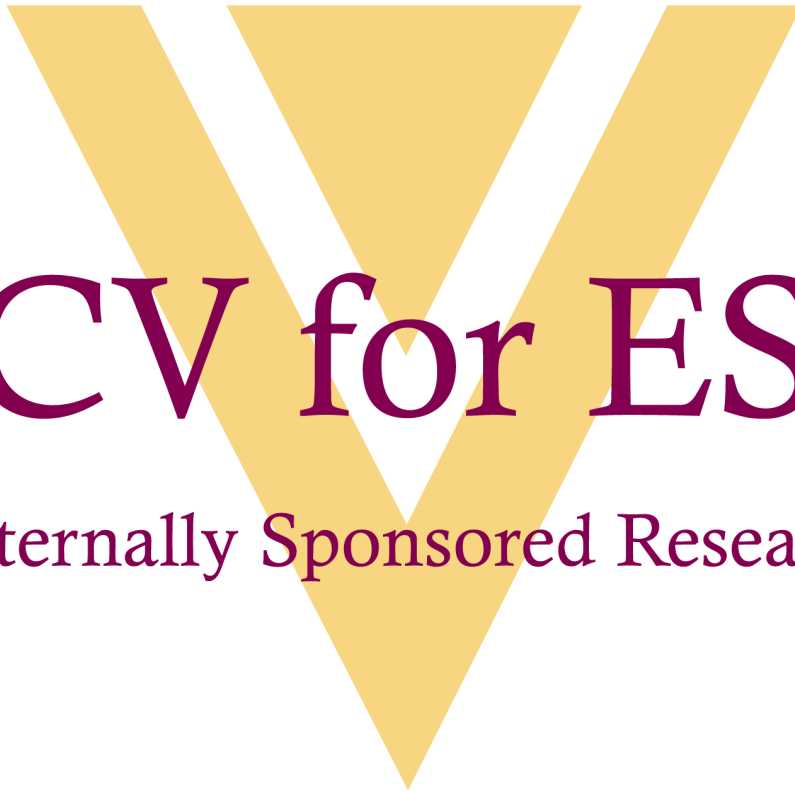
The screenshot displays the Veeva Vault Clinical interface for a study titled "Externally Sponsored Research: ESR-23-00018". The interface is divided into a left sidebar with a navigation menu and a main content area. The navigation menu includes sections like Acknowledgement, General Information, Proposal Synopsis, Study Information, Investigational Products (1), Product Shipments (0), Budget / Support Information, Payments (0), Classification, Performance Assessments (0), Publications (1), Review Log (2), Primary Resource Management (2), Primary Investigator & Site Information, Site Personnel (1), Sites (1), Communication Log (0), Related Documents (3), Submission Checklist, and Hold Details. The main content area shows a list of sections for the proposal, each with a right-pointing arrow: Acknowledgement, General Information, Proposal Synopsis, Study Information, Investigational Products, Product Shipments, Budget / Support Information, Payments, Classification, Performance Assessments, Publications, and Review Log. A blue box highlights the "Proposal in Review" status in the top right corner of the main content area. A dashed line connects the text in the orange box to this status indicator.



2

How to submit Additional Information Requested for a proposal QC/Review

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VCV for ESR

Externally Sponsored Research



VCV Walkthrough - How to submit Additional Information Requested for a proposal QC/Review

If the **Verdict** of the **Proposal QC** is **Additional Information Requested**, a notification and a new task will be generated for the External User: **Add Info Requested/Proposal QC** with **Due Date** and **Instructions**.

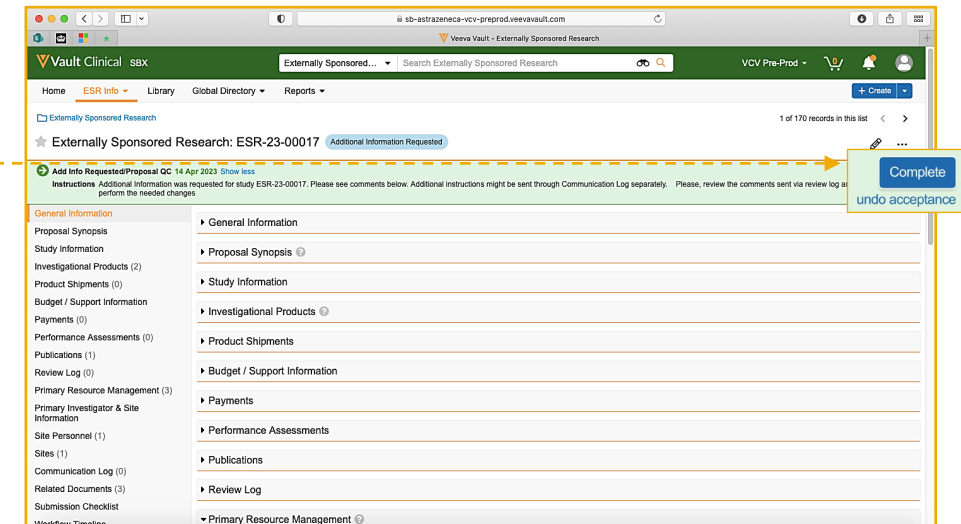
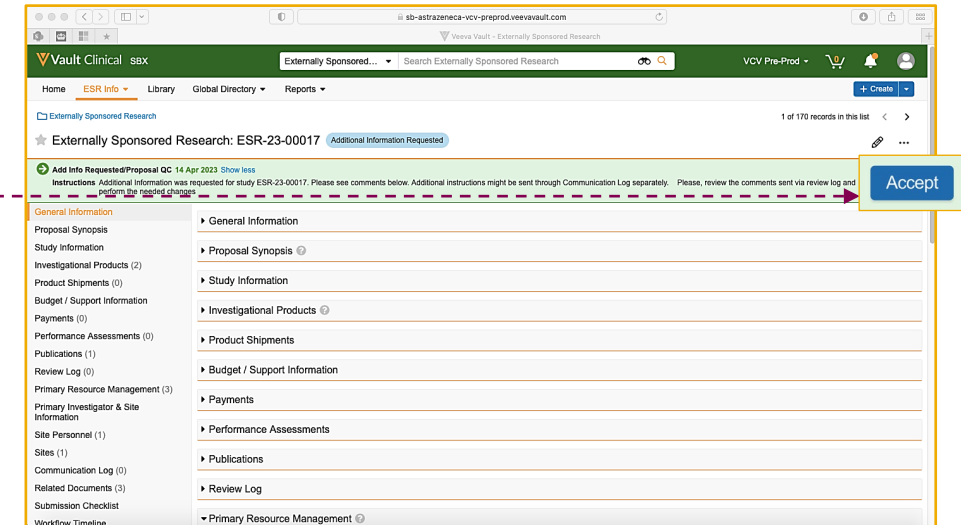
1

Click **Accept** and provide **Additional Information** as requested

2

Click **Complete**

All tasks for external users (e.g., Investigator) are also assigned to the **ESR Local Coordinator – Primary** in case the action needs to be completed on behalf of the Sponsor.



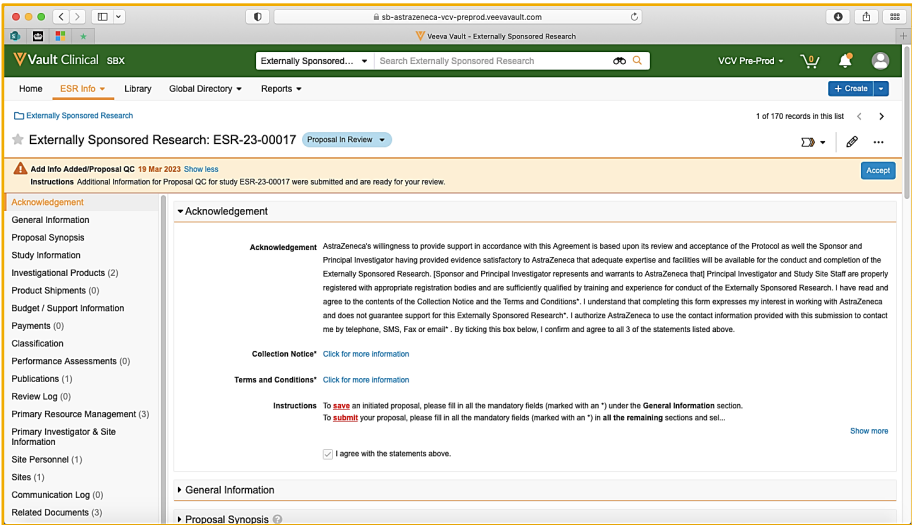
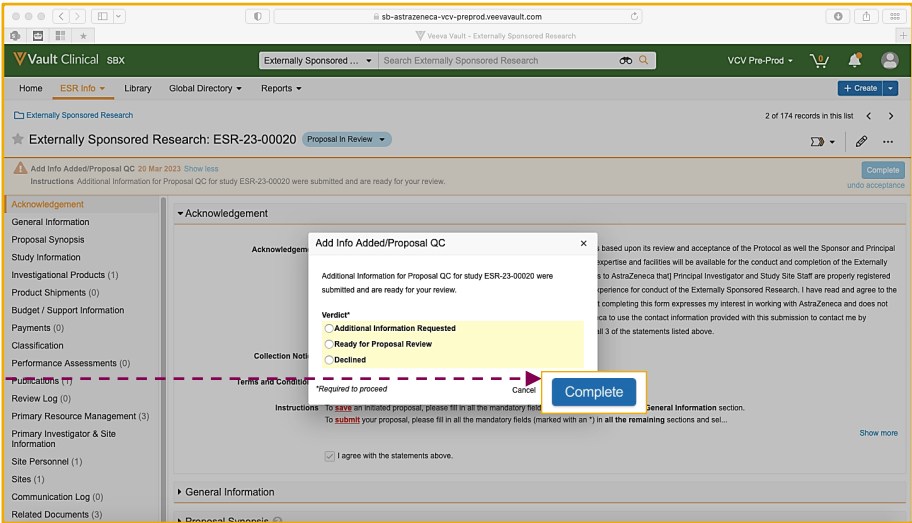
VCV Walkthrough - How to submit Additional Information Requested for a proposal QC/Review

A pop-up box appears:
Add Info Added/ Proposal QC.

3

Follow instructions and click **Complete**

Add Info Added/Proposal QC with Due Date and Instructions will appear in the taskbar for the user assigned to the task.



VCV Walkthrough - How to submit Additional Information Requested for a proposal QC/Review

After the proposal has been through **Local Proposal Review**, the Investigator may receive a task: **Add Info Requested/Local Proposal Review** with **Due Date** and **Instructions**.

4

Follow instructions and click **Accept**

The screenshot shows the Veeva Vault Clinical interface for study ESR-23-00018. A notification banner at the top states: "Add Info Requested/Local Proposal Review 15 Apr 2023 Show less". Below this, instructions are provided: "Instructions: Additional information was requested for study ESR-23-00018. Please see comments below. Additional instructions might be sent through Communication Log separately." The main content area is divided into two columns. The left column lists categories: General Information, Proposal Synopsis, Study Information, Investigational Products (1), Product Shipments (0), Budget / Support Information, Payments (0), Performance Assessments (0), Publications (1), Review Log (1), Primary Resource Management (2), Primary Investigator & Site Information, Site Personnel (1), Sites (1), Communication Log (0), Related Documents (3), Submission Checklist, and Workflow Timeline. The right column shows the details for each category, with expandable sections for General Information, Proposal Synopsis, Study Information, Investigational Products, Product Shipments, Budget / Support Information, Payments, Performance Assessments, Publications, Review Log, and Primary Resource Management. An "Accept" button is located in the top right corner of the task view.

5

Click **Complete**

This screenshot is identical to the one above, showing the same task view for study ESR-23-00018. However, the "Accept" button in the top right corner has been replaced by a "Complete" button, with the text "undo acceptance" appearing below it.

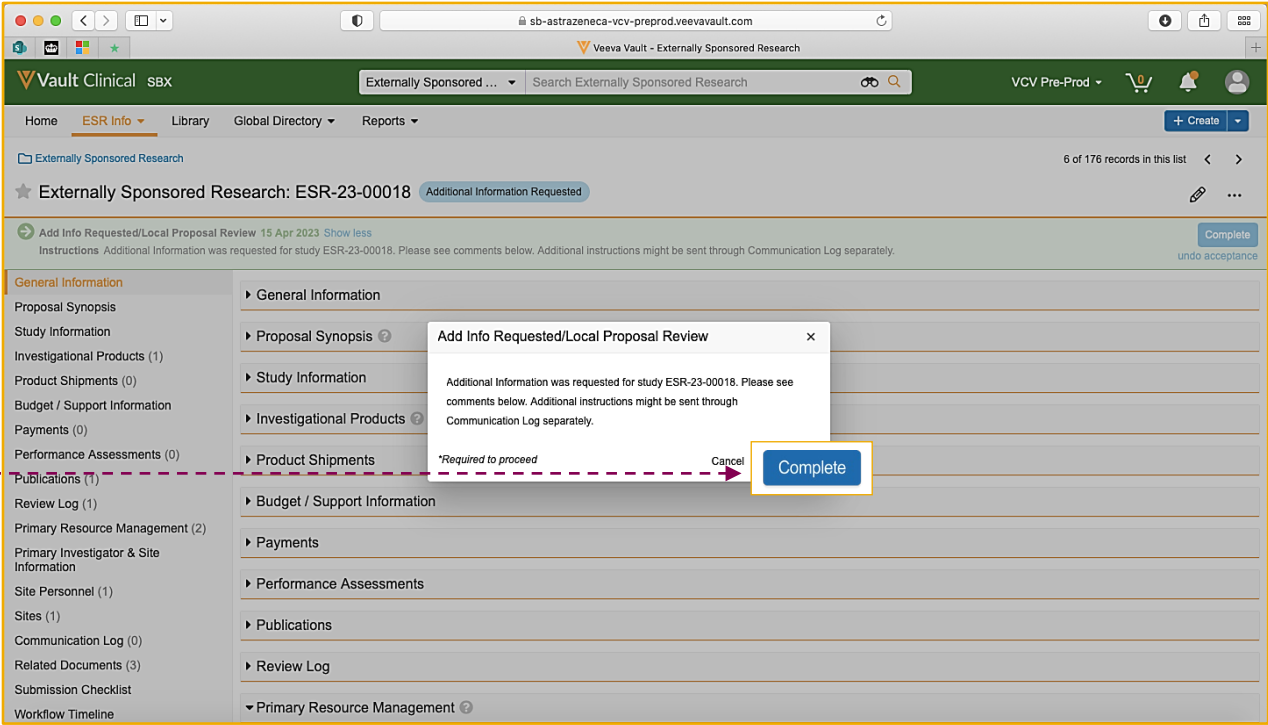
All tasks for external users (e.g., Investigator) are also assigned to the **ESR Local Coordinator - Primary** in case an activity needs to be completed on behalf of the Sponsor.

VCV Walkthrough - How to submit Additional Information Requested for a proposal QC/Review

A pop-up box appears:
Add Info Requested/Local Proposal Review.

6

Click **Complete**



VCV Walkthrough - How to submit Additional Information Requested for a proposal QC/Review

If the **Verdict** of the HQ Proposal Review is **Additional Information Requested**, a new task will be generated for the Investigator:
Add Info Requested/HQ Proposal Review with **Due Date** and **Instructions**.

7

Follow the instructions and click **Accept**

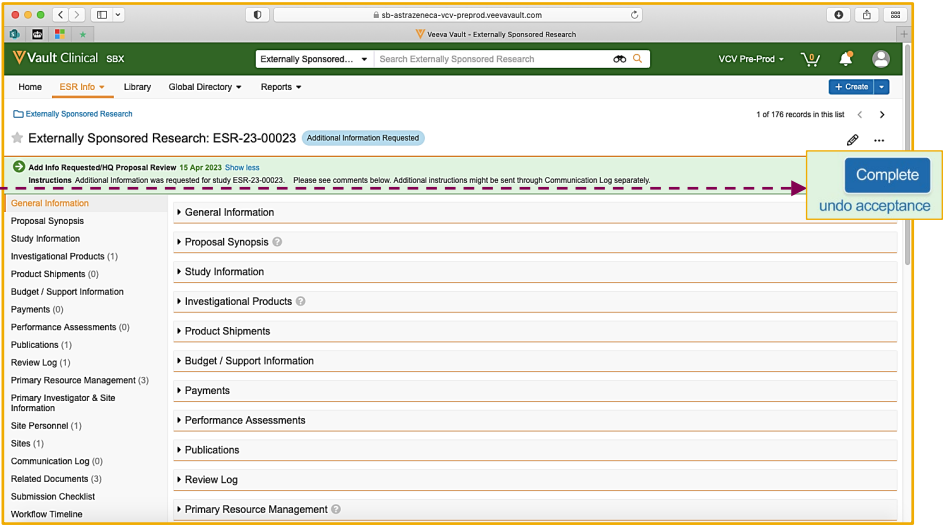
The screenshot displays the Veeva Vault Clinical SBX interface. The top navigation bar includes 'Home', 'ESR Info', 'Library', 'Global Directory', and 'Reports'. A search bar is present with the text 'Externally Sponsored...'. The main content area shows a list of 'Externally Sponsored Research' records. The first record, 'Externally Sponsored Research: ESR-23-00023', is highlighted with a blue 'Additional Information Requested' tag. Below this, a green banner contains the task title 'Add Info Requested/HQ Proposal Review' with a due date of '15 Apr 2023' and a 'Show less' link. The banner also includes instructions: 'Additional Information was requested for study ESR-23-00023. Please see comments below. Additional instructions might be sent through Communication Log separately.' A blue 'Accept' button is located on the right side of the banner. The left sidebar lists various sections under 'General Information', including 'Proposal Synopsis', 'Study Information', 'Investigational Products (1)', 'Product Shipments (0)', 'Budget / Support Information', 'Payments (0)', 'Performance Assessments (0)', 'Publications (1)', 'Review Log (1)', 'Primary Resource Management (3)', 'Primary Investigator & Site Information', 'Site Personnel (1)', 'Sites (1)', 'Communication Log (0)', 'Related Documents (3)', 'Submission Checklist', and 'Workflow Timeline'. The main content area on the right shows a list of sections under 'General Information', including 'General Information', 'Proposal Synopsis', 'Study Information', 'Investigational Products', 'Product Shipments', 'Budget / Support Information', 'Payments', 'Performance Assessments', 'Publications', 'Review Log', and 'Primary Resource Management'.



VCV Walkthrough - How to submit Additional Information Requested for a proposal QC/Review

8

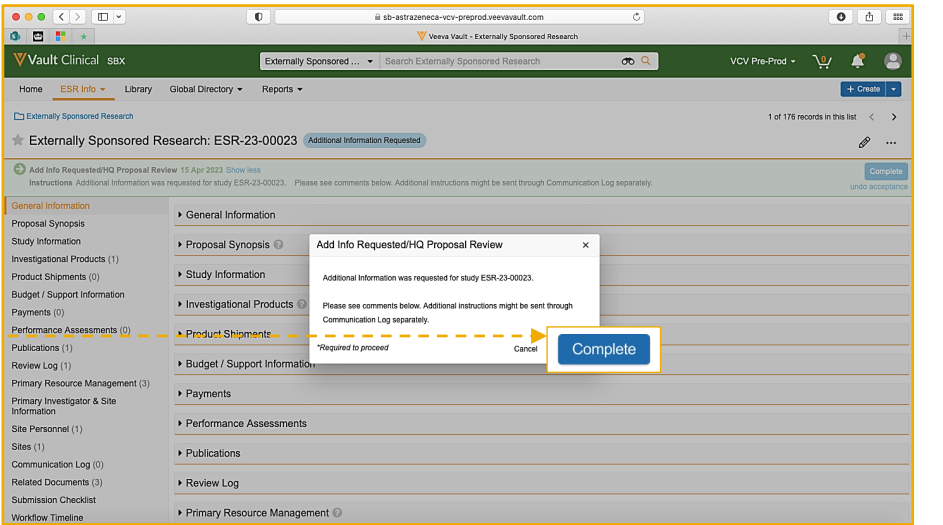
Provide additional information based on the **Comments**, and additional communication (if applicable), and click **Complete**



A pop-up box appears:
Add Info Requested/HQ Proposal Review.

9

Follow the instructions and click **Complete**



3

How to submit a study Protocol

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VCV for ESR

Externally Sponsored Research



VCV Walkthrough - How to submit a study Protocol

Protocol submission

When a Proposal shows as **Proposal Approved**, the **Protocol** may be submitted for **QC and Review**.

1

Upload the **Protocol** in the **Related Documents** section (see [How to upload a document](#))

Initial Protocol should be selected from the **Document Type** pick list when uploading the **Protocol**.

The screenshot displays the Veeva Vault Clinical interface for 'Externally Sponsored Research'. The top navigation bar includes 'Home', 'ESR Info', 'Library', 'Global Directory', and 'Reports'. The main content area shows the details for 'Externally Sponsored Research: ESR-23-00057', with a 'Proposal Approved' status highlighted. The left sidebar lists various sections, including 'Acknowledgement', 'General Information', 'Proposal Synopsis', 'Study Information', 'Investigational Products (0)', 'Product Shipments (0)', 'Budget / Support Information', 'Payments (0)', 'Milestones (5)', 'Contracts', 'Project Status Updates (0)', 'Classification', 'Performance Assessments (0)', 'Regulatory Identifiers', 'Publications (1)', 'Review Log (2)', 'Primary Resource Management (5)', 'Primary Investigator & Site Information', 'Site Personnel (1)', and 'Sites (1)'. The 'Related Documents' section is expanded, showing a table with one entry: 'ESR-23-00057', 'Details Report', 'Draft', 'System', '19 Apr 2023 5:4'. The table has columns for 'Name', 'Subtype', 'Description', 'Status', 'Created By', and 'Created Date'.

Name	Subtype	Description	Status	Created By	Created Date
ESR-23-00057	Details Report		Draft	System	19 Apr 2023 5:4



VCV Walkthrough - How to submit a study Protocol

Protocol submission

The **Protocol** has been **Saved** but it has not yet been **submitted**.

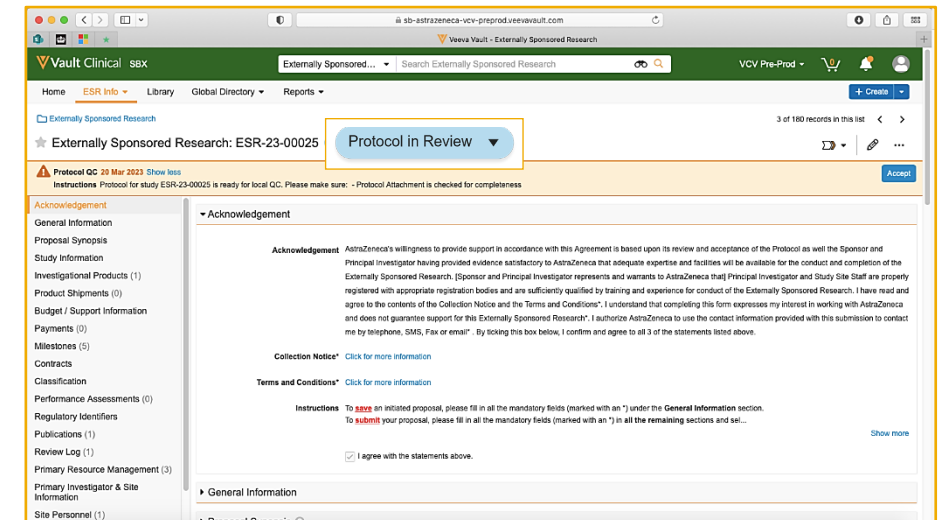
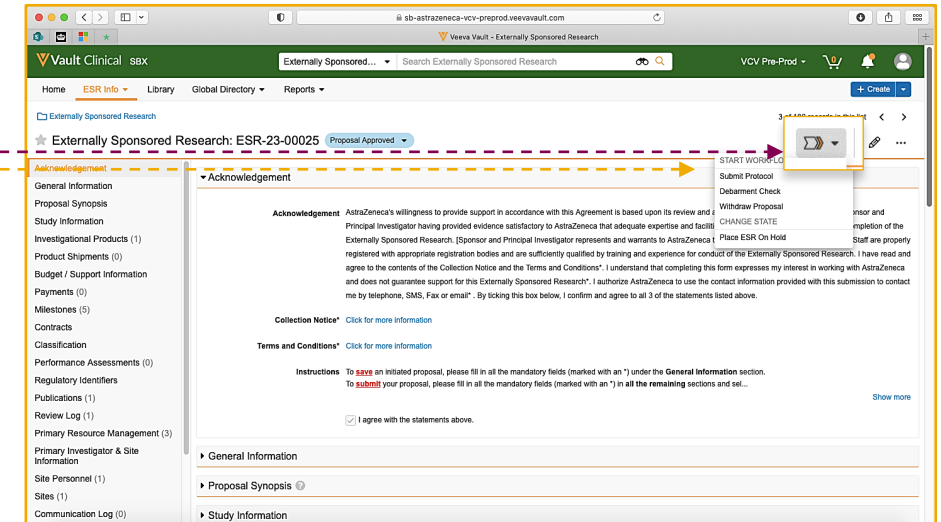
2

To submit the Protocol, click on the **workflow** icon

3

Select **Submit Protocol** from the drop-down menu

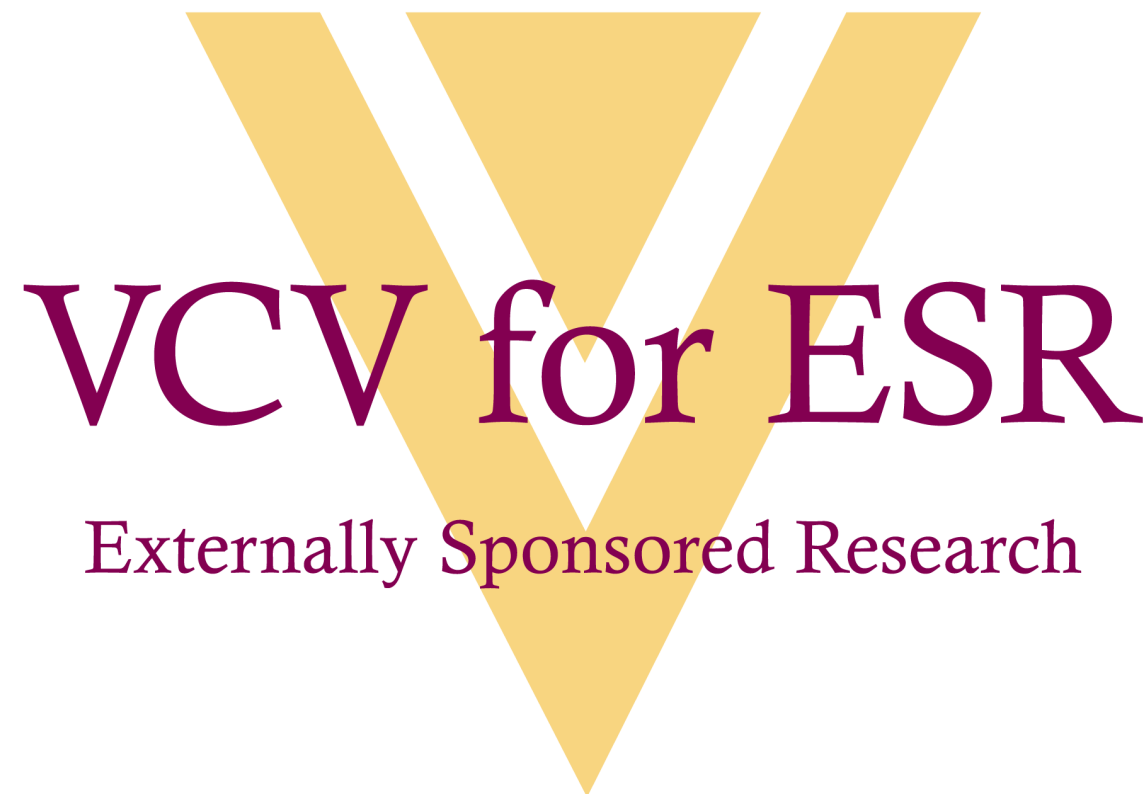
Once the Protocol is submitted, the **study lifecycle state** changes to **Protocol in Review**.



4

How to submit Additional Information Requested for a Protocol QC/Review

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VCV Walkthrough - How to submit Additional Information Requested for a Protocol QC/Review

If the **Verdict** of the **Protocol QC** is **Additional Information Requested**, the Investigator receives a notification and a task: **Add Info Requested/Protocol QC** with **Due Date** and **Instructions**.

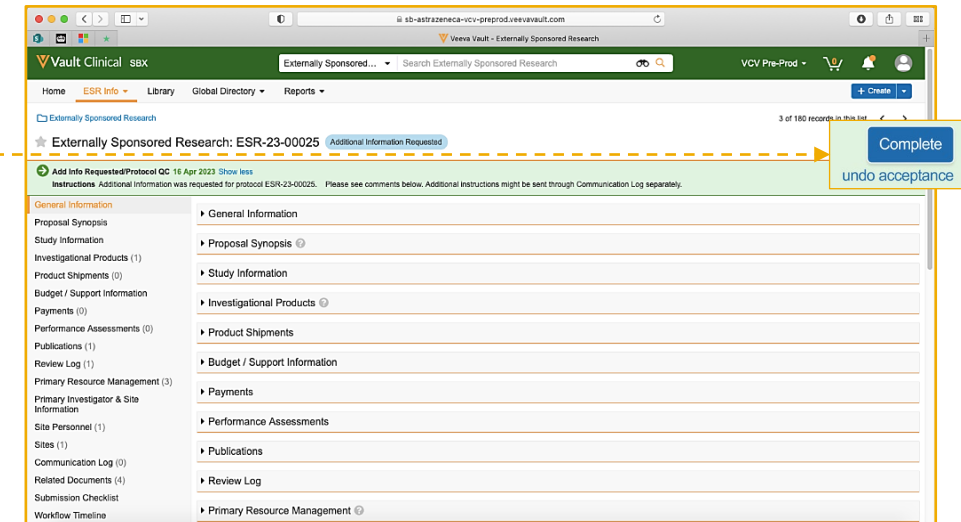
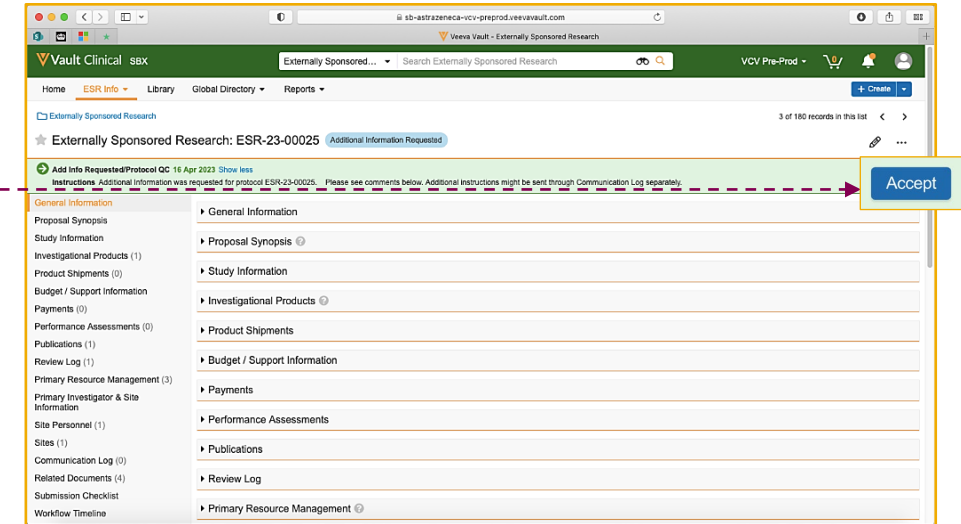
1

Note **instructions** and click **Accept**, then provide **Additional Information** for the **Protocol** as requested

2

Click **Complete**

Additional instructions may be sent separately through the **Communication Log**.

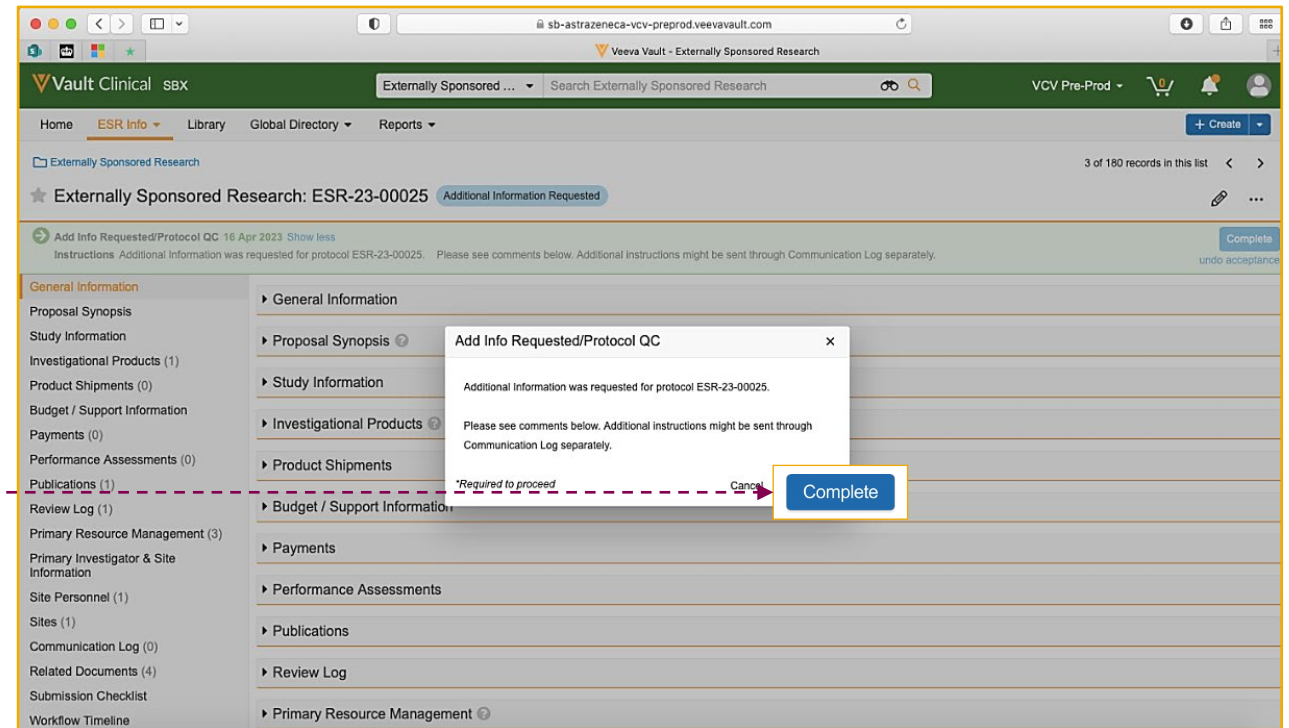


VCV Walkthrough - How to submit Additional Information Requested for a Protocol QC/Review

A pop-up window appears:
Add Info Requested/Protocol QC.

3

Follow instructions and click **Complete**



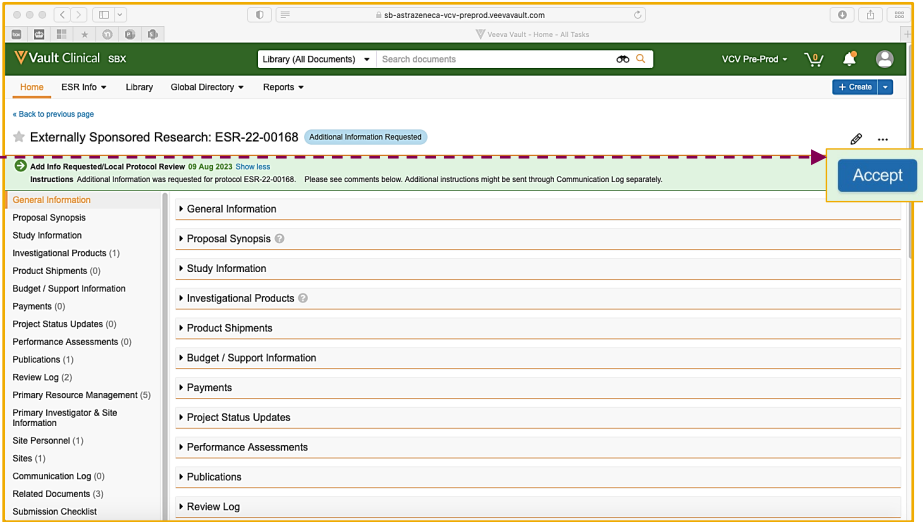
VCV Walkthrough - How to submit Additional Information Requested for a Protocol QC/Review

If the **Verdict** of the **Local Protocol Review** is **Additional Information Requested**, **Add Info Requested/ Local Protocol Review** appears in the taskbar with **Due Date** and **Instructions**.

The study shows as **Additional Information Requested**.

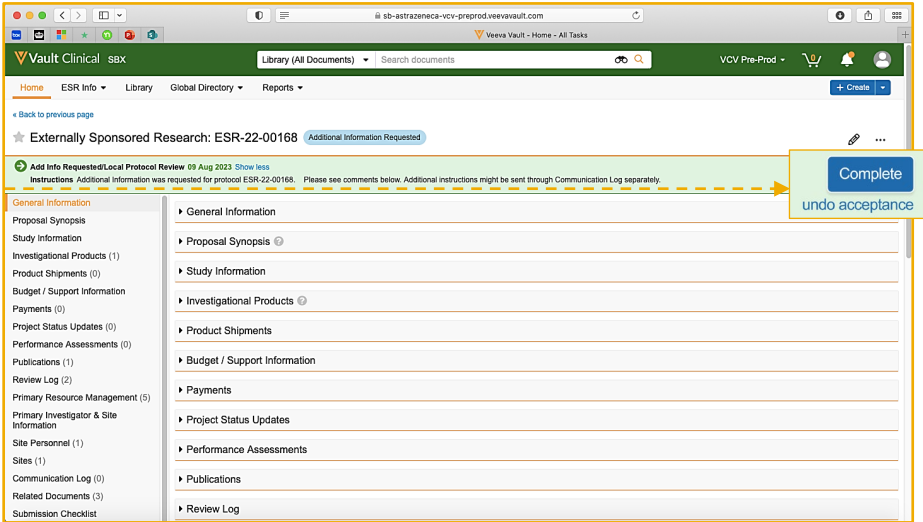
4

Note instructions and click **Accept** then provide updated **Protocol**



5

Click **Complete**



VCV Walkthrough - How to submit Additional Information Requested for a Protocol QC/Review

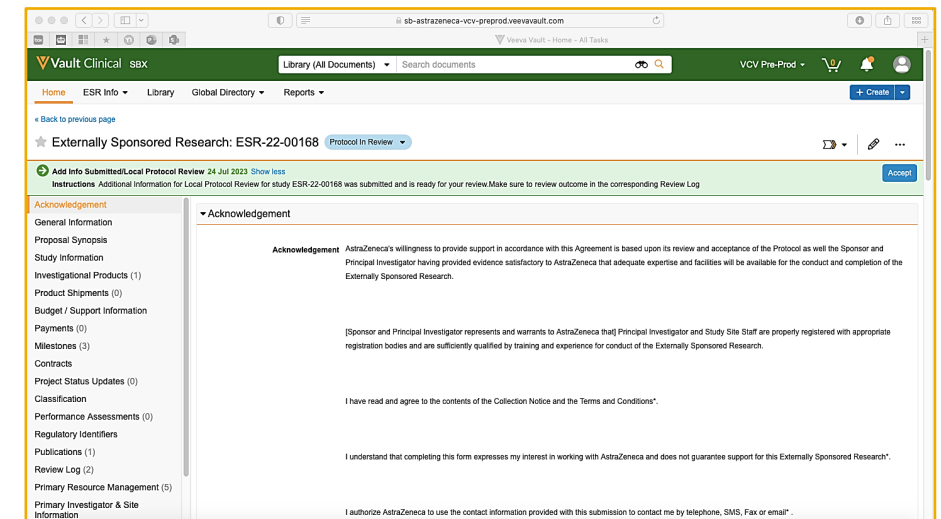
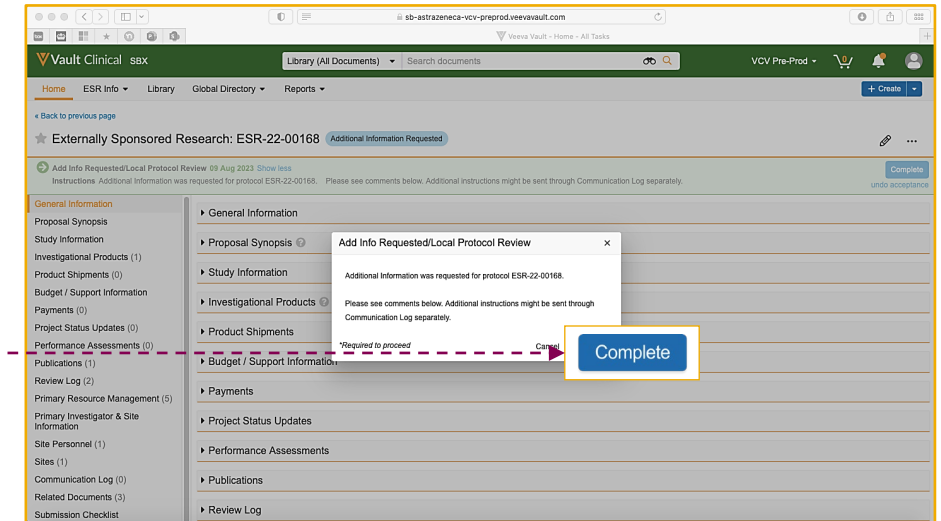
A pop-up window appears:
Add Info Requested/Local Protocol Review.

6

Follow instructions and click **Complete**

The study shows as **Protocol in Review** and **Add Info Submitted/Local Protocol Review** will appear in the taskbar for the user assigned to the task.

Additional instructions may be sent separately through the **Communication Log**.



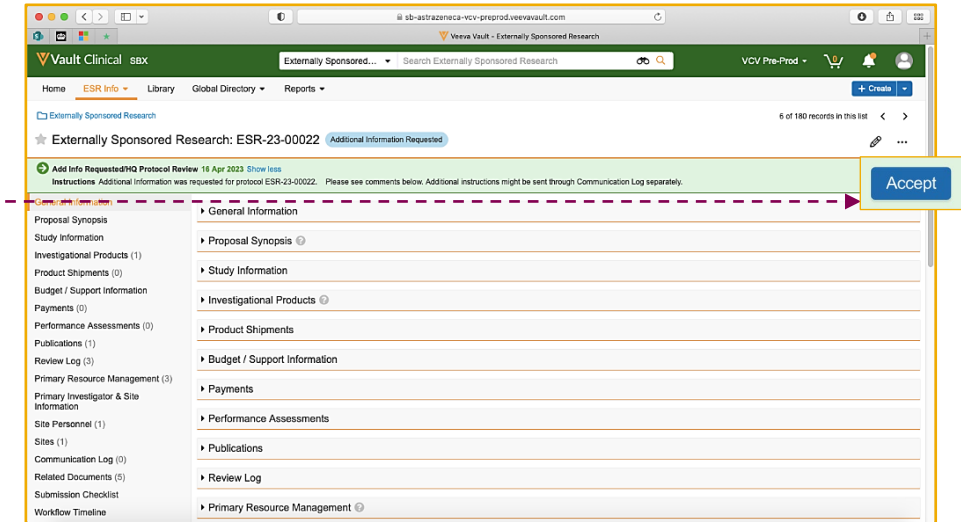
VCV Walkthrough - How to submit Additional Information Requested for a Protocol QC/Review

If the Verdict of the HQ Protocol Review is **Additional Information Requested**, Add Info Requested/HQ Protocol Review appears in the taskbar with **Due Date** and **Instructions**.

The study shows as **Additional Information Requested**.

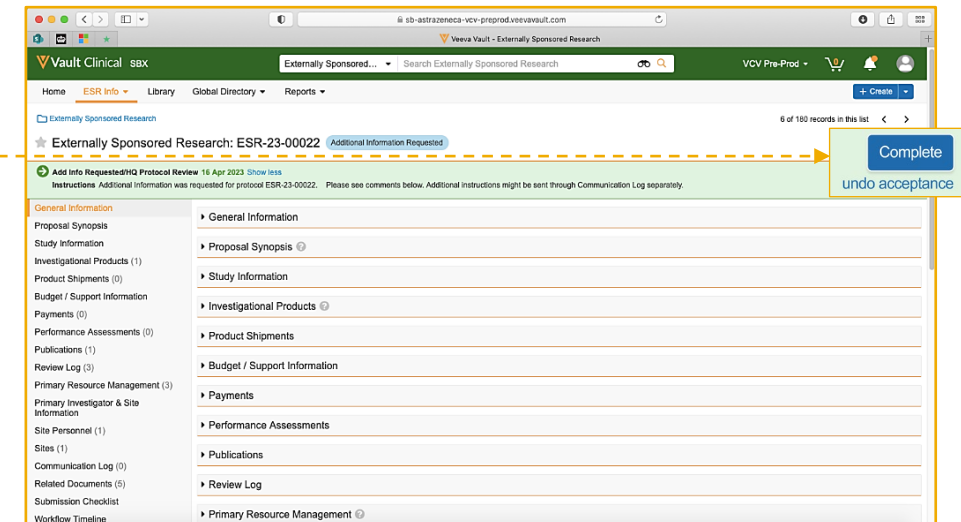
7

Click **Accept**, provide **additional information** as requested, or upload the updated **Protocol**



8

Click **Complete**



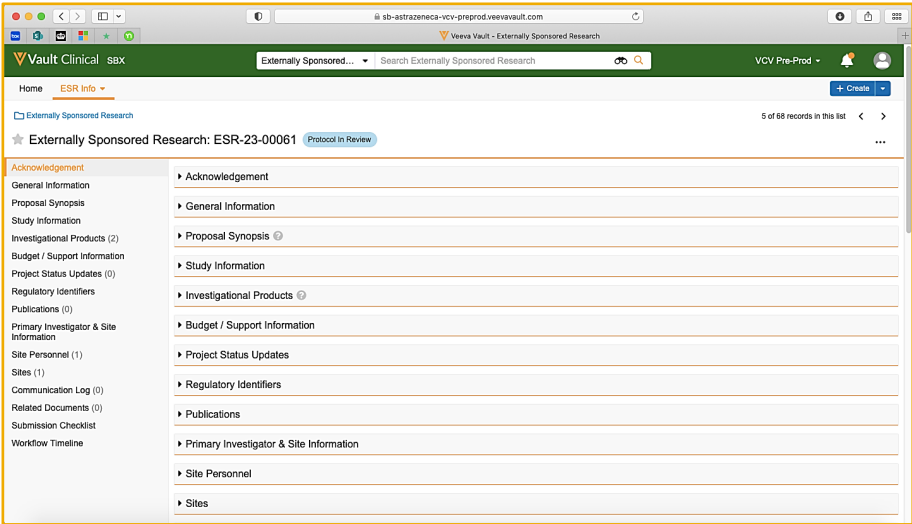
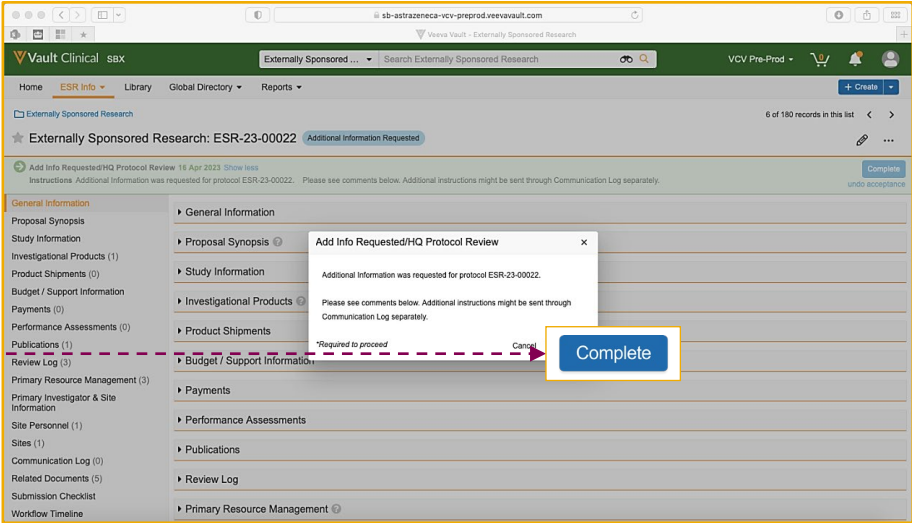
VCV Walkthrough - How to submit Additional Information Requested for a Protocol QC/Review

A pop-up window appears:
Add Info Requested/HQ Protocol Review.

9

Follow the instructions and click **Complete**

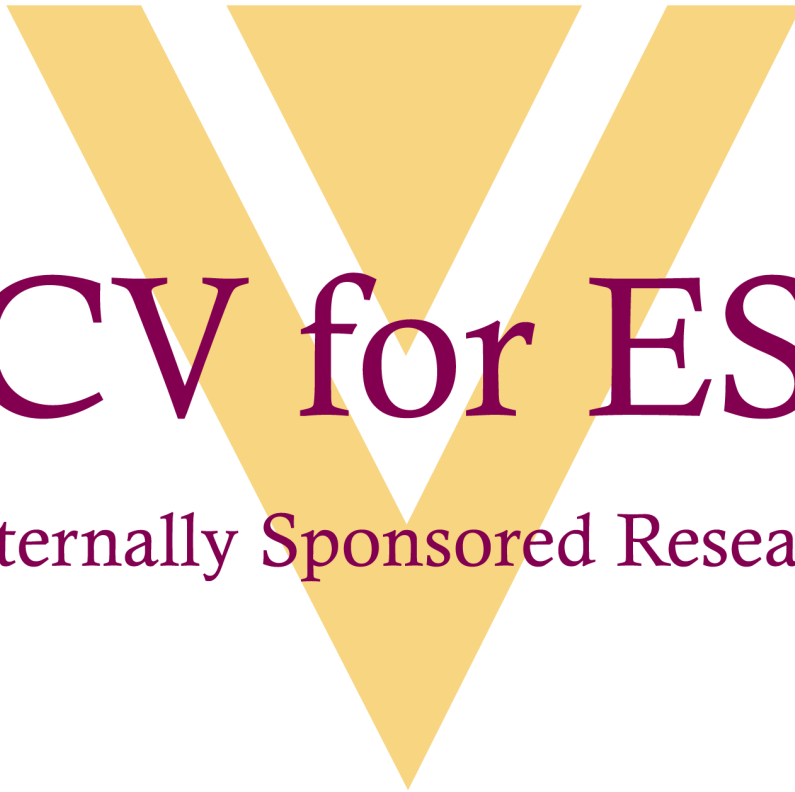
The study shows as **Protocol in Review**.



5

How to create and submit a Project Status Update (PSU)

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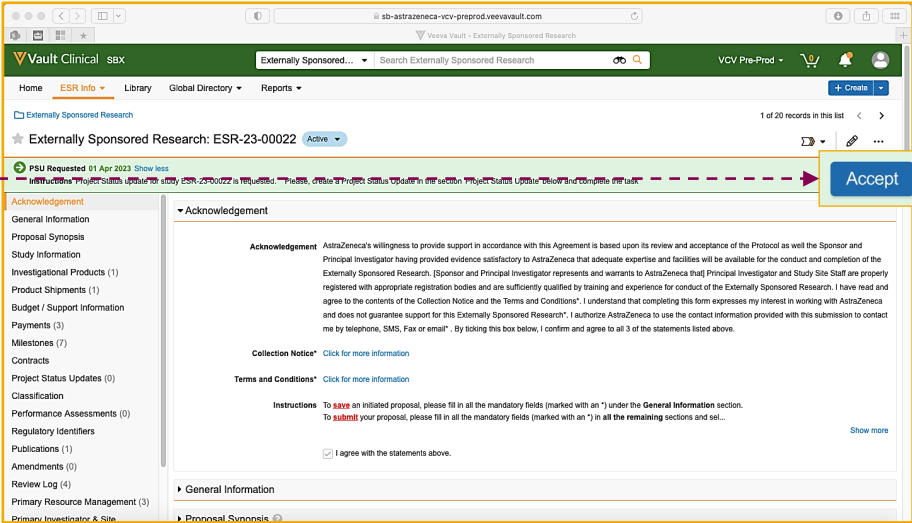
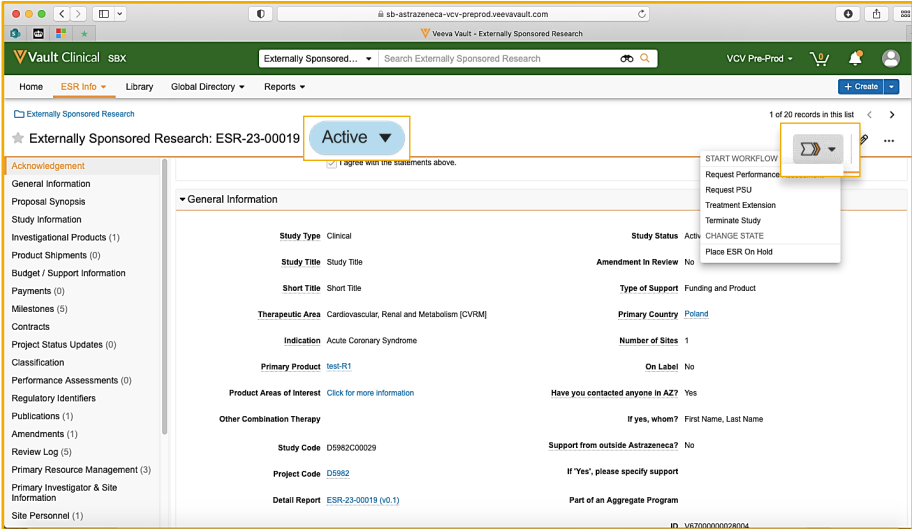
VCV for ESR

Externally Sponsored Research



VCV Walkthrough - How to create and submit a Project Status Update

Once **Request PSU** has been selected from the **workflow icon** drop-down menu, the study shows as **Active**, and **PSU (Project Status Update) Requested with Due Date and Instructions** appears in the taskbar for the external user (e.g., the Investigator).



1

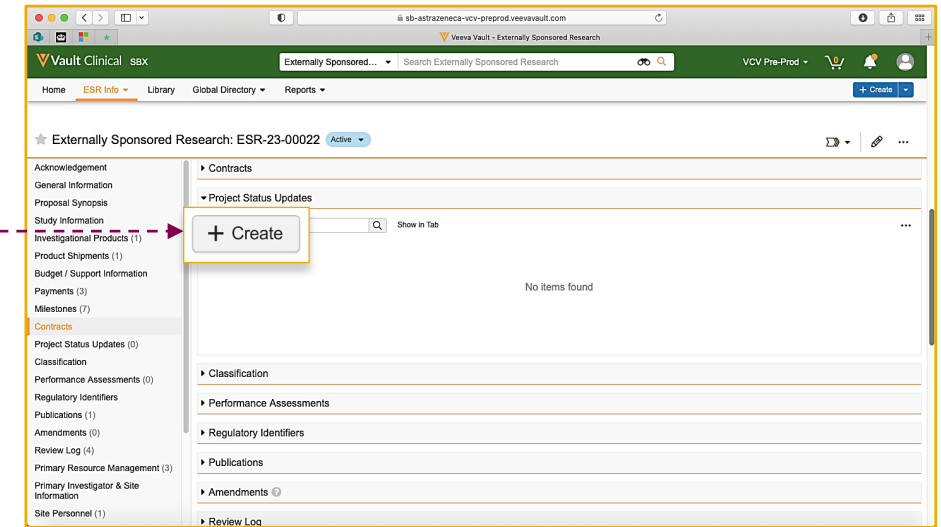
Click Accept



VCV Walkthrough - How to create and submit a Project Status Update

2

To create a **Project Status Update**, go to the **Project Status Updates** section and click **+Create**

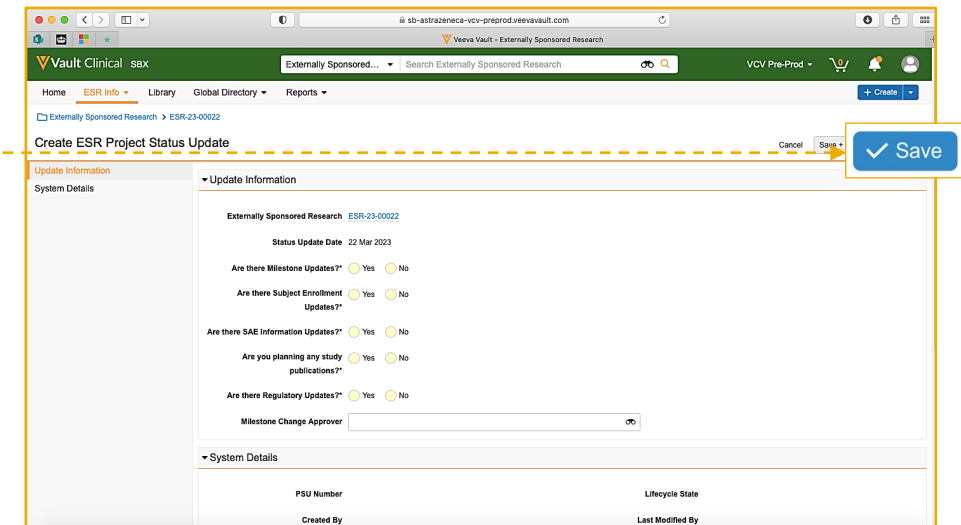


The screenshot shows the Veeva Vault Clinical interface. The left sidebar contains a list of sections: Acknowledgement, General Information, Proposal Synopsis, Study Information, Investigational Products (1), Product Shipments (1), Budget / Support Information, Payments (3), Milestones (7), Contracts, Project Status Updates (0), Classification, Performance Assessments (0), Regulatory Identifiers, Publications (1), Amendments (0), Review Log (4), Primary Resource Management (3), Primary Investigator & Site Information, and Site Personnel (1). The 'Project Status Updates' section is selected, and the '+ Create' button is highlighted with a red box. The main content area shows 'No items found'.

The **Update Information** sub-section shows up.

3

Complete the mandatory fields and click **Save**



The screenshot shows the 'Create ESR Project Status Update' form. The 'Update Information' sub-section is visible, containing the following fields and questions:

- Externally Sponsored Research: ESR-23-00022
- Status Update Date: 22 Mar 2023
- Are there Milestone Updates?: Yes No
- Are there Subject Enrollment Updates?: Yes No
- Are there SAE Information Updates?: Yes No
- Are you planning any study publications?: Yes No
- Are there Regulatory Updates?: Yes No
- Milestone Change Approver: [Text Field]

The 'System Details' sub-section is also visible, containing fields for PSU Number, Lifecycle State, Created By, and Last Modified By. The 'Save' button is highlighted with a red box.



VCV Walkthrough - How to create and submit a Project Status Update

Milestone Change Approver

If the answer to **Are there Milestone Updates?** is **Yes**, the **Milestone Change Approver** field should be filled in.

4

Click on the **Milestone Change Approver** field and select from the drop-down menu, then click **Save**

5

Alternatively, click the **binoculars icon** in the **Milestone Change Approver** field and select a value from the table in the pop-up box:
Search: Milestone Change Approver, then click **Close**

Update Information

System Details

RECENT

ESR Business Admin User 1

Abbie Phillis

Abby Lin

Acq Study Viewer

AcqPowerContributor UAT

Acquired eTMF Power Contributor

Acquired etmfuser

Acquired eTMFViewer

Acquired PowerContributor

Acquired StudyManagement

AcquiredeTMFContributor UAT

AcquiredTMFViewer UAT

AcquiredViewer eTMFContributor

Adam Kohagyi

Milestone Change Approver

System Details

PSU Number

Lifecycle State

Created By

Last Modified By

Search: Milestone Change Approver

Use search bar to find an item, and then use the table below to make selection

Filters

Start typing to see options...

Name	Email	Alternate Email	Last Name	Mobile
Abbie Phillis	Abbie.Phillis-Consultant@		Phillis	
Abby Lin	abbylin@astrazeneca.com		Lin	
Acq Study Viewer	shamili.alphonsemary@ac		Viewer	55454
AcqPowerContributor UAT	julia.dreksler@astrazene		UAT	
Acquired eTMF Power Contributor	renugadevi.man@astraze		eTMF Power Contributor	
Acquired etmfuser	manojkumar.j@astrazene		etmfuser	
Acquired eTMFViewer	olga.labeledz@astrazene		eTMFViewer	
Acquired PowerContributor	olga.labeledz@astrazene		PowerContributor	
Acquired StudyManagement	olga.labeledz@astrazene		StudyManagement	
AcquiredViewer eTMFContributor				

Close



VCV Walkthrough - How to create and submit a Project Status Update

Project Status Update shows as **Saved**.

If there were updates to **Milestones**, they will automatically be copied over to the **Milestones** section.

If there were updates to **Enrolment metrics**, they will automatically be copied over to the **Study Information** section.

If there were updates to **Regulatory dates**, they will automatically be copied over to the **Regulatory Identifiers** section.

The screenshot displays the Veeva Vault Clinical interface for an ESR Project Status Update. The browser address bar shows 'sb-astrazeneca-vcv-preprod.veevavault.com'. The page header includes 'Vault Clinical', 'Externally Sponsored...', and a search bar. The main content area shows the 'Update Information' section for 'Externally Sponsored Research ESR-23-00022'. The 'Status Update Date' is '22 Mar 2023'. Below this, there are several questions with 'Yes' answers: 'Are there Milestone Updates?', 'Are there Subject Enrollment Updates?', 'Are there SAE Information Updates?', 'Are you planning any study publications?', and 'Are there Regulatory Updates?'. The 'Milestone Change Approver' field is also visible. On the left sidebar, the 'Update Information' section is expanded, showing 'Milestone Update (0)', 'Subject Enrollment Update', 'SAE Information Update', 'Publication Plans Update', 'Regulatory Update', 'System Details', 'Workflow Timeline', and 'Sharing Settings'. A 'Saved' button is highlighted in the top right corner of the form.



VCV Walkthrough - How to create and submit a Project Status Update

6

Click **Complete**

sb-astrazeneca-vcv-preprod.veevavault.com

Veeva Vault - Externally Sponsored Research

Vault Clinical SBX

Externally Sponsored... Search Externally Sponsored Research

VCV Pre-Prod

Home ESR Info Library Global Directory Reports

Externally Sponsored Research

1 of 20 records in this list

★ Externally Sponsored Research: ESR-23-00022 Active

PSU Requested 01 Apr 2023 Show less

Instructions Project Status update for study ESR-23-00022 is requested. Please, create a Project Status Update in the section 'Project Status Update' below and complete the task

Complete

undo acceptance

Acknowledgement

General Information

Proposal Synopsis

Study Information

Investigational Products (1)

Product Shipments (1)

Budget / Support Information

Payments (3)

Milestones (7)

Contracts

Project Status Updates (0)

Classification

Performance Assessments (0)

Regulatory Identifiers

Publications (1)

Amendments (0)

Review Log (4)

Primary Resource Management (3)

Primary Investigator & Site

▼ Acknowledgement

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

Collection Notice* [Click for more information](#)

Terms and Conditions* [Click for more information](#)

Instructions To **save** an initiated proposal, please fill in all the mandatory fields (marked with an *) under the **General Information** section.
To **submit** your proposal, please fill in all the mandatory fields (marked with an *) in **all the remaining** sections and sel...

☒ I agree with the statements above.

Show more

► General Information

► Proposal Synopsis

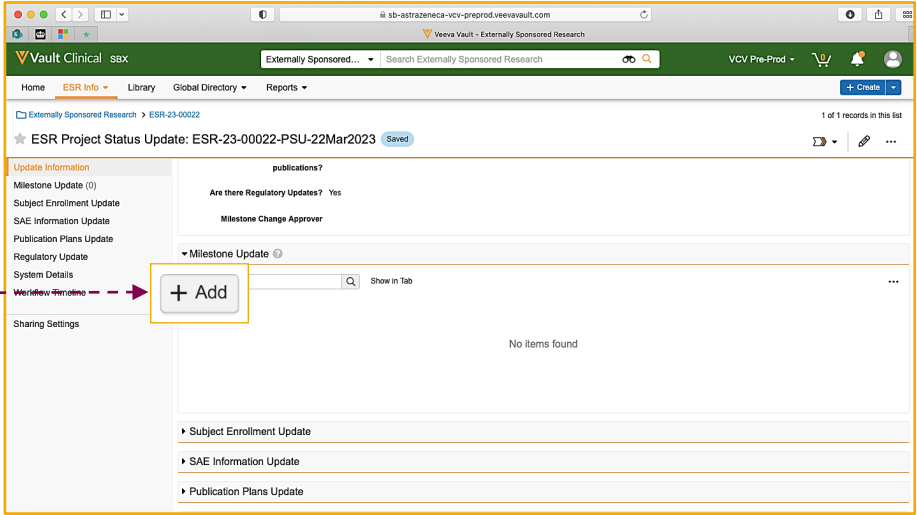


VCV Walkthrough - How to create and submit a Project Status Update

Milestone Update

7

If the answer to 'Are there Milestones Updates?' was **Yes**, go to **Milestone Update** sub-section and click **+Add**

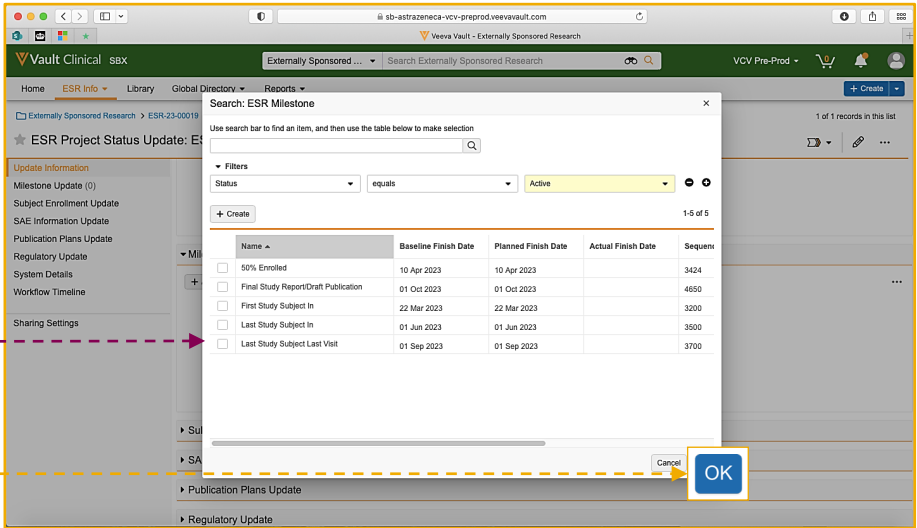


All **Milestones** in **Planned** state can be selected for an update.

A pop-up box appears: **Search ESR Milestone.**

8

Select the **Milestone**, e.g., **Last Study Subject Last Visit** in the table, and click **OK**



VCV Walkthrough - How to create and submit a Project Status Update

Updates to Milestone

Last Study Subject Last Visit shows in Milestone Update sub-section.

9

Click on **Last Study Subject Last Visit** – if the Milestone is being updated with the actual date, the **Milestone is Achieved** box should be ticked

You can also update the fields directly in the table view by double-clicking on the field. **Updated Date** and **Reason for Change** are mandatory fields (see **Steps 11 and 12**).

10

Open the **Updates to Milestone** sub-section and click **pencil icon** top right

Update Information

Milestone Update (1)

Subject Enrollment Update

SAE Information Update

Publication Plans Update

Regulatory Update

System Details

Workflow Timeline

Sharing Settings

Are there Regulatory Updates? Yes

Milestone Change Approver ESR Business Admin User 1

ESR Project Status Update: ESR-23-00019-PSU-22Mar2023

1 of 1 records in this list

ESR Milestone

Name	Current Planned Finish Date	Current Actual Finish Date	Updated Date	Milestone is achieved	Reason for Change
Last Study Subject Last Visit	01 Sep 2023			☐	

Subject Enrollment Update

SAE Information Update

Publication Plans Update

Regulatory Update

System Details

ESR Milestone Last Study Subject Last Visit

ESR PSU Number ESR-23-00023-PSU-22May2023

Updates to Milestone

Current Planned Finish Date 01 Jun 2023

Current Actual Finish Date

Updated Date

Reason for Change

Milestone is achieved ☐

If 'Other', reason for change

Workflow Timeline



VCV Walkthrough - How to create and submit a Project Status Update

Updates to Milestone

11

Add Updated Date

12

Select Reason for Change from the pick list

13

Tick **Milestone is achieved** if you are providing the actual date for the milestone

14

Click Save

The screenshot shows the 'Updates to Milestone' section of the VCV Clinical sax interface. The 'Updated Date' field is empty, and the 'Reason for Change' dropdown is open. The 'Milestone is achieved' checkbox is unchecked.

The screenshot shows the 'Updates to Milestone' section of the VCV Clinical sax interface. The 'Updated Date' field is filled with '01 Sep 2023', and the 'Milestone is achieved' checkbox is checked. The 'Save' button is highlighted.



VCV Walkthrough - How to create and submit a Project Status Update

Subject Enrolment Update

When opened, the **Subject Enrolment Update** sub-section shows with original values in each field.

ESR Project Status Update: ESR-23-00019-PSU-22Mar2023

Update Information

- Milestone Update (1)
- Subject Enrolment Update
- SAE Information Update
- Publication Plans Update
- Regulatory Update
- System Details
- Workflow Timeline

Sharing Settings

Subject Enrolment Update

Current Planned No. of Enrolled	100	Updated Planned No. of Enrolled	100
Current Actual No. of Enrolled	0	Updated Actual No. of Enrolled	0
Current Planned No. of Entered Treatment	100	Updated Planned No. of Entered Treatment	100
Current Actual No. of Entered Treatment	0	Updated Actual No. of Entered Treatment	0
Current Planned No. of Completed	90	Updated Planned No. of Completed	90
Current Actual No. of Completed	0	Updated Actual No. of Completed	0

SAE Information Update

Publication Plans Update

Regulatory Update

15

To update the fields click **pencil icon** top right

16

Update applicable fields and click **Save**

ESR Project Status Update: ESR-23-00019-PSU-22Mar2023

Update Information

- Milestone Update (1)
- Subject Enrolment Update
- SAE Information Update
- Publication Plans Update
- Regulatory Update
- System Details
- Workflow Timeline

Sharing Settings

Subject Enrolment Update

Current Planned No. of Enrolled	100	Updated Planned No. of Enrolled*	6
Current Actual No. of Enrolled	0	Updated Actual No. of Enrolled*	6
Current Planned No. of Entered Treatment	100	Updated Planned No. of Entered Treatment*	6
Current Actual No. of Entered Treatment	0	Updated Actual No. of Entered Treatment*	6
Current Planned No. of Completed	90	Updated Planned No. of Completed*	6
Current Actual No. of Completed	0	Updated Actual No. of Completed*	6

SAE Information Update

Publication Plans Update

Regulatory Update

System Details



VCV Walkthrough - How to create and submit a Project Status Update

Subject Enrolment Update

The **Subject Enrolment Update** sub-section shows with **updates**.

When the PSU is approved, **updated enrolment metrics** automatically change in the **Study Information** section.

The screenshot displays the Veeva Vault Clinical interface for an Externally Sponsored Research (ESR) project. The breadcrumb trail is: Externally Sponsored Research > ESR-23-00019. The page title is "ESR Project Status Update: ESR-23-00019-PSU-22Mar2023" with a "Saved" status. The left sidebar lists update categories: Update Information, Milestone Update (1), Subject Enrollment Update, SAE Information Update, Publication Plans Update, Regulatory Update, System Details, and Workflow Timeline. The main content area shows the "Subject Enrollment Update" section. It contains two columns of metrics: "Current" and "Updated". A callout box highlights the "Updated" metrics.

Current	Updated
Current Planned No. of Enrolled	Updated Planned No. of Enrolled
Current Actual No. of Enrolled	Updated Actual No. of Enrolled
Current Planned No. of Entered Treatment	Updated Planned No. of Entered Treatment
Current Actual No. of Entered Treatment	Updated Actual No. of Entered Treatment
Current Planned No. of Completed	Updated Planned No. of Completed
Current Actual No. of Completed	Updated Actual No. of Completed

Values from the screenshot:

- Current Planned No. of Enrolled: 100
- Current Actual No. of Enrolled: 0
- Current Planned No. of Entered Treatment: 100
- Current Actual No. of Entered Treatment: 0
- Current Planned No. of Completed: 90
- Current Actual No. of Completed: 0
- Updated Planned No. of Enrolled: 8
- Updated Actual No. of Enrolled: 12
- Updated Planned No. of Entered Treatment: 12
- Updated Actual No. of Entered Treatment: 11
- Updated Planned No. of Completed: 11
- Updated Actual No. of Completed: 9



VCV Walkthrough - How to create and submit a Project Status Update

Serious Adverse Event Information Update

When opened, the **SAE Information Update** sub-section shows with 'I confirm the SAE has been reported.'

The screenshot shows the 'ESR Project Status Update' form for ESR-23-00019-PSU-22Mar2023. The 'SAE Information Update' sub-section is expanded, showing the text 'I confirm the SAE has been reported.' A pencil icon is visible in the top right corner of the form area.

17

Click the **pencil icon** top right to open the fields

The screenshot shows the 'ESR Project Status Update' form for ESR-23-00019-PSU-22Mar2023. The 'SAE Information Update' sub-section is expanded, showing the text 'I confirm the SAE has been reported' with radio buttons for 'Yes' and 'No'. A 'Save' button is visible in the top right corner.

18

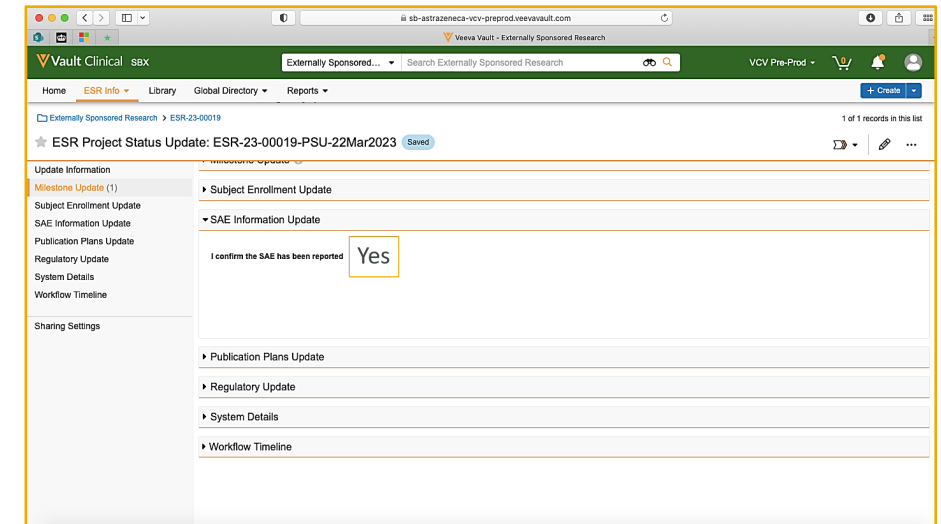
Click **Yes** or **No** then click **Save**



VCV Walkthrough - How to create and submit a Project Status Update

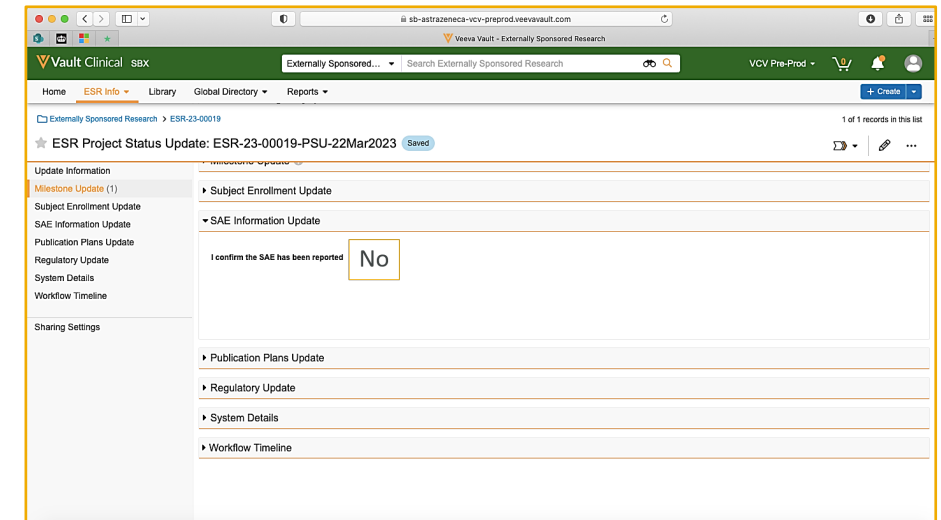
Serious Adverse Event Information Update

If **Yes** is selected, '**Yes**' shows up in the SAE Information Update sub-section.



The screenshot shows the Veeva Vault Clinical interface for an 'Externally Sponsored' project. The left sidebar lists update categories: Milestone Update (1), Subject Enrollment Update, SAE Information Update, Publication Plans Update, Regulatory Update, System Details, and Workflow Timeline. The 'SAE Information Update' sub-section is active, displaying a form with the text 'I confirm the SAE has been reported' followed by a yellow box containing the word 'Yes'. Below this are sections for Publication Plans Update, Regulatory Update, System Details, and Workflow Timeline.

If **No** is selected, '**No**' shows up in the SAE Information Update sub-section.



The screenshot shows the same Veeva Vault Clinical interface, but with the 'SAE Information Update' sub-section displaying 'No' in the yellow box. The rest of the interface, including the sidebar and other update sections, remains the same.



VCV Walkthrough - How to create and submit a Project Status Update

Publication Plans Update

When opened, the **Publication Plans Update** sub-section shows with instructions.

19

Click the **pencil icon** top right

The screenshot shows the Veeva Vault Clinical interface for 'Externally Sponsored Research'. The left sidebar lists various update sections: Update Information, Milestone Update (1), Subject Enrollment Update, SAE Information Update, Publication Plans Update, Regulatory Update, System Details, Workflow Timeline, and Sharing Settings. The main content area shows the 'Publication Plans Update' section with a text input field and a 'Please provide likely timing and details' prompt. A pencil icon is visible in the top right corner of the main content area.

20

Provide **likely timing** and details for **Publication Plans**, and click **Save**

The screenshot shows the Veeva Vault Clinical interface for 'Externally Sponsored Research'. The left sidebar lists various update sections: Update Information, Milestone Update (1), Subject Enrollment Update, SAE Information Update, Publication Plans Update, Regulatory Update, System Details, Workflow Timeline, and Sharing Settings. The main content area shows the 'Publication Plans Update' section with a text input field and a 'Please provide likely timing and details' prompt. A 'Save' button is visible in the top right corner of the main content area.



VCV Walkthrough - How to create and submit a Project Status Update

Publication Plans Update

The **Update** shows in the **Publication Plans Update** sub-section.

The screenshot displays the Veeva Vault Clinical interface for an Externally Sponsored Research (ESR) project. The browser address bar shows 'sb-astrazeneca-vcv-preprod.veevavault.com'. The page title is 'Veeva Vault - Externally Sponsored Research'. The navigation bar includes 'Home', 'ESR Info', 'Library', 'Global Directory', and 'Reports'. A search bar is present with the text 'Externally Sponsored Research'. The main content area shows the 'ESR Project Status Update: ESR-23-00019-PSU-22Mar2023' form. The left sidebar lists the following sections: 'Update Information', 'Milestone Update (1)', 'Subject Enrollment Update', 'SAE Information Update', 'Publication Plans Update', 'Regulatory Update', 'System Details', 'Workflow Timeline', and 'Sharing Settings'. The 'Publication Plans Update' section is expanded, showing a text area with the prompt 'Please provide likely timing and details' and a 'Likely timings/details' label. The right sidebar shows '1 of 1 records in this list' and a '+ Create' button.



VCV Walkthrough - How to create and submit a Project Status Update

Regulatory Update

When opened, the **Regulatory Update** sub-section shows with **IRB/EC Approval Date** and **IRB/EC Expiration Date**.

The screenshot shows the Veeva Vault Clinical interface for an 'Externally Sponsored' project. The left sidebar contains a list of update categories: Update Information, Milestone Update (1), Subject Enrollment Update, SAE Information Update, Publication Plans Update, Regulatory Update, System Details, and Workflow Timeline. The 'Regulatory Update' section is expanded, showing the 'IRB/EC Approval Date' and 'IRB/EC Expiration Date' fields. A pencil icon in the top right corner is highlighted with a dashed line, indicating it should be clicked to open the fields for editing.

21

Click the **pencil icon** top right to open fields

The screenshot shows the Veeva Vault Clinical interface for an 'Externally Sponsored' project. The left sidebar contains a list of update categories: Update Information, Milestone Update (1), Subject Enrollment Update, SAE Information Update, Publication Plans Update, Regulatory Update, System Details, and Workflow Timeline. The 'Regulatory Update' section is expanded, showing the 'IRB/EC Approval Date' and 'IRB/EC Expiration Date' fields. The 'IRB/EC Approval Date' field is set to '22 Mar 2023' and the 'IRB/EC Expiration Date' field is set to '22 Mar 2023'. A 'Save' button in the top right corner is highlighted with a dashed line, indicating it should be clicked to submit the update.

22

Edit the fields and click **Save**

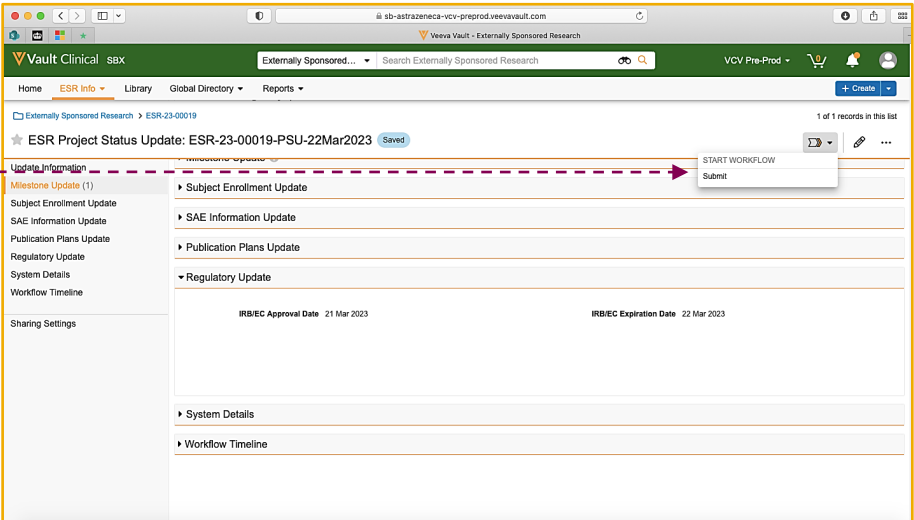
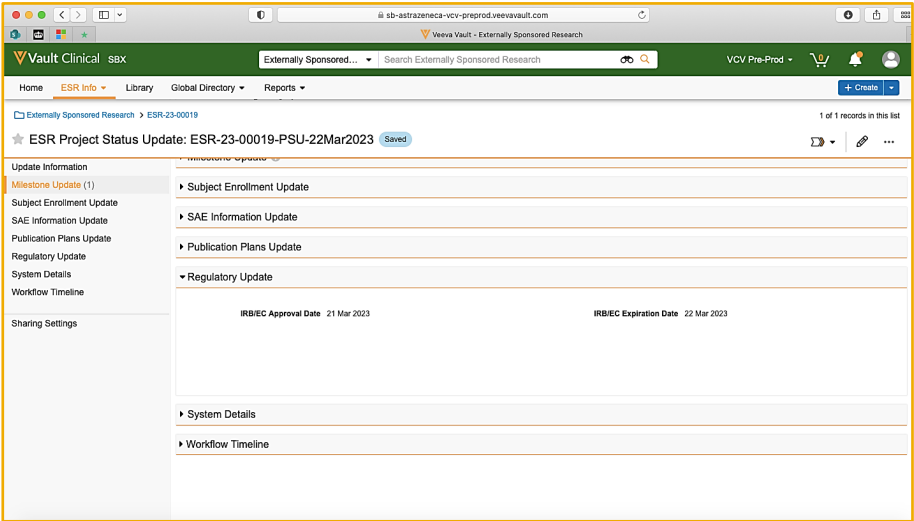


VCV Walkthrough - How to create and submit a Project Status Update

Regulatory Update

The **Regulatory Update** sub-section shows with updated dates.

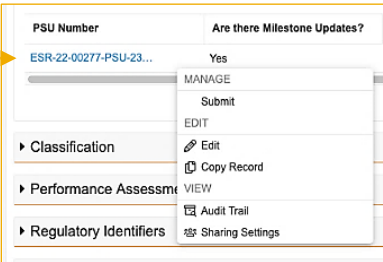
When the PSU is approved, the updated **Regulatory dates** will automatically change in the **Regulatory Identifiers** section.



23

Select **Submit** from the workflow icon top right to **submit the PSU**

The **PSU** may also be **submitted** by clicking on the **PSU number** in the **Project Status Updates** section and selecting **Submit** from the drop-down menu.



VCV Walkthrough - How to create and submit a Project Status Update

PSU review

The Local Coordinator reviews the PSU.
If the Verdict of the review is **Additional Information Requested**, PSU sent for review and resubmit appears in the taskbar with **Instructions** for the external user (e.g., the Investigator).

24

Click **Accept** and update the PSU based on the comments provided

Accept

25

Click **Complete**

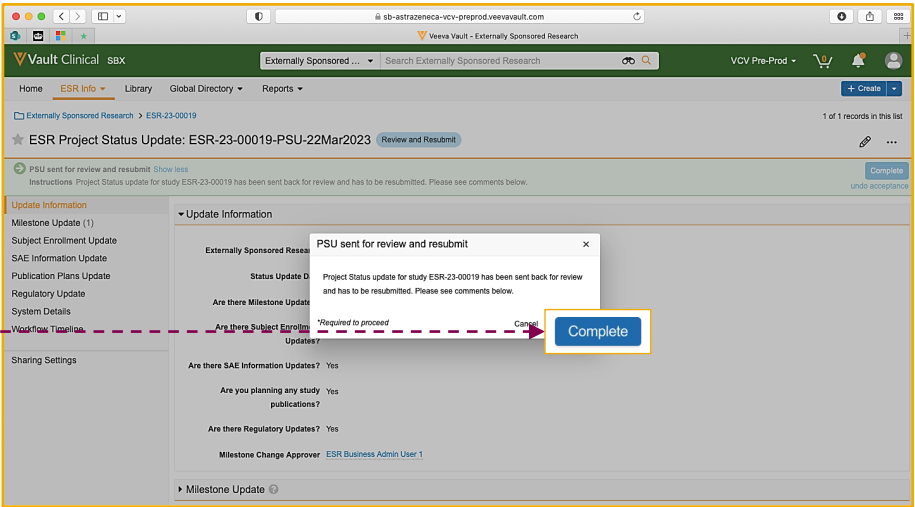
Complete
undo acceptance



VCV Walkthrough - How to create and submit a Project Status Update

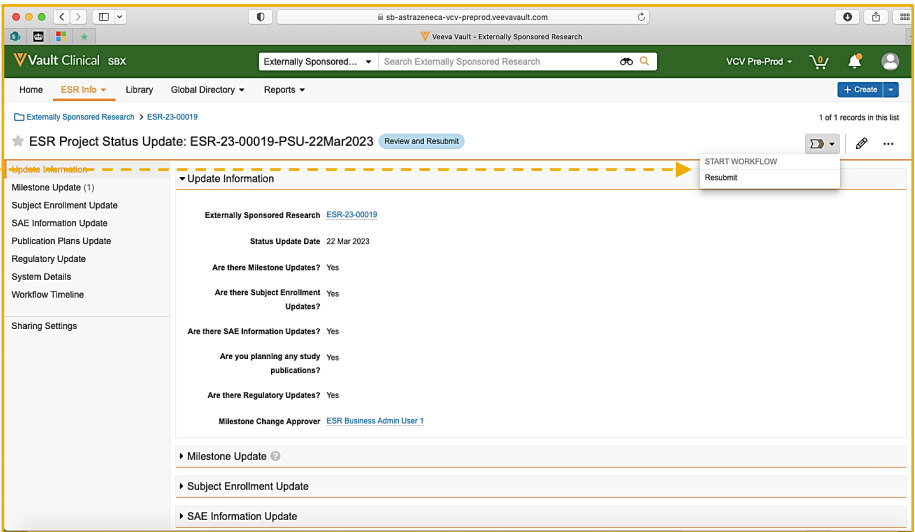
PSU review

A pop-up box appears: **PSU sent for review and resubmit.**



26

See **Comments** and click **Complete**



27

Select **Resubmit** from the workflow icon top right



VCV Walkthrough - How to create and submit a Project Status Update

Project Status Update accepted

When AstraZeneca has completed the review of the PSU and approved it, Project Status Update shows as **Accepted**.

If there were updates to **Milestones**, they will automatically be copied over to the **Milestones** section.

If there were updates to **Enrolment metrics**, they will automatically be copied over to the **Study Information** section.

If there were updates to **Regulatory dates**, they will automatically be copied over to the **Regulatory Identifiers** section.

The screenshot displays the 'Vault Clinical' interface for an 'Externally Sponsored Research' project. The breadcrumb trail shows 'Externally Sponsored Research > ESR-22-00277'. The main heading is '★ ESR Project Status Update: ESR-22-00277-PSU-24Nov2022'. A blue button labeled 'Accepted' is highlighted with a yellow box. The left sidebar contains a menu with 'Update Information' selected, listing 'Milestone Update (1)', 'Subject Enrollment Update', 'SAE Information Update', 'Publication Plans Update', 'Regulatory Update', 'System Details', 'Workflow Timeline', and 'Sharing Settings'. The main content area under 'Update Information' shows 'Externally Sponsored Research ESR-22-00277' and 'Status Update Date 24 Nov 2022'. It includes a series of questions with 'Yes' answers: 'Are there Milestone Updates?', 'Are there Subject Enrollment Updates?', 'Are there SAE Information Updates?', 'Are you planning any study publications?', and 'Are there Regulatory Updates?'. The 'Milestone Change Approver' is listed as 'System'. At the bottom, there are expandable sections for 'Milestone Update', 'Subject Enrollment Update', and 'SAE Information Update'.



6

How to create an Amendment

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VCV for ESR

Externally Sponsored Research



VCV Walkthrough - How to create an Amendment

1

Open the **Related Documents** section and click **+Add**

The screenshot shows the Veeva Vault Clinical interface for 'Externally Sponsored Research: ESR-23-00019'. The left sidebar contains a navigation menu with sections like Acknowledgement, General Information, Proposal Synopsis, Study Information, Investigational Products (1), Product Shipments (0), Budget / Support Information, Payments (0), Milestones (5), Contracts, Classification, Performance Assessments (0), Regulatory Identifiers, Publications (1), Amendments (0), Review Log (3), Primary Resource Management (3), Primary Investigator & Site Information, Site Personnel (1), and Sites (1). The main content area shows the 'Related Documents' section with a table of documents. An '+ Add' button is highlighted in the top left of the table.

Subtype	Description	Status	Created By	Created Date
Initial Protocol	Description	Draft	ESR Local Coordinator User 1	17 Mar 2023 9:2
CV	test	Draft	ESR External User 1	28 Nov 2022 2:1
Details Report		Draft	System	16 Mar 2023 4:4
Budget	BUDGETs	Draft	ESR External User 1	22 Jun 2022 12:2

To upload an **Amendment**, see [How to upload a document](#).

Once added, the **Amendment** shows in the **Related Documents** section.

The screenshot shows the Veeva Vault Clinical interface for 'Externally Sponsored Research: ESR-23-00019'. The 'Related Documents' section now includes an additional row for 'Protocol Amendment - ESR-23-0002'. The table shows the following documents:

Name	Subtype	Description	Status	Created By	Created Date
Protocol-ESR-23-00025	Initial Protocol	Description	Draft	ESR Local Coordinator User 1	17 Mar 2023 9:2
Protocol Amendment - ESR-23-0002	Protocol Amendment	Desc	Draft	ESR Local Coordinator User 1	17 Mar 2023 11:1
PI CV-ESR-22-00149	CV	test	Draft	ESR External User 1	28 Nov 2022 2:1
ESR-23-00019	Details Report		Draft	System	16 Mar 2023 4:4
Budget - ESR-22-00001	Budget	BUDGETs	Draft	ESR External User 1	22 Jun 2022 12:2



VCV Walkthrough - How to create an Amendment

2

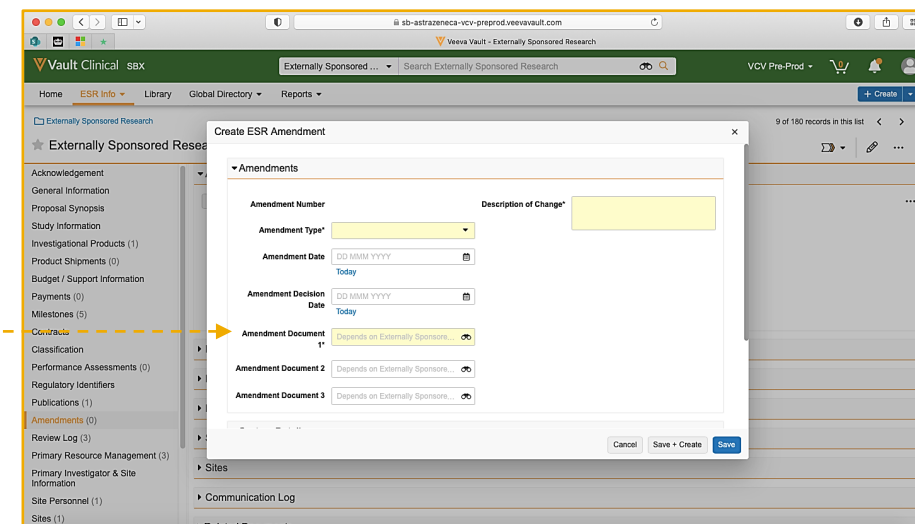
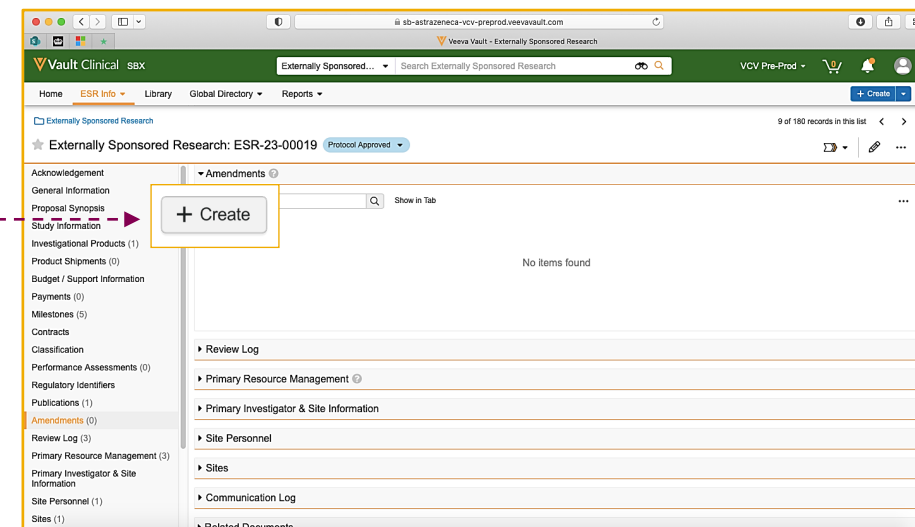
Open the **Amendments** section and click **+Create**

A pop-up box appears: **Create ESR Amendment**.

3

Complete the mandatory fields

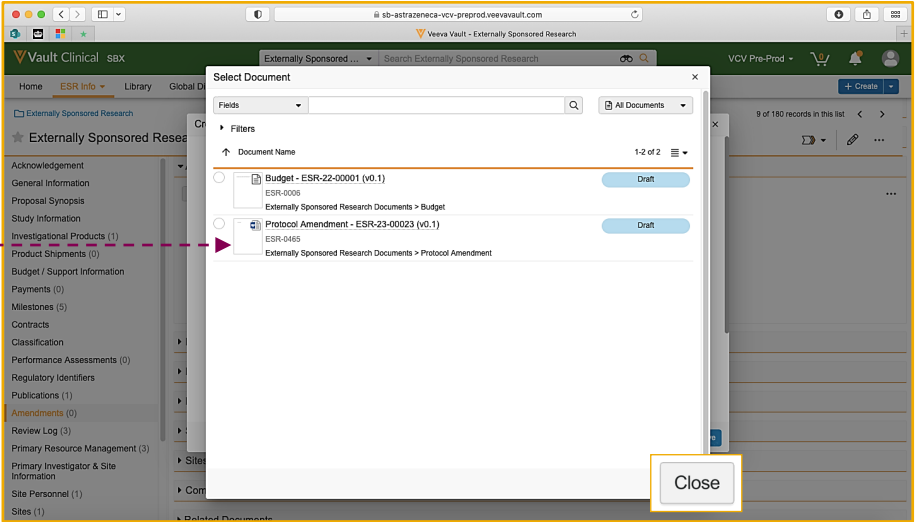
When the user clicks on the **binoculars icon** in the mandatory **Amendment Document 1** field, the **Amendment** that was added to the **Related Documents** section will appear in the pick list.



VCV Walkthrough - How to create an Amendment

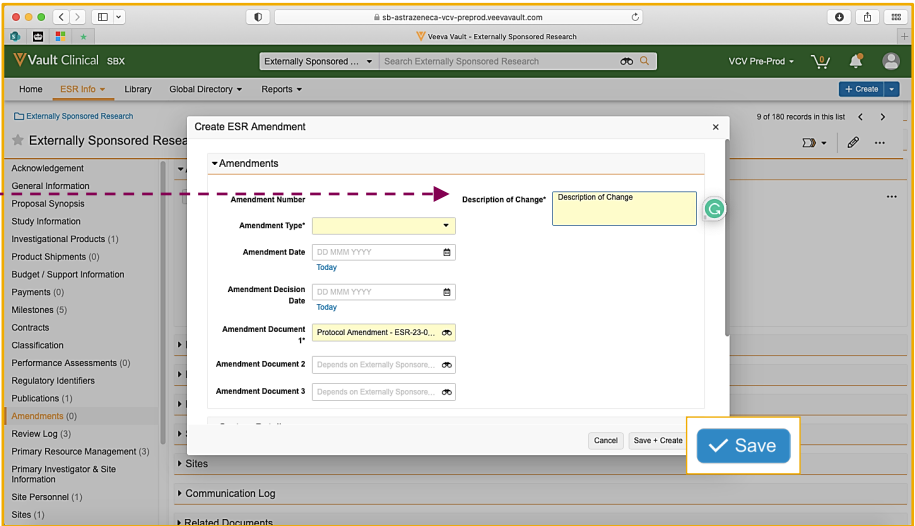
4

Select the **Amendment** and click **Close**



5

Fill in the remaining mandatory field and click **Save**



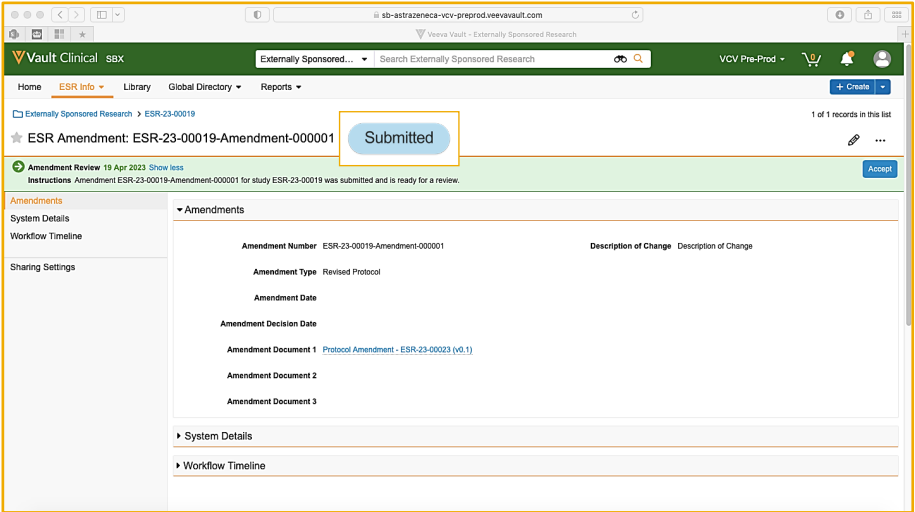
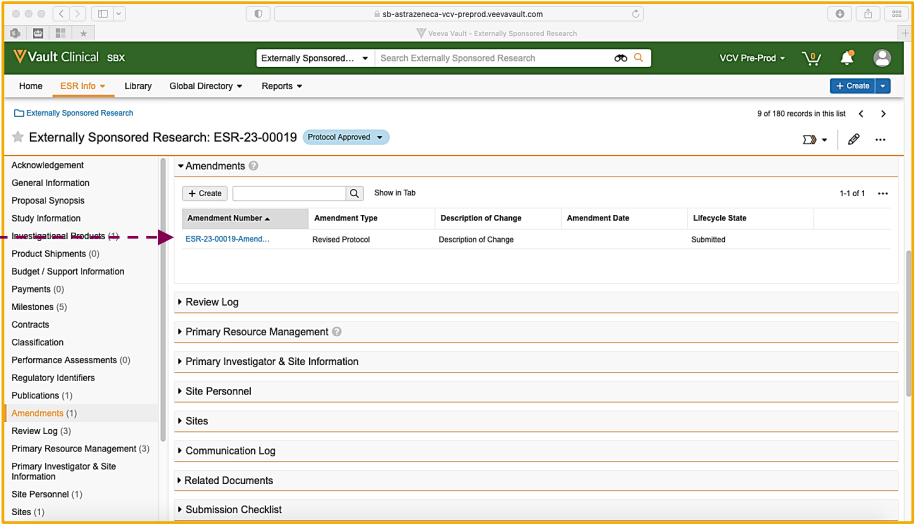
VCV Walkthrough - How to create an Amendment

6

The Amendment Number shows in the Amendments section.

Click on the Amendment Number

The Amendment shows as Submitted and Amendment Review will appear in the taskbar with Due Date and Instructions for the user assigned to the task.

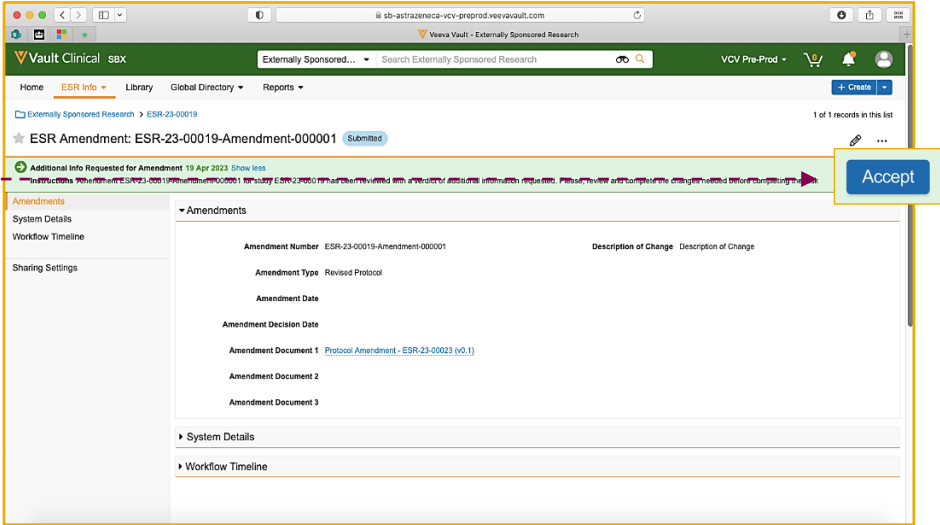


VCV Walkthrough - How to create an Amendment

If the **Verdict** of the **Amendment Review** is **Additional Information Requested**, **Additional Info Requested** for Amendment with **Due Date** and **Instructions** appears in the taskbar.

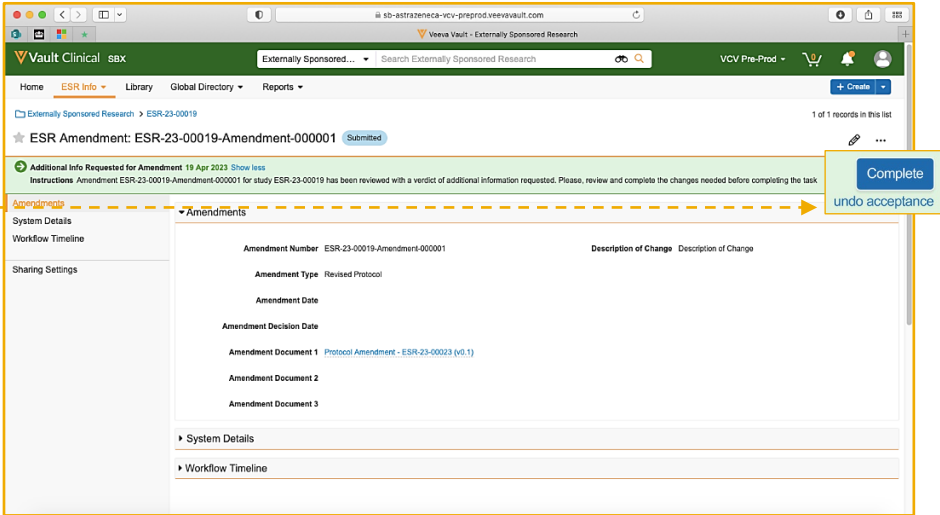
7

Click **Accept** and provide **Additional Information** for the **Amendment** record and **upload the updated document** if required



8

Click **Complete**



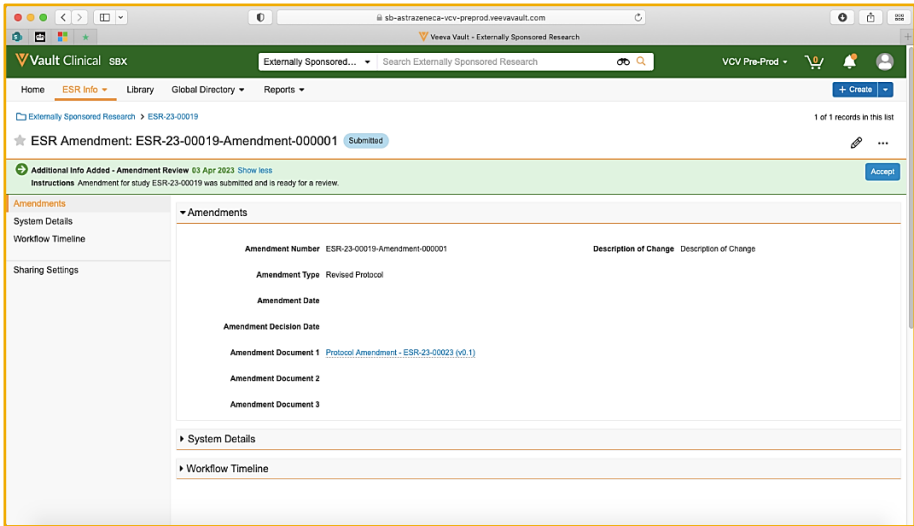
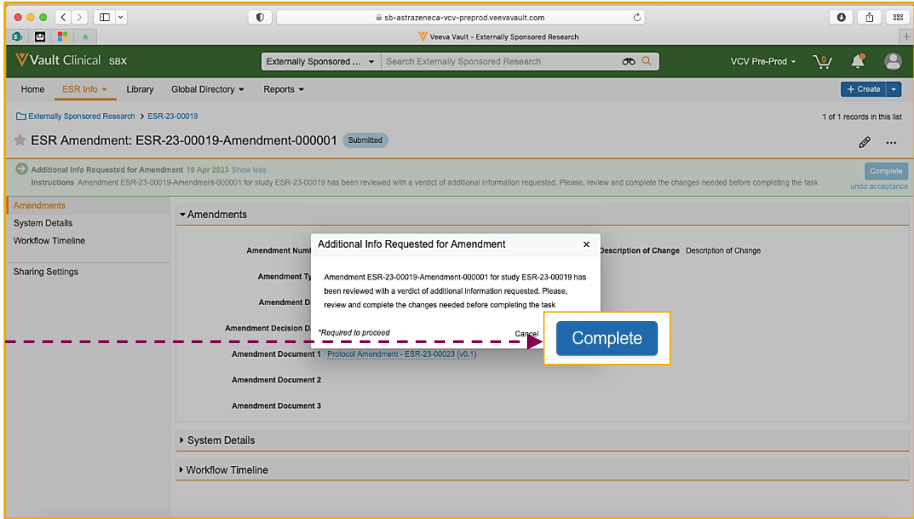
VCV Walkthrough - How to create an Amendment

A pop-up box appears:
Additional Info Requested for Amendment.

9

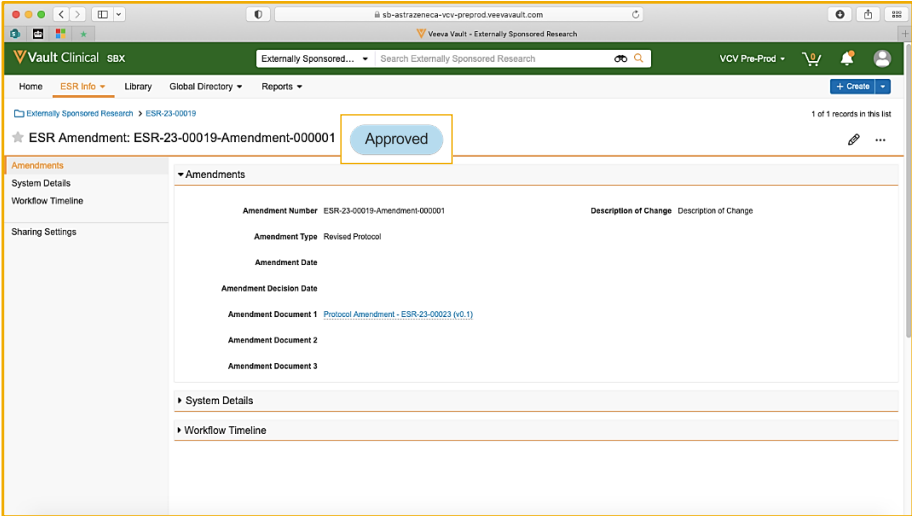
Click **Complete**

Additional Info Added – Amendment Review will appear
in the taskbar with **Due Date** and **Instructions**.

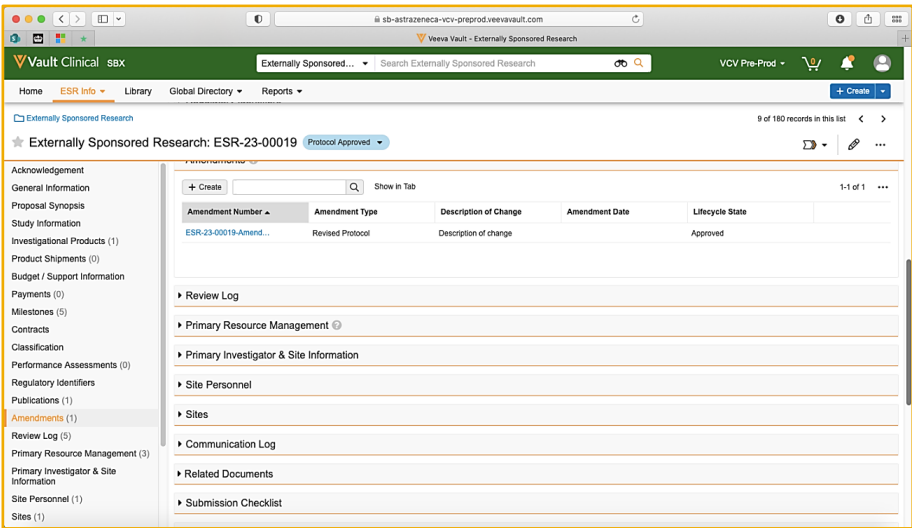


VCV Walkthrough - How to create an Amendment

If the **Verdict** is **Approved**, the **Amendment** shows as **Approved** in the **Amendment** record.



The **Amendment Record** shows as **Approved** in the **Amendment** section.



7

How to provide Final Deliverables

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VCV for ESR

Externally Sponsored Research

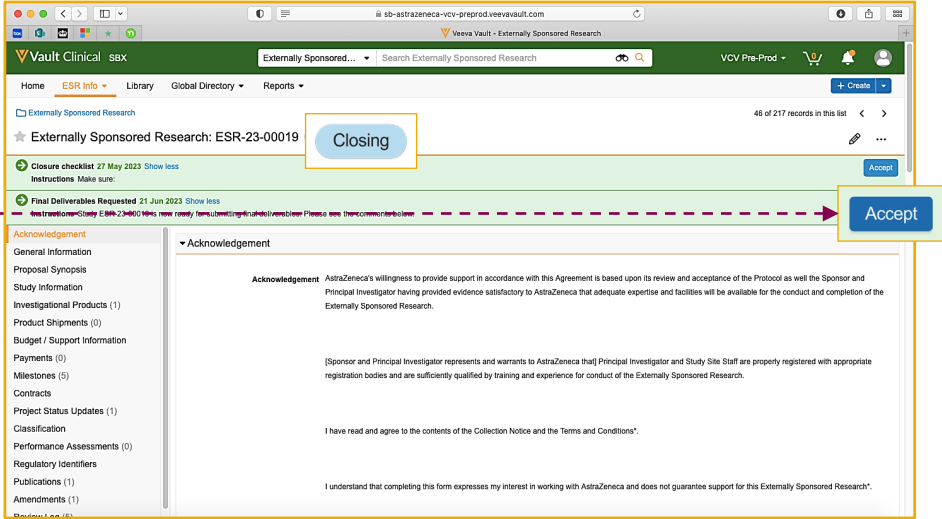


VCV Walkthrough - How to provide Final Deliverables

When the study shows as **Closing**, a task appears in the taskbar for the Investigator: **Final Deliverables Requested** with **Due Date** and **Instructions**.

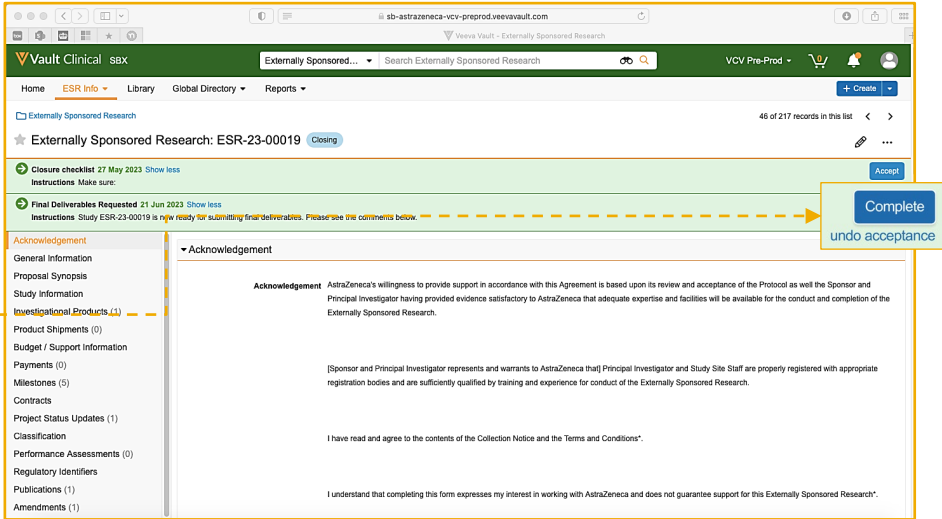
1

Click **Accept**



2

Provide **Final Deliverables** and click **Complete**

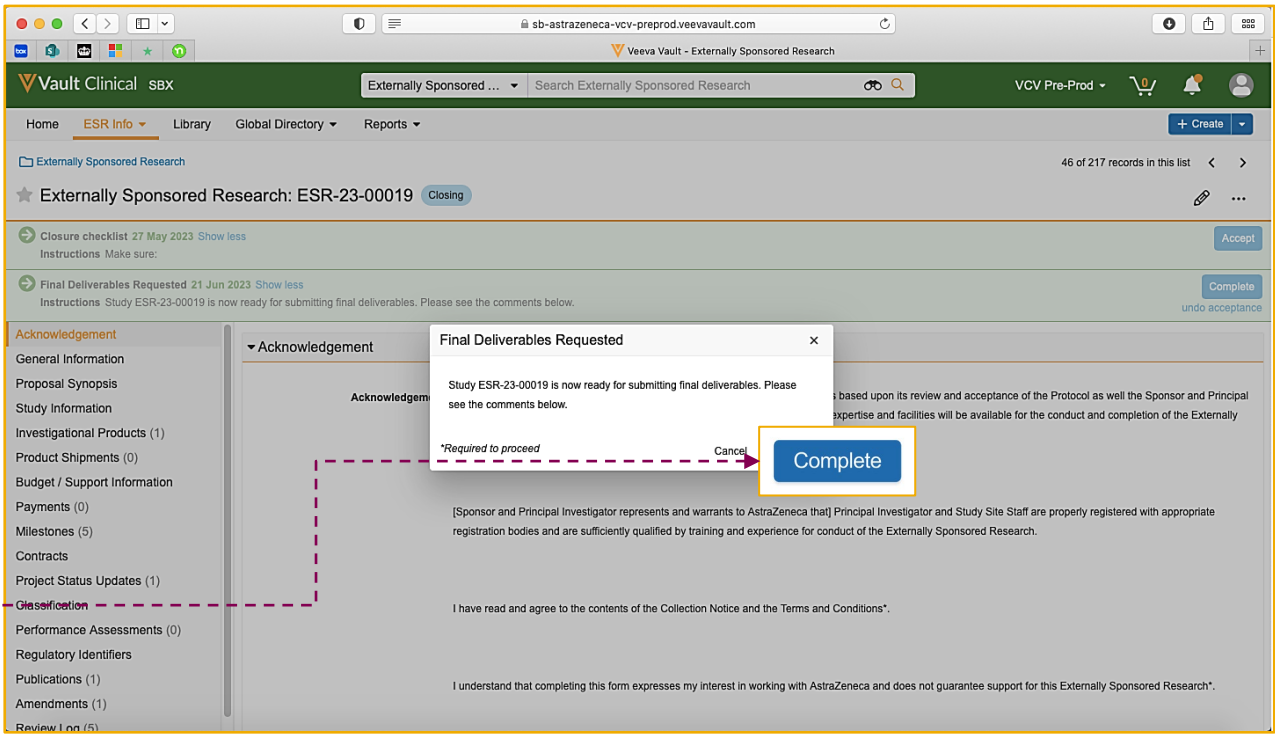


VCV Walkthrough - How to provide Final Deliverables

A pop-up box appears: Final Deliverables Requested.

3

Click **Complete**



8

How to view an audit trail

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VCV for ESR

Externally Sponsored Research



VCV Walkthrough - How to view an audit trail

Study level audit trail

Once a **study** has been opened in VCV,
its **Audit Trail** may be viewed.

1

To view the **Audit Trail** for a **study**, click on
the **three dots icon** top right and select **Audit Trail**
from the drop-down menu

A pop-up box appears: **Audit trail for Externally
Sponsored Research with ESR Number.**

The first screenshot shows the 'Externally Sponsored Research: ESR-22-00289' page. A dashed red line points from the 'three dots' menu icon in the top right corner to the 'Audit Trail' option in the dropdown menu.

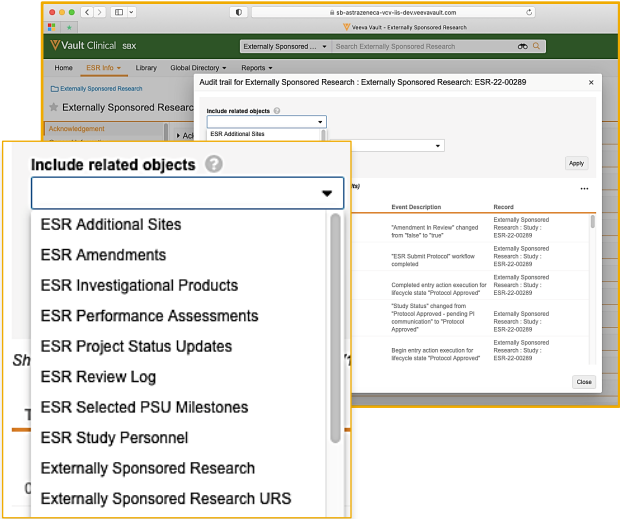
The second screenshot shows the 'Audit trail for Externally Sponsored Research : Externally Sponsored Research: ESR-22-00289' pop-up box. It includes a table of events with the following data:

Timestamp (dd MMM yyyy)	User Name	Event Description	Record
04 Jan 2023 9:10 AM EST	System	"Amendment In Review" changed from "Raise" to "True"	Externally Sponsored Research : Study : ESR-22-00289
04 Jan 2023 8:20 AM EST	System	"ESR Submit Protocol" workflow completed	Externally Sponsored Research : Study : ESR-22-00289
04 Jan 2023 8:20 AM EST	System	Completed entry action execution for lifecycle state "Protocol Approved"	Externally Sponsored Research : Study : ESR-22-00289
04 Jan 2023 8:20 AM EST	System	"Study Status" changed from "Protocol Approved - pending PI communication" to "Protocol Approved"	Externally Sponsored Research : Study : ESR-22-00289
04 Jan 2023 8:20 AM EST	System	Begin entry action execution for lifecycle state "Protocol Approved"	Externally Sponsored Research : Study : ESR-22-00289

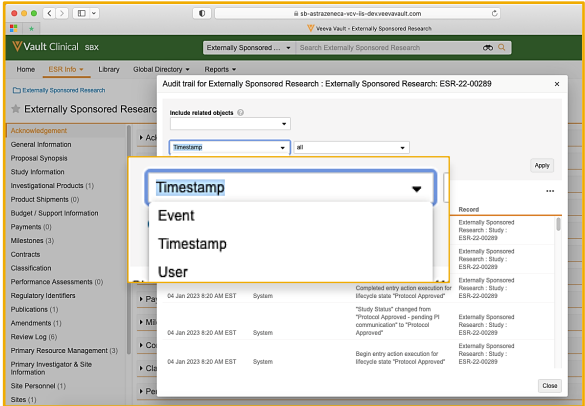


VCV Walkthrough - How to view an audit trail

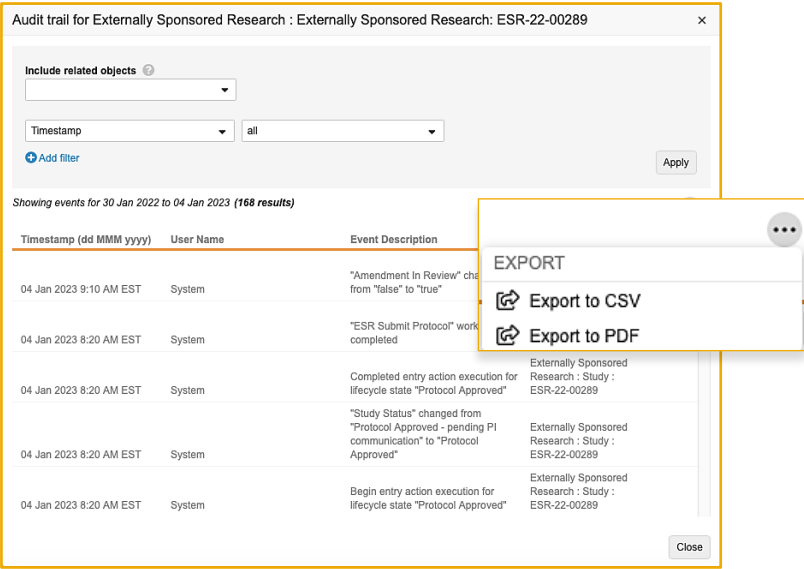
The Audit Trail may be searched for **related objects**.



It may also be searched for **event, timestamp or user**, or for all three.



The Audit Trail may be **exported as CSV or PDF** by clicking on the **three dots icon** top right in the pop-up box.



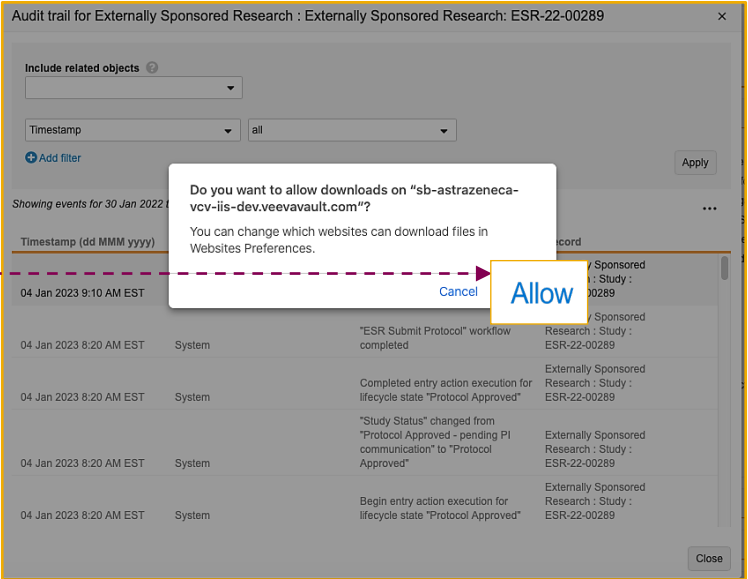
VCV Walkthrough - How to view an audit trail

Study level audit trail

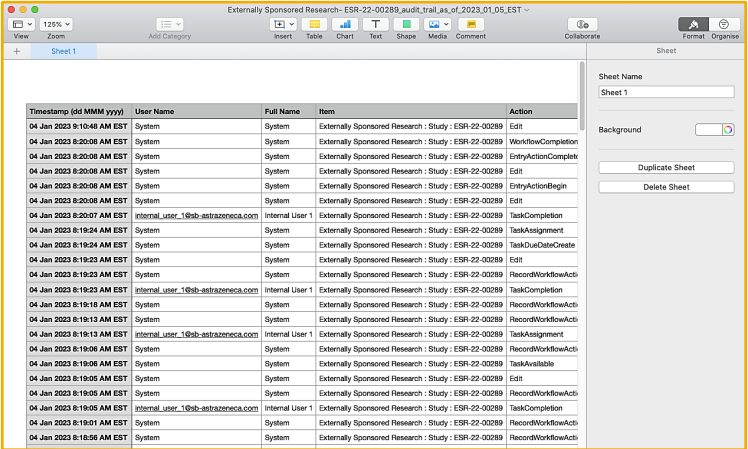
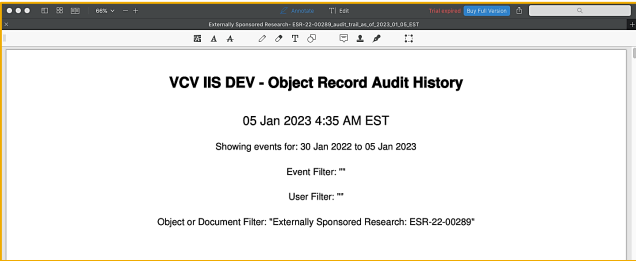
A further pop-up box appears with a prompt asking if the user wants to download the **Audit Trail**.

2

To download the Audit Trail, click **Allow**



The user can select to download the Audit Trail as a PDF or a CSV.



VCV Walkthrough - How to view an audit trail

Object level audit trail – e.g. for investigational products

1

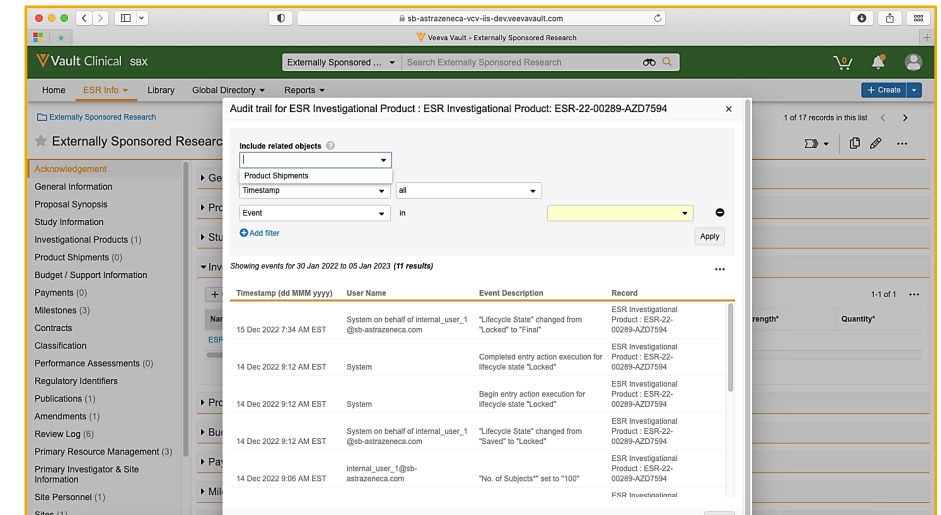
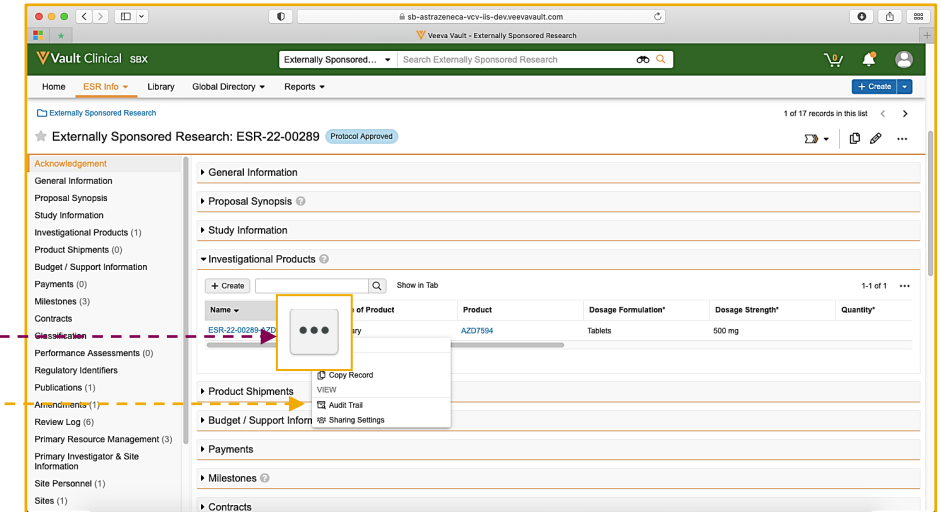
To view the **audit trail** for an **investigational product**, go to the study's **Investigational Products** section and click the **three dots icon** next to the product number

2

From the drop-down menu, select **Audit Trail**

A pop-up box appears: **Audit trail for ESR Investigational Product with Product Number.**

The audit trail for the product may be searched by going to the **Include related objects** field and selecting **Product Shipments** from the drop-down menu.



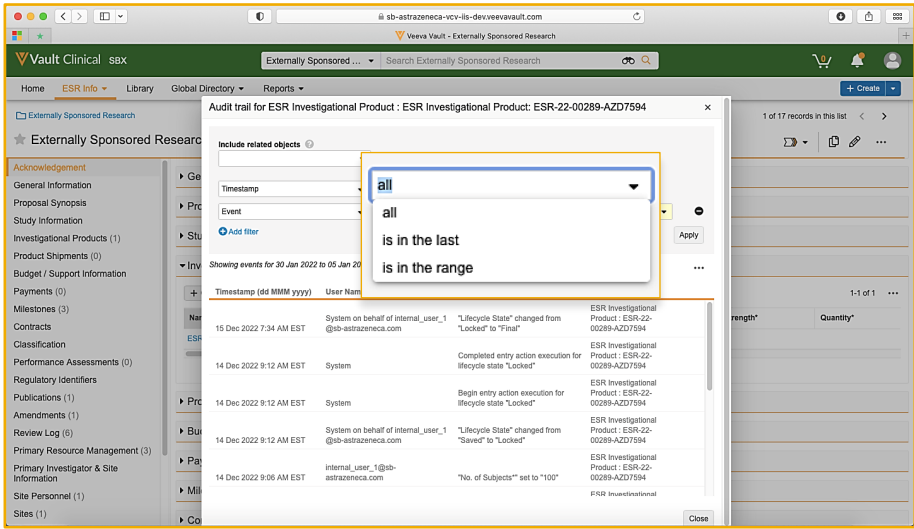
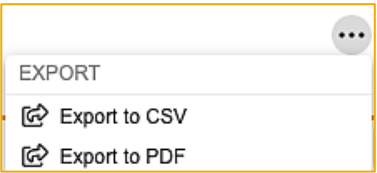
VCV Walkthrough - How to view an audit trail

Object level audit trail

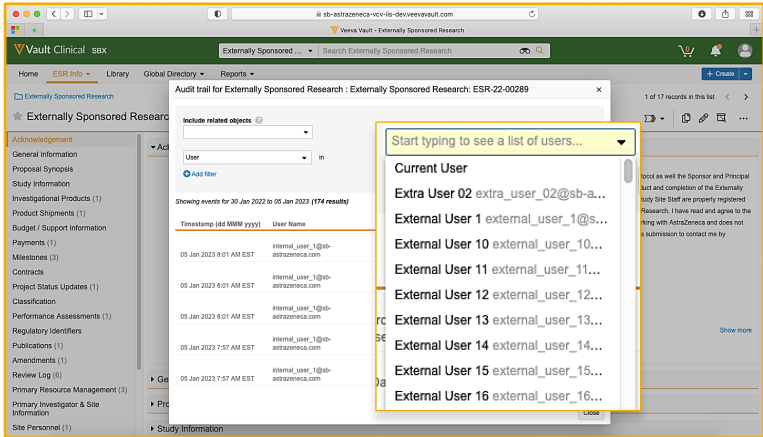
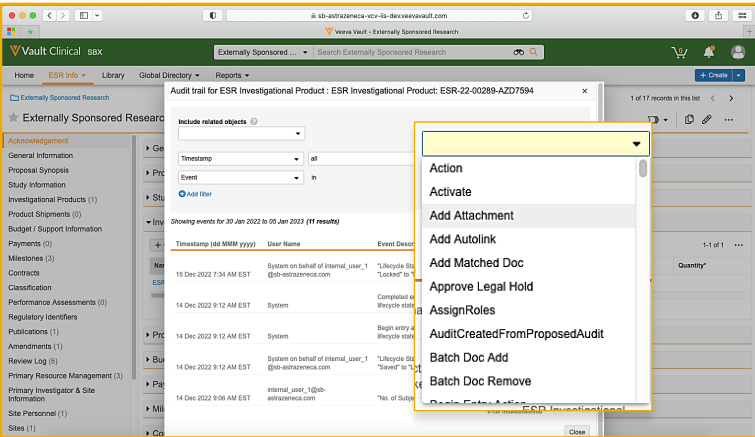
The audit trail for the product may also be searched by adding and applying filters for **Timestamp**, **Event** and **User**.

Timestamp search may be filtered by selecting from the drop-down menu.

The audit trail for the Product may be **downloaded** as a **CSV** or **PDF** by clicking on the **three dots icon** in the pop-up box and selecting from the drop-down menu.



User and **Event** searches may be filtered by going to the **yellow field** and selecting from the drop-down menu.



VCV Walkthrough - How to view an audit trail

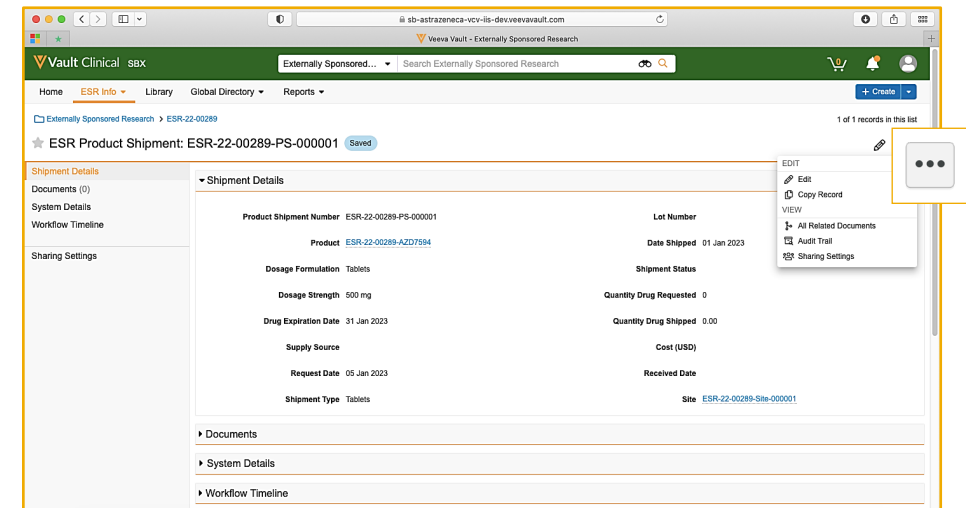
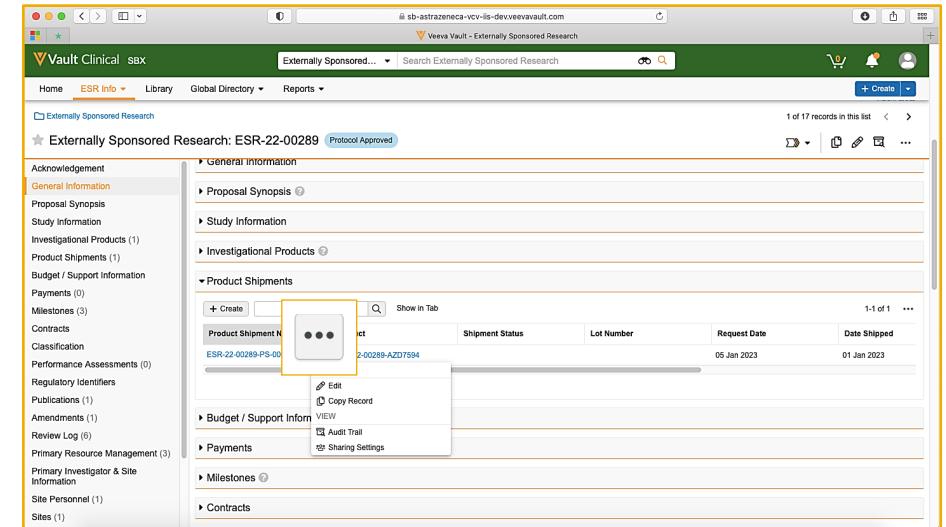
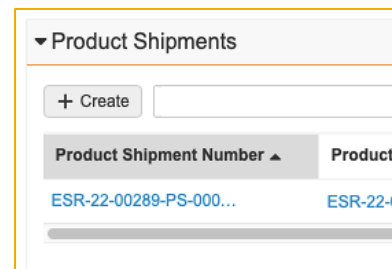
Object level audit trail – e.g. for Product Shipments

The **audit trail** for **Product Shipments** may be viewed:

by opening the **Product Shipments** section and clicking on the three dots icon next to the **Product Shipment Number**, then clicking **Audit Trail**;

or,

by opening the **Product Shipment** sub-section by clicking on the **Product Shipment Number**, then clicking on the **three dots icon** top right and selecting **Audit Trail** from the drop-down menu.

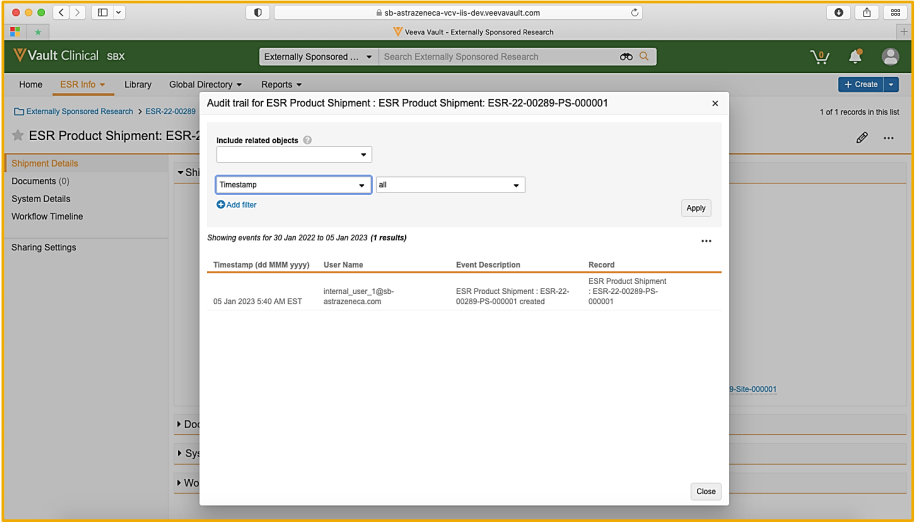


VCV Walkthrough - How to view an audit trail

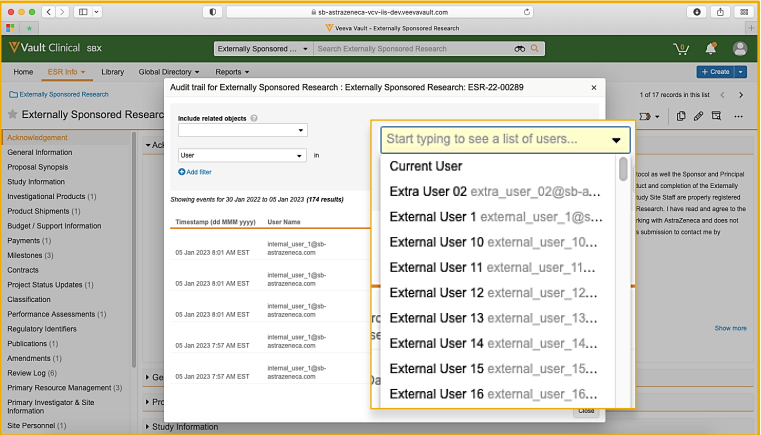
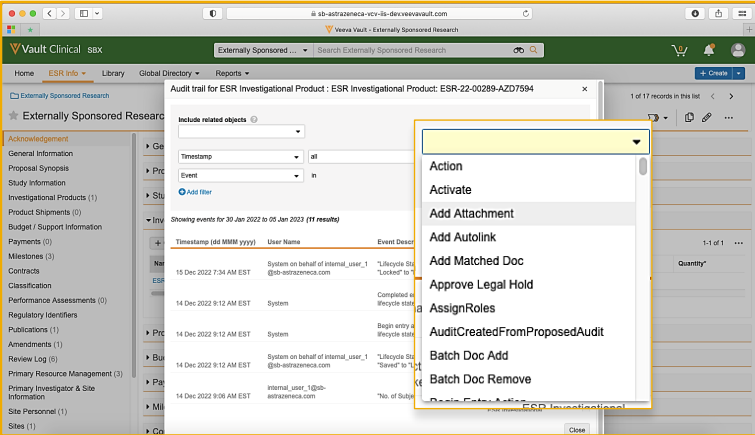
Object level Audit Trail – e.g. for Product Shipments

A pop-up box appears: **Audit trail for ESR Product Shipment with Shipment Number.**

The audit trail for a **Product Shipment** may be searched by adding and applying filters for **Related objects**, **Timestamp**, **Event** and **User**.



If **Event** and/or **User** are added as filters, a **yellow search field** appears with drop-down menus from which **Event** or **User** values may be selected.



VCV Walkthrough - How to view an audit trail

Object level audit trail – other objects

The Audit Trails for Payments, Milestones, Project Status Updates, Performance Assessments, Publications, Amendments, Review Log, Primary Resource Management, Primary Investigator & Site Information, Site Personnel, Sites and Communication Log **may be viewed in exactly the same way** as the Audit Trails for Investigational Products and Product Shipments.

To view the Audit Trails for other objects, open the **relevant section**, click the **three dots icon** next to the **relevant number**, then click **Audit Trail**;

- or -

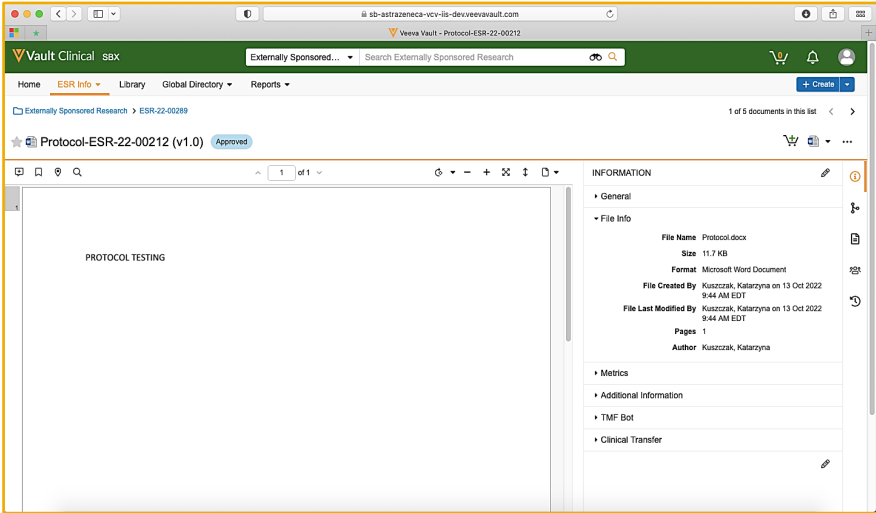
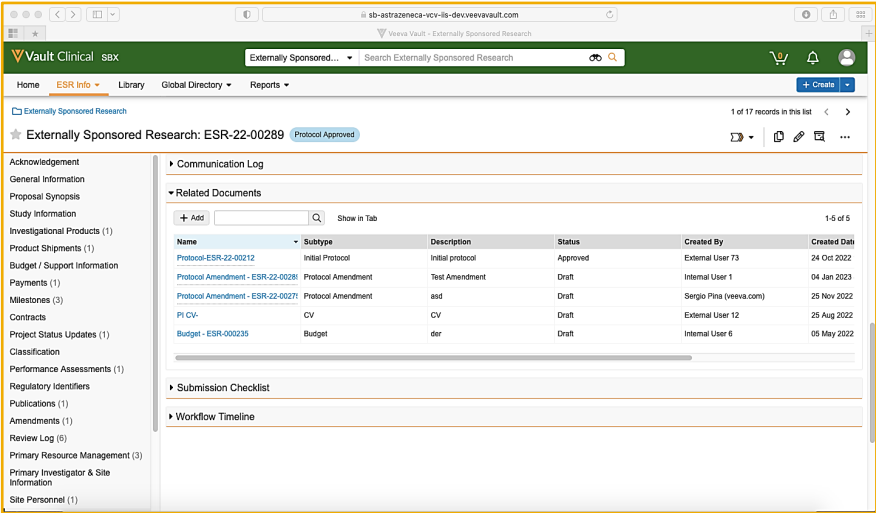
open a **relevant sub-section** then click on the **three dots icon** top right and select **Audit Trail** from the drop-down menu.



VCV Walkthrough - How to view an audit trail

Audit trail - users

Although it is not possible to view an audit trail for documents stored in the study's Related Documents section, the user who created a file and the user who last modified a file may be viewed, firstly by clicking on the document number in the Related Documents section and secondly by opening the File Info section on the righthand side of the screen.



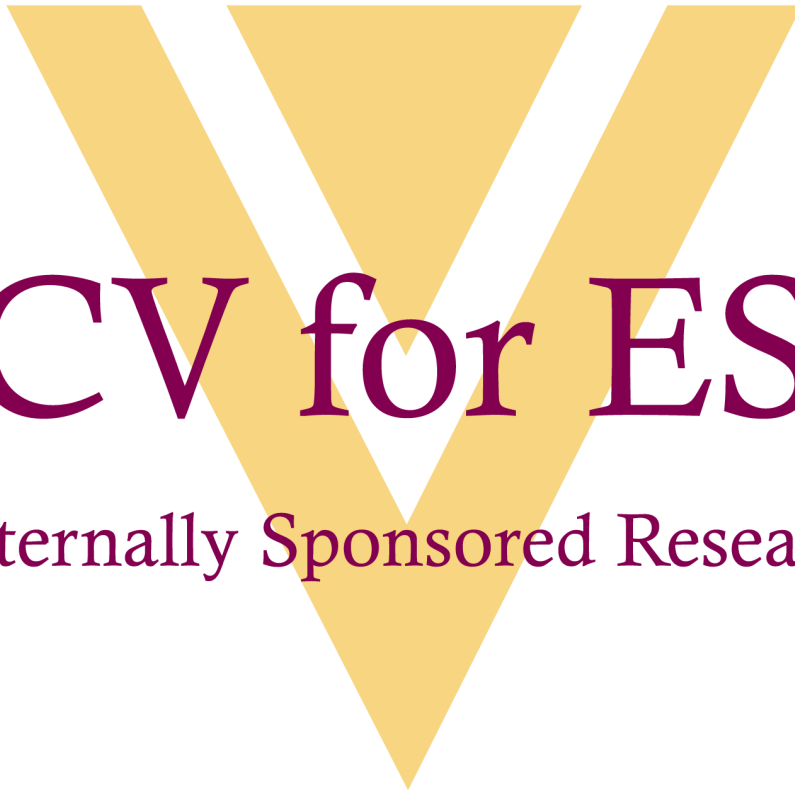
Hovering the cursor over the document number brings up a pop-up box identifying the user who last modified the document and the date when this took place.



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How to upload a document

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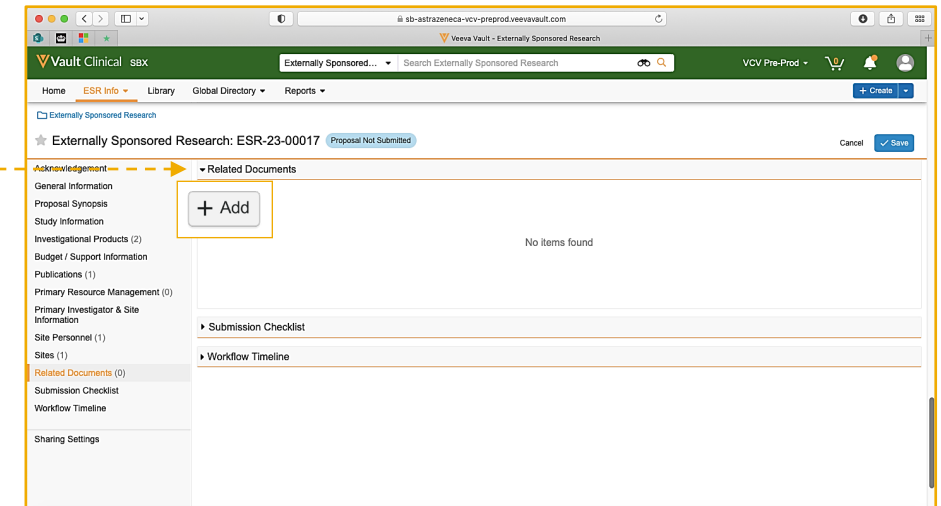
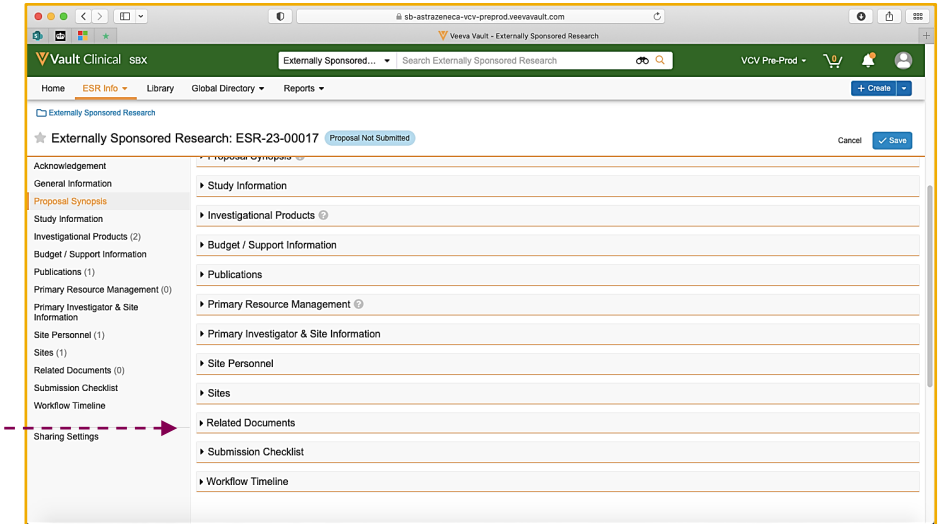


VCV Walkthrough - How to upload a document

Related Documents

1

To upload a document for an ESR study, go to the **Related Documents** section and click **+Add**



VCV Walkthrough - How to upload a document

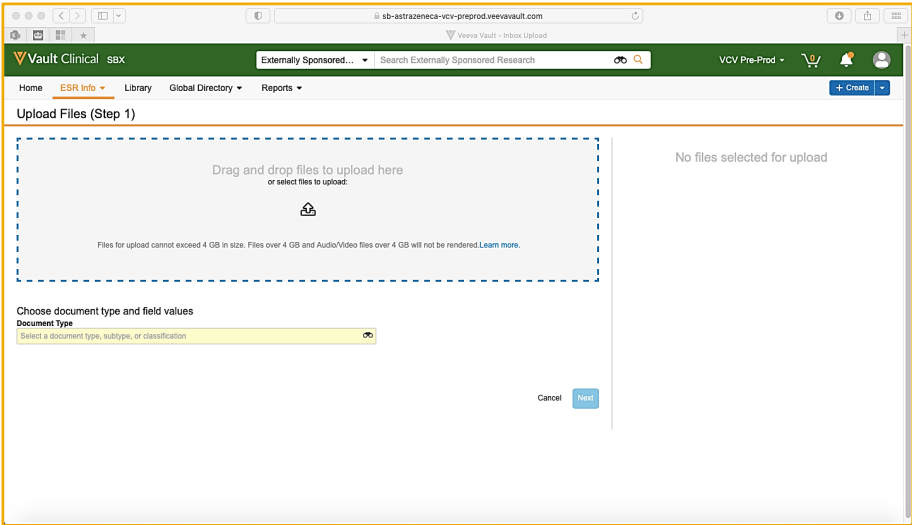
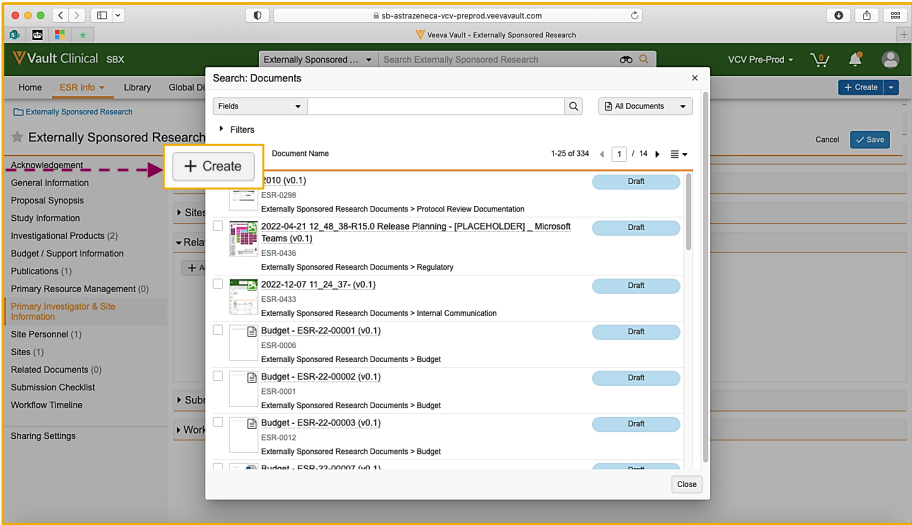
Related Documents

A pop-up window appears: **Search: Documents.**

2

Select a document from the list then click **Close**, or click **Create**

If **Create** is selected, a new field appears:
Upload Files (Step 1).



VCV Walkthrough - How to upload a document

Related Documents

3

Follow the instructions to **upload files**

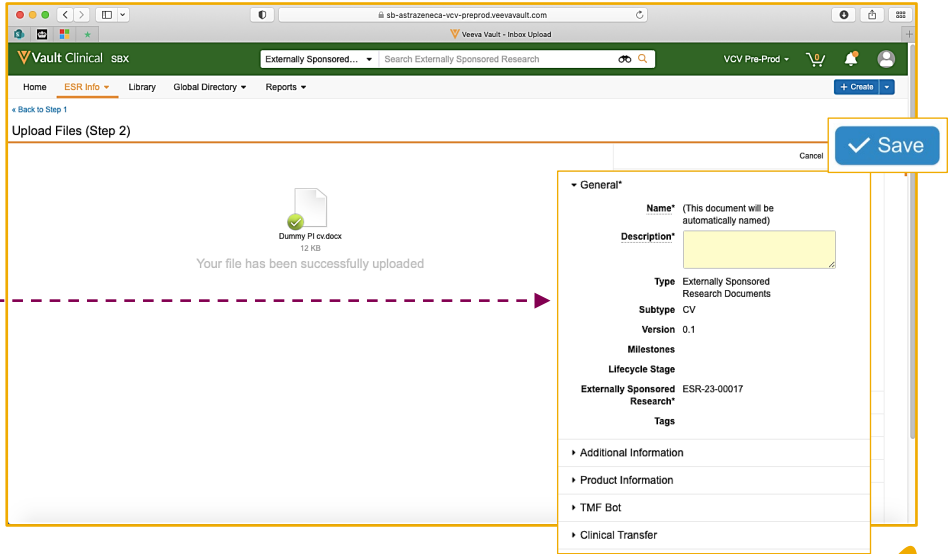
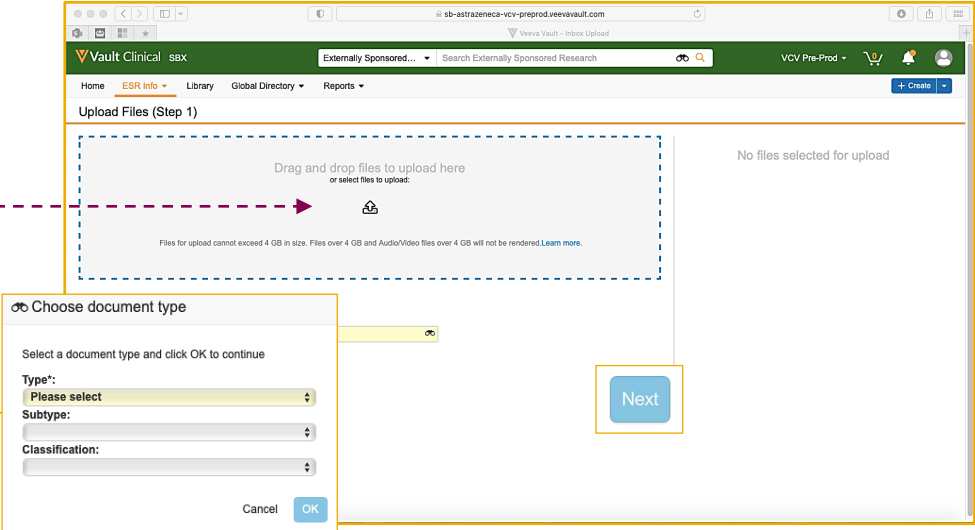
4

Choose document **type** and **subtype** from the drop-down menu, and click **OK** then click **Next**

Field appears: **Upload Files (Step 2)**.

5

Fill in the mandatory yellow field and click **Save**



VCV Walkthrough - How to upload a document

Related Documents

The uploaded document shows in the **Related Documents** section.

sb-astrazeneca-vcv-dev.veevavault.com

Veeva Vault - Externally Sponsored Research

Vault Clinical

sbx

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Search Externally Sponsored Research

Home

ESR Info

Library

Global Directory

Reports

+ Create

Externally Sponsored Research

1 of 17 records in this list

★ Externally Sponsored Research: ESR-22-00285

Closing

Acknowledgement

General Information

Proposal Synopsis

Study Information

Investigational Products (1)

Product Shipments (0)

Budget / Support Information

Payments (0)

Milestones (3)

Contracts

Project Status Updates (1)

Classification

Performance Assessments (0)

Regulatory Identifiers

Publications (1)

Amendments (0)

Review Log (6)

Primary Resource Management (3)

Primary Investigator & Site Information

Site Personnel (1)

Site Personnel

Sites

Communication Log

Related Documents

Submission Checklist

Workflow Timeline

+ Add

Q

Show in Tab

1-3 of 3

Name	Subtype	Description	Status	Created By	Created Date
Protocol-ESR-22-00079	Initial Protocol	proto	Draft	External User 6	28 Oct 2022 2:1
PI CV	CV	grzqrz	Draft	External User 6	26 Oct 2022 11:
Budget - ESR-000235	Budget	der	Draft	Internal User 6	05 May 2022 6:1

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Any questions?

If you have any questions about VCV or your ESR, please contact the AstraZeneca Local Coordinator for your study.

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