



# 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.

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



# 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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# 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**, if funding is requested, 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 **QC (Quality Check) and 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**.



# System Navigation Instructions



To provide or edit information in the study section or record, click on the pencil icon top right

Mandatory fields are highlighted in yellow and/or marked with asterisks.

Please note: Before moving on to the next sections, remember to click **Save** each time after editing the fields in a specific section or record.

Required fields will display in red if the user does not fill them out before clicking **Save**.

Short Title*	<input type="text"/>	This field is required.
Therapeutic Area*	<input type="text"/>	This field is required.
Indication*	<input type="text" value="Depends on Therapeutic Area"/>	This field is required.

Externally Sponsored Research: ESR-24-22374 (Proposal Not Submitted)

General Information

Study Type: Clinical

Study Title: Study Title

Short Title: Short Title

Therapeutic Area: Cardiovascular, Renal and Metabolism (CVRM)

Indication: Acute Kidney Injury

Primary Product: AZD1236

Product Areas of Interest: [Click for more information](#)

Other Combination Therapy

Submission Requested Date: 19 Jul 2024

Type of Support: Funding and Product

Primary Country: Alabama

Number of Sites: 1

On Label: No

Have you contacted anyone in AZ?: No

Support from outside AstraZeneca?: No

If 'Yes', please specify support

ID: V6500000000005

Externally Sponsored Research: ESR-24-22374 (Proposal Not Submitted)

Study Type\*: Clinical

Study Title\*: Study Title

Short Title\*: Short Title

Therapeutic Area\*: Cardiovascular, Renal and Metabolism (CVRM)

Indication\*: Depends on Therapeutic Area

Primary Product\*: AZD1236

Product Areas of Interest: [Click for more information](#)

Other Combination Therapy

Submission Requested Date: 19 Jul 2024

Type of Support\*: Funding and Product

Primary Country\*: Alabama

Number of Sites\*: 1

On Label\*:  Yes  No

Have you contacted anyone in AZ?\*:  Yes  No

Support from outside AstraZeneca?\*:  Yes  No

If 'Yes', please specify support

ID: V6500000000005

**Save**



# System Navigation Instructions

Clicking on the fields with an **arrow** displays a dropdown list, allowing you to select the preferred option, e.g., **Therapeutic Area** or **Type of Support**.

In certain fields, e.g., **Primary Product**, there is a **binoculars icon**. Clicking the icon will cause a **pop-up Search box** to appear, providing more options to complete the field.

Select an item and click **Close** to populate the field with the chosen item. Fill in the remaining fields and click **Save**

This screenshot shows the 'Externally Sponsored Research' form for ESR-24-22374. The 'Therapeutic Area' field is highlighted with a yellow box, and a dropdown menu is open, listing various therapeutic areas such as Cardiovascular, Renal and Metabolism [CVRM], Gastrointestinal [GI], Infection [INFEC], Autoimmune [AI], Neuroscience [NEURO], Oncology [ONC], Immuno-oncology [IMMUONC], Respiratory [RESP], Inflammation [INFLA], Across TAs [AT], Rare Diseases [RAREDIS], and Vaccines & Immune Therapies [V&I]. A yellow arrow points to the dropdown arrow icon.

This screenshot shows the same form with the 'Primary Product' field highlighted. A binoculars icon is visible next to the field. A yellow arrow points to this icon. In the top right corner, a yellow box highlights the 'Save' button. A dashed purple line indicates the flow from the binoculars icon to the search box in the next screenshot.

This screenshot shows a search pop-up window titled 'Search Primary Product'. It contains a search bar with 'Ac' entered and a list of search results. A 'Close' button is located at the bottom right of the window.

Product Name	Development Code	Active Substance	Primary Brand Name	ESR App
<input type="radio"/> Bydureon	AC-2993	exenatide	Bydureon	Yes
<input type="radio"/> Epanova	AZD0555	omega-3-carboxylic acids	Epanova	Yes
<input type="radio"/> Zoladex	ZD9393	goserelin acetate	Zoladex	Yes
<input type="radio"/> Calquence	ACP-195	acalabrutinib	Calquence	Yes
<input type="radio"/> Vemtocopan	ALXN2550, ACH-5228, AI	vemtocopan		Yes
<input type="radio"/> Acoramidis	ALXN2060, AG19	acoramidis		Yes
<input type="radio"/> Vydoya	ALXN2040, ACH-4471	daricopan	Vydoya	Yes
<input type="radio"/> Acetylcysteine		acetylcysteine	Mucovent, Acetabate, Flu	Yes



# System Navigation Instructions

In some sections, such as **Investigational Products**, **multiple records** can be created by clicking **+Create**

A pop-up window appears:  
**Create ESR Investigational Product.**

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

Hovering a cursor over the field name **underlined with dots** will show **additional instructions** for the field.

Vault Clinical SBX

Externally Sponsored... Search Externally Sponsored Research

VCV Pre-Test

Home ESR Info + Create

Externally Sponsored Research 1 of 3 records in this list

Externally Sponsored Research: ESR-24-22374 Proposal Not Submitted

Investigational Products

+ Create

Type of Product	Product	Dosage Formulation*	Dosage Strength*	Total Quantity
Primary	AZD1236			

Vault Clinical SBX

Externally Sponsored... Search Externally Sponsored Research

VCV Pre-Test

Home ESR Info + Create

Create ESR Investigational Product

Cancel Save

No. of Subjects\*

Number of Subjects Receiving Product. Please fill in this mandatory field

Comments

System Details

Externally Sponsored Research ESR-24-22374

Created Date

Created By Name\*



# System Navigation Instructions

Clicking **Save** will cause a new window to appear, displaying the created **record details**. To **edit** its information, follow these instructions.



Click on the **ESR Number** top left to go back to the **Study view**

Created record appears under its respective section. Clicking the **record Number** will open the previous window with record's information.

Certain fields can be updated directly in the **table view** by **double-clicking** on them. To **Save** changes, **click** anywhere outside the edited field.

**Please note:** Use this feature **only** for individual field updates to avoid missing important record details.

ESR-24-22374

ESR Investigational Product: Secondary Product

Field	Value
Type of Product	Secondary
Product	Abediterol
Dosage Formulation	Capsules
Dosage Strength	100
No. of Subjects	100
Total Quantity	100
Quantity of Placebo Drug	
Comments	

ESR-24-22374

Name	Type of Product	Product	Dosage Formulation	Dosage Strength	Total Quantity
ESR-24-22374-AZD1236	Primary	AZD1236	Injectable	100	
Secondary Product	Secondary	Abediterol	Capsules	100	

Publication Number	Publication Category	Type	Publication Date	Publication Name	Journal/Congress
ESR-24-22374-PUB-0000	Planned		03 Jul 2025		Journal





# System Navigation Instructions

Blue-link objects in VCV e.g., **Product** are clickable and can be opened to see their details. However, unlike created records, the object information **cannot be edited**.

Home ESR Info

Externally Sponsored Research > ESR-24-22376

★ Product: Tezspire Active

Details

ESR Studies (1)

Workflow Timeline

System Details

Sharing Settings

Product Name Tezspire

Development Code MEDI9929, AMG 157

Active Substance tezepelumab

Primary Brand Name Tezspire

Vault Clinical srx

Externally Sponsored

Search Externally Sponsored Research

VCV Pre-Test

Home ESR Info

Externally Sponsored Research

Externally Sponsored Research: ESR-24-22376

Investigational Products

Name	Type of Product	Product	Dosage Formulation*	Dosage Strength*	Total Quantity*
ESR-24-22376-Tezspire	Primary	Tezspire	Injectable	200mg	

Project Status Updates

+ Create

PSU Number

Are there Milestone Updates?

Are there Subject Enrollment ...

Are there Regulatory Updates?

Are there SAE Information Upd...

ESR-24-22376-PSU-08Au...

Yes No Yes

Publications

Amendments

Objects or records may have **sub-sections** that are not accessible from the Study view and can be seen after **clicking** on a specific object or record number e.g., **Project Status Update**.

In certain sub-sections, objects and/or documents can be added. They will **only** appear in a specific **record's subsection**.

Vault Clinical srx

Externally Sponsored

Search Externally Sponsored Research

VCV Pre-Test

Home ESR Info

Externally Sponsored Research > ESR-24-22376

ESR Project Status Update: ESR-24-22376-PSU-08Aug2024

Update Information

Externally Sponsored Research ESR-24-22376

Status Update Date: 08 Aug 2024

Are there Milestone Updates? Yes

Are there Subject Enrollment Updates? Yes

Are there SAE Information Updates? Yes

Are you planning any study publications? Yes

Are there Regulatory Updates? No

confirm PSU to be submitted

Milestone Update

+ Add

System Details

Workflow Timeline



1

# How to create a Proposal



Click the link to see the training video,

[How to create a proposal](#)

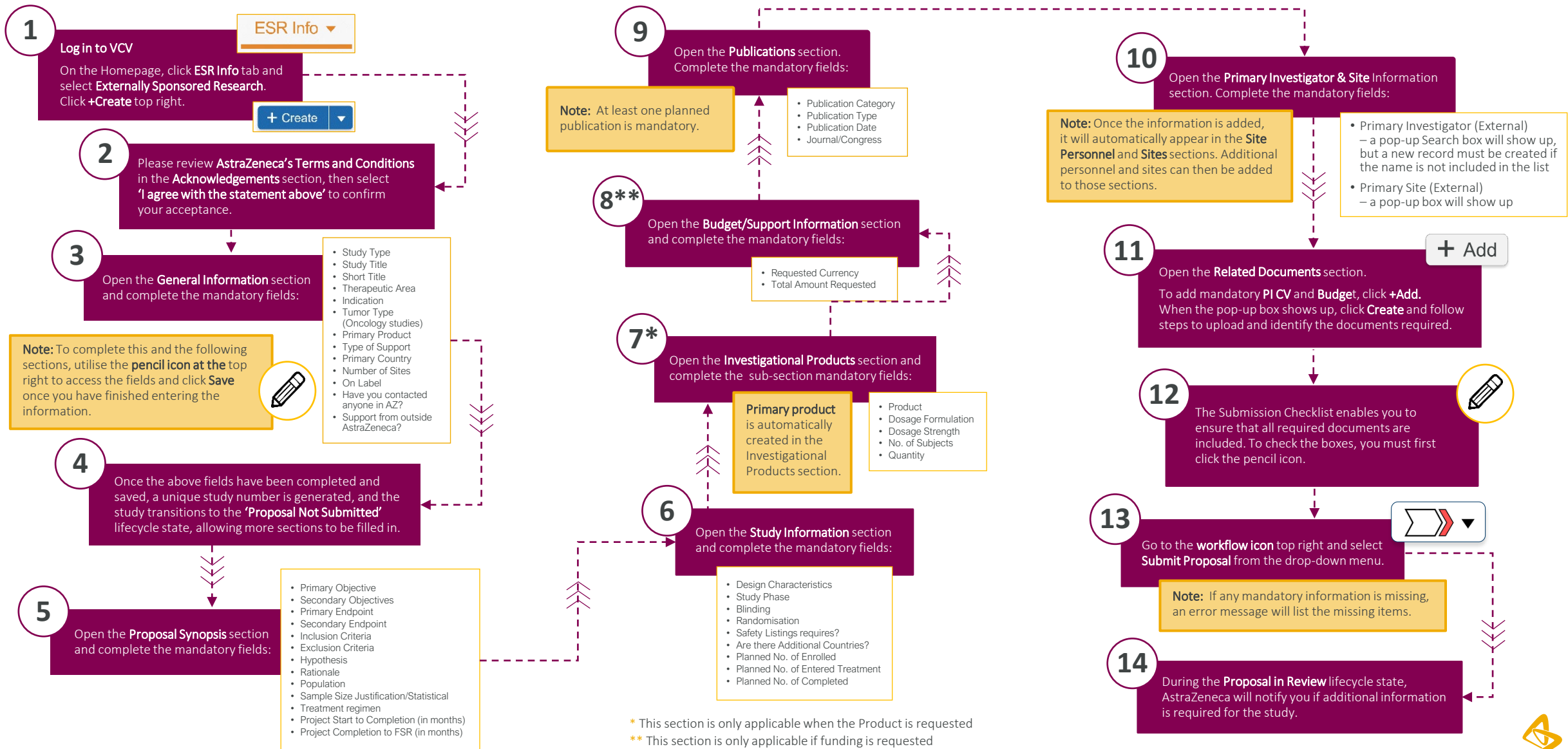
[Return to Contents](#)

# VCV for ESR

Externally Sponsored Research



# Overview – How to create an ESR study proposal



\* This section is only applicable when the Product is requested  
 \*\* This section is only applicable if funding is requested



# VCV Walkthrough - How to create an ESR study proposal

## Externally Sponsored Research creation

1

To create an ESR study proposal, click on the ESR Info tab and select Externally Sponsored Research

2

Click +Create top right

A new window appears: Create Externally Sponsored Research

If you have previously created or been assigned to a study, all related Externally Sponsored Research can be seen in the ESR Info Tab.

The screenshot shows the 'Externally Sponsored Research' page in the Vault Clinical system. The page has a search bar at the top right with a '+ Create' button. Below the search bar is a table with columns: Externally Sponsored Research Number, Primary Product, Primary Country, Therapeutic Area, Type of Support, and Support from outside AstraZeneca. The table contains several rows of data, including studies with numbers like ESR-24-22340 and ESR-24-22371.

Externally Sponsored Research Number	Primary Product	Primary Country	Therapeutic Area	Type of Support	Support from outside AstraZeneca?
ESR-24-22340	AZD1199	Albania	Respiratory (RESP)	Funding	No
ESR-24-22371	AZD1136	Albania	Rare Diseases (RAREDIS)	Funding and Product	No
ESR-24-22374	AZD1136	Albania	Cardiovascular, Fibrosis and Metabolism (CF/MF)	Funding and Product	No
ESR-24-22376	Tecope	United States of America	Oncology (ONC)	Funding and Product	No
ESR-24-22381	Alveico	Canada	Respiratory (RESP)	Funding and Product	No
ESR-24-22385	ALXN2800	Albania	Cardiovascular, Fibrosis and Metabolism (CF/MF)	Product	No
ESR-24-22388	Acroramids	Antarctica	Gastrointestinal (GI)	Funding and Product	No

The screenshot shows the 'Create Externally Sponsored Research' form. The 'Acknowledgement' section is visible, containing text about AstraZeneca's willingness to provide support and the Principal Investigator's acceptance of the Protocol. There are also sections for 'Collection Notice' and 'Terms and Conditions'.

**Acknowledgement** AstraZeneca's willingness to provide support in accordance with this Agreement is based upon its review and acceptance of the Protocol as well as 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 the submission to contact me by telephone, SMS, Fax or email.

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



# VCV Walkthrough - How to create an ESR study proposal

## Acknowledgement / General Information sections

3

Read and ensure you understand information in the **Acknowledgement** section  
Then, check the box 'I agree with the statements above'

When the box is checked, the **General Information** section appears.

4

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

If the selected Type of Support is **Funding** or **Funding and Product**, the **Budget/Support Information** section appears and may be completed at this stage or later.

VCV Clinical - sdx

Externally Sponsored

Home ESR Info

Create Externally Sponsored Research

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 as 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.

Collection Notice: Click for more information

Terms and Conditions: Click for more information

Instructions: To **submit** 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 so...

I agree with the statements above.

VCV Clinical - sdx

Externally Sponsored

Home ESR Info

Create Externally Sponsored Research

Save

Acknowledgement

General Information

Study Type\*

Study Title\*

Short Title\*

Therapeutic Area\*

Indication\* Depends on Therapeutic Area

Primary Product\*

Product Areas of Interest: Click for more information

Other Combination Therapy

Submission Requested Date

Primary Country\*

Number of Sites\* 1

On Label\* Yes No

Have you contacted anyone in AZ? Yes No

Support from outside AstraZeneca? Yes No

If 'Yes', please specify support

ID

Type of Support\* Funding and Product

Budget / Support Information

Requested Currency\*

Total Amount Requested\*



# VCV Walkthrough - How to create an ESR study proposal

Proposal not submitted

Saving the completed fields in the General Information section prompts the **main view** of the **Study** to appear, with a unique **ESR number** assigned to this study.

Lifecycle of the Study shows as **Proposal Not Submitted**. Further sections are visible and require completion.

Follow **instructions** on the next slides to prepare your Study Proposal for **submission**.

The screenshot shows the Vault Clinical interface for an ESR proposal. The top navigation bar includes 'Vault Clinical', 'Externally Sponsored', and a search bar. The main header displays 'Externally Sponsored Research: ESR-24-22389' and a blue box with the text 'Proposal Not Submitted'. A sidebar on the left lists various sections: Acknowledgement, General Information, Proposal Synopsis, Study Information, Investigational Products (1), Budget / Support Information, Publications (0), Primary Investigator & Site Information, Site Personnel (0), Sites (0), Related Documents (0), Submission Checklist, and Workflow Timeline. The main content area shows the 'Acknowledgement' section with text regarding AstraZeneca's support and the investigator's agreement. Below this, the 'General Information' section is partially visible, showing a dropdown menu with options for 'General Information', 'Proposal Synopsis', and 'Study Information'. On the right side, there are links for 'Collection Notice\*', 'Terms and Conditions\*', and 'Instructions'. The 'Instructions' section contains text about saving and submitting the proposal, and a checkbox for 'I agree with the statements above.' which is checked.



# VCV Walkthrough - How to create an ESR study proposal

## Proposal Synopsis and Study information sections

5

Open the **Proposal Synopsis** section and click on the pencil icon top right

The screenshot shows the 'Proposal Synopsis' section of an ESR proposal form. The form is titled 'Externally Sponsored Research: ESR-24-22389' and is in 'Proposal Not Submitted' status. The 'Proposal Synopsis' section is expanded, showing fields for Primary Objective, Secondary Objective, Primary Endpoint, Secondary Endpoint, Inclusion Criteria, Exclusion Criteria, Hypothesis, Rationale, Population, Sample Size Justification / Statistical, and Treatment Regimen. On the right side, there are input fields for 'Contract Execution to FSI (in months)', 'FSI to 50% Enrollment (in months)', '50% Enrollment to LSI (in months)', 'LSI to LSLV (in months)', and 'LSLV to FSR (in months)'. A pencil icon in the top right corner is highlighted with a dashed line pointing to a callout box.

6

Complete the mandatory fields and click **Save**

The screenshot shows the 'Proposal Synopsis' section of the ESR proposal form, now with input fields for each mandatory field. The 'Save' button in the top right corner is highlighted with a dashed line pointing to a callout box.

Follow the same steps to add information in the **Study information** section.



# VCV Walkthrough - How to create an ESR study proposal

## Investigational Products section

7

Open the **Investigational Products** section

The **Primary Product** record is automatically created based on information from the **Primary Product** field in the **General Information** section. However, not all required fields are filled in and must be populated manually.

8

Click on the **record Number** to open and review its details

9

Complete the required fields and click **Save**

Vault Clinical SBX

Externally Sponsored Research

Home ESR Info

Externally Sponsored Research

1 of 3 records in this list

Externally Sponsored Research: ESR-24-22374 Proposal Not Submitted

Acknowledgement

General Information

Proposal Synopsis

Study Information

Investigational Products (1)

Budget / Support Information

Publications (1)

Primary Investigator & Site Information

Site Personnel (0)

Sites (0)

Related Documents (1)

Submission Checklist

Workflow Timeline

Investigational Products

+ Create

Show in Tab

Name	Type of Product	Product	Dosage
ESR-24-22374-AZD1236	Primary	AZD1236	Injectable

Budget / Support Information

Publications

Primary Investigator & Site Information

Site Personnel

Sites

Related Documents

Vault Clinical SBX

Externally Sponsor... Search Externally Sponsored Research

VCV Pre-Test

Home ESR Info

Externally Sponsored Research ESR-24-22374

ESR Investigational Product: ESR-24-22374-AZD1236

Save

Details

System Details

Workflow Timeline

Details

Type of Product\* Primary

Product\* AZD1236

Dosage Formulation\* Capsules

Dosage Strength\* 100

No. of Subjects\* 100

Total Quantity\* 100

Quantity of Placebo Drug

Comments

System Details

Workflow Timeline





# VCV Walkthrough - How to create an ESR study proposal

## Investigational Products section

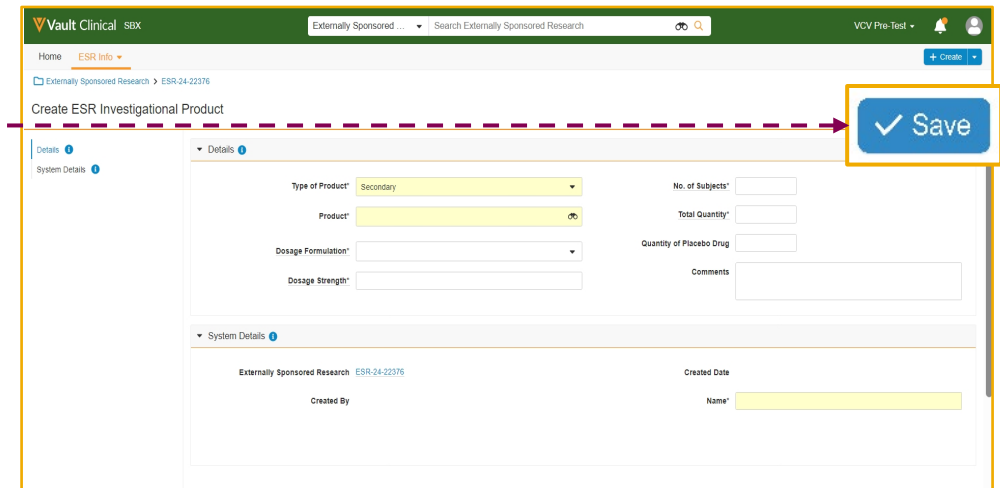
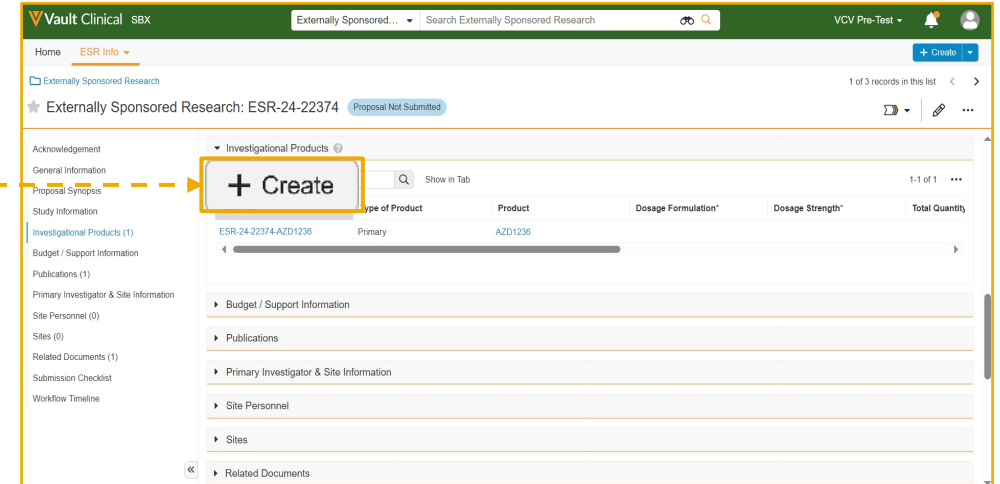
10

To add secondary product, click **+Create** under the **Investigational Products** section

11

Complete the mandatory fields and click **Save**

Created Product appears in the **Investigational Products** section.



Investigational Products		
+ Create <input type="text"/> <input type="button" value="Show in Tab"/>		
Name	Type of Product	Product
ESR-24-22374-AZD1236	Primary	AZD1236
Secondary Product	Secondary	Abediterol



# VCV Walkthrough - How to create an ESR study proposal

## Budget / Support Information section

12

Open the **Budget/Support Information** section and click on the **pencil icon**

The screenshot shows the 'Budget / Support Information' section in the Vault Clinical SBX interface. The section header is highlighted with a yellow box, and a pencil icon is highlighted in the top right corner of the header. The main content area is currently empty, with fields for 'Requested Currency\*' and 'Total Amount Requested\*'. The left sidebar contains a list of sections: Acknowledgement, General Information, Proposal Synopsis, Study Information, Budget / Support Information (selected), Publications (0), Primary Investigator & Site Information, Site Personnel (0), Sites (0), Related Documents (0), Submission Checklist, and Workflow Timeline.

13

Complete the mandatory fields and click **Save**

The screenshot shows the 'Budget / Support Information' section in the Vault Clinical SBX interface. The 'Requested Currency\*' field is set to 'US Dollar (USD)' and the 'Total Amount Requested\*' field is set to '10000'. A blue 'Save' button is highlighted in the top right corner. The left sidebar is the same as in the previous screenshot.

If the selected Type of Support is NOT **Funding** or both **Funding and Product**, go to step 14

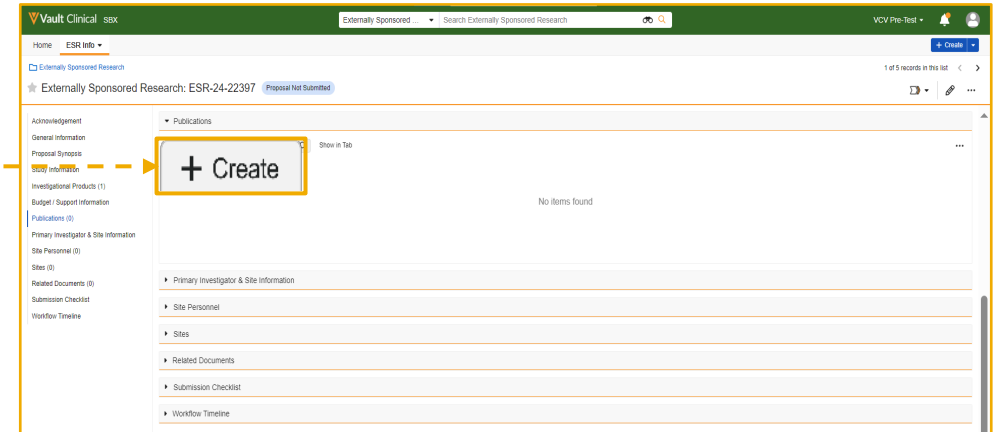


# VCV Walkthrough - How to create an ESR study proposal

## Publications section

14

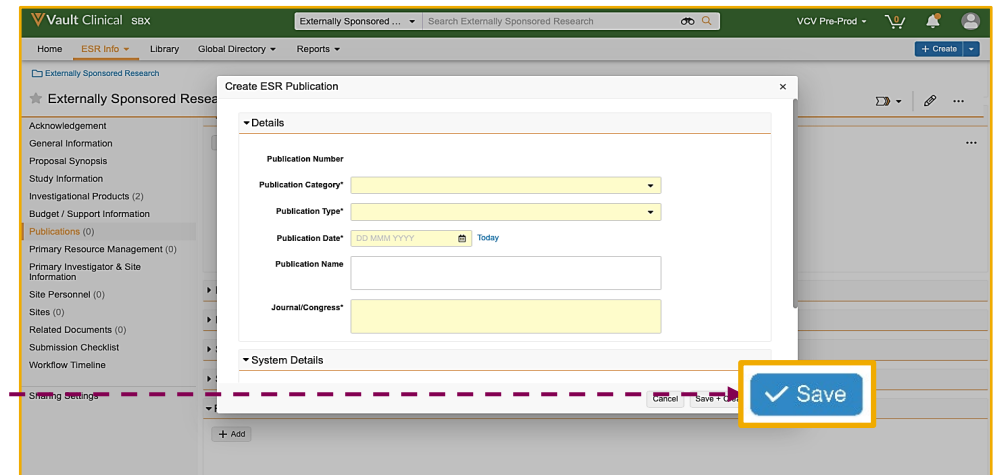
Open the **Publications** section and click **+Create** to add a planned publication



A pop-up window appears:  
**Create ESR Publication.**

15

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



Publication record appears in  
the **Publications** section.

Publications	
<a href="#">+ Create</a>	<input type="text"/>
<b>Publication Number</b>	<b>Publication Category</b>
ESR-24-22374-PUB-000001	Planned



# VCV Walkthrough - How to create an ESR study proposal

## Primary Investigator & Site Information section

16

Open the **Primary Investigator & Site Information** section and click on the pencil icon

The screenshot shows the 'Externally Sponsored Research' page for 'ESR-24-22371'. The 'Primary Investigator & Site Information' section is expanded, showing fields for 'Primary Investigator (External)\*' and 'Primary Site (External)\*'. A pencil icon in the top right corner is highlighted with a yellow box and a dashed line pointing to the section header.

17

Click the **Primary Investigator (External)** field and select **+Create ESR Site Person** from the dropdown menu

The screenshot shows the 'Externally Sponsored Research' page for 'ESR-24-22371'. The 'Primary Investigator & Site Information' section is expanded. The 'Primary Investigator (External)\*' field is highlighted with a yellow box, and a dropdown menu is open showing the option '+ Create ESR Site Person'.



# VCV Walkthrough - How to create an ESR study proposal

## Primary Investigator & Site Information section

A pop-up window appears: **Create ESR Site Person.**

18

Enter the information required for the **Primary Investigator**

**Please note:** If the selected Country is **United States of America**, new mandatory\* fields will appear.

19

Click **Save**

Follow the same steps to add **Primary Site (External)**.



# VCV Walkthrough - How to create an ESR study proposal

## Primary Investigator & Site Information section

Added Primary Investigator and Site records appear in their fields within the **Primary Investigator & Site Information** section but remain in **edit mode**.  
**Remember to Save** the records from the Study view.

20

Click Save

Added **Primary Investigator** with assigned person number shows up in the **Site Personnel** section.

Added **Primary Site** with assigned site number shows up in the **Sites** section.

Additional personnel and/or site may be added at any time during the study.

The screenshot shows the 'Externally Sponsored Research' page for ESR-24-22374. The 'Primary Investigator & Site Information' section is expanded, showing fields for 'Primary Investigator (External)' and 'Primary Site (External)'. A blue 'Save' button is highlighted in the top right corner.

The screenshot shows the 'Externally Sponsored Research' page for ESR-24-22374. The 'Site Personnel' and 'Sites' sections are expanded. The 'Primary Investigator' record is highlighted with an orange box, and the 'Primary Site' record is also highlighted with an orange box.

Person Number	Personnel Type	Lifecycle State	First Name
ESR-24-22374-Person-000001	Primary Investigator	Saved	Name

Site Number	Site Type	Lifecycle State	Institution Name
ESR-24-22374-Site-000001	Primary	Saved	hogwart



# VCV Walkthrough - How to create an ESR study proposal

## Site Personnel and Sites sections

21

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

A pop-up window appears:  
**Create ESR Site.**

The screenshot shows the 'Externally Sponsored Research' page for ESR-24-22374. The 'Sites' section is expanded, and a '+ Create' button is highlighted with a yellow box. Below it, a table lists existing sites:

Site Number	Site Type	Lifecycle State	Institution Name
ESR-24-22374-Site-000001	Primary	Saved	hogwart

**Please note:** If the selected Country is **United States of America**, new mandatory\* field will appear.

22

Complete the mandatory fields and click **Save**

Follow the same steps to add further Personnel (see [Create ESR Site Person](#))

The screenshot shows the 'Create ESR Site' pop-up window. The 'Country' field is set to 'United States of America' and is highlighted with a yellow box. Below it, the 'Employer Identification Number\*' field is also highlighted. A blue 'Save' button with a checkmark is highlighted with a yellow box.

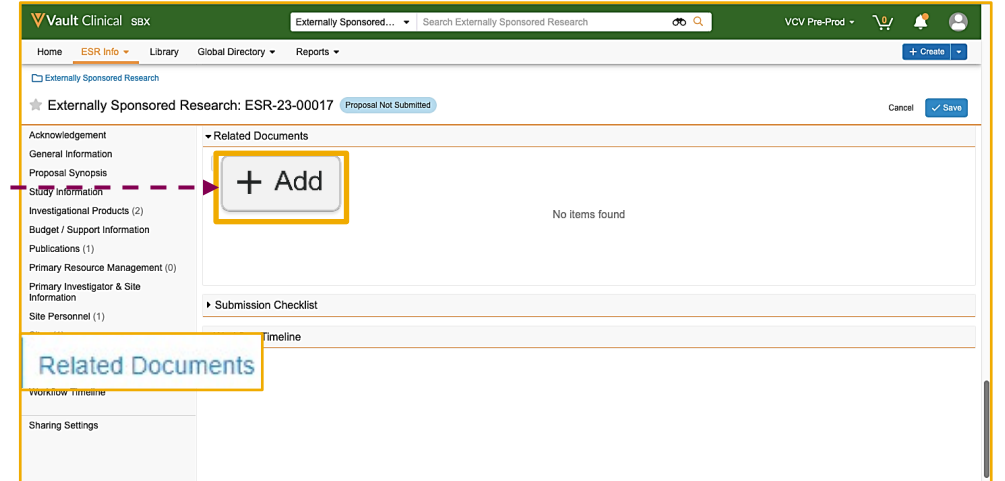


# VCV Walkthrough - How to create an ESR study proposal

## Related Documents section

23

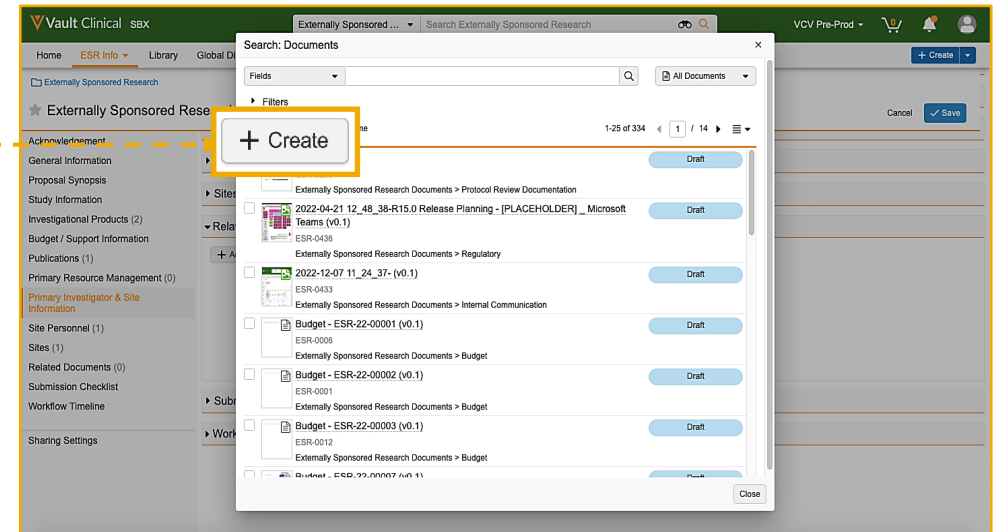
To upload a document (PI CV, Budget), open the **Related Documents** section and click **+Add**



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

24

Click **+Create**



For more information, see **Appendix** →  
**How to upload a document**





# VCV Walkthrough - How to create an ESR study proposal

## Related Documents section

A new window appears:  
**Upload Files (Step 1).**

25

Follow instructions to **upload files**.  
Click on the **Document Type** field and select the proper **Type** and **Subtype** from the drop-down menu

26

Click **Next**

The image displays two screenshots of the Vault Clinical web application interface during the 'Upload Files (Step 1)' process. The top screenshot shows a 'Document Type' dropdown menu with the following options: 'Externally Sponsored Research Documents > Budget', 'Externally Sponsored Research Documents > Protocol Amendment', 'Externally Sponsored Research Documents > CV', 'ALL', 'Externally Sponsored Research Documents > Agreements', 'Externally Sponsored Research Documents > Budget', and 'Externally Sponsored Research Documents > CV'. The bottom screenshot shows the 'Next' button highlighted in a yellow box, indicating the next step in the process. A notification on the right side of the interface states '1 classified document(s) to be uploaded' with a file named 'BUDGET DOCUMENT 27-07.docx'.



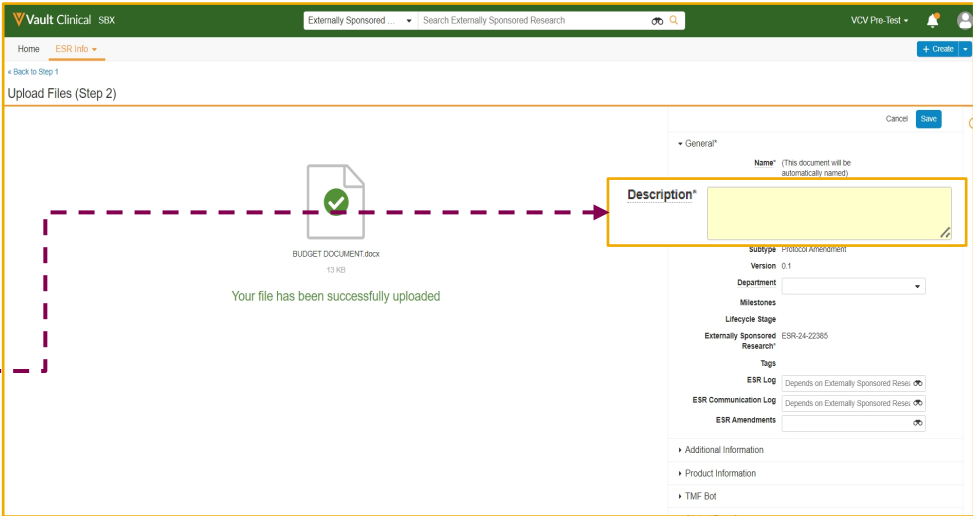
# VCV Walkthrough - How to create an ESR study proposal

## Related Documents section

A new window appears:  
**Upload Files (Step 2).**

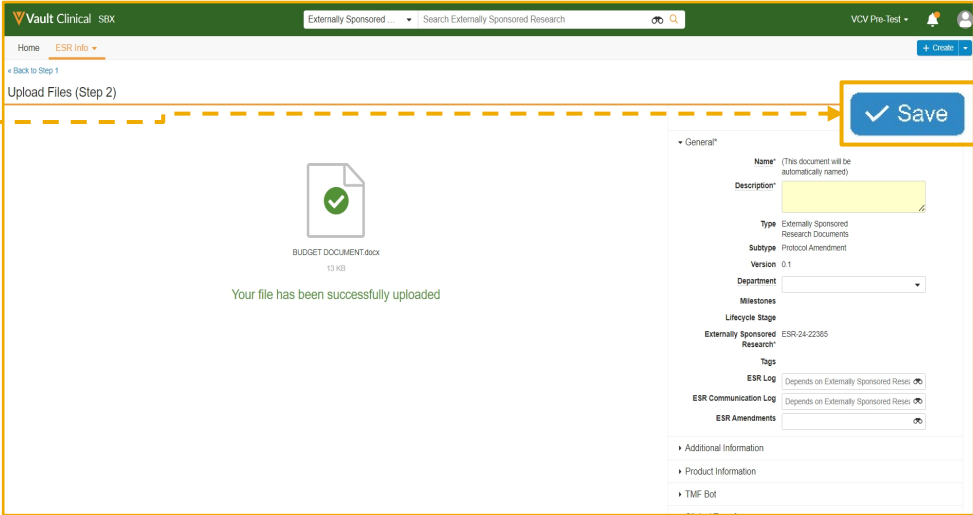
27

Please enter an appropriate **description**, including the document's **name** and **date**, if applicable



28

Click **Save**



The uploaded document appears  
the **Related Documents** section.

Related Documents				
Name	Subtype	Description	Status	Created Date
PI CV-ESR-24-22374	CV	PI CV	Draft	02 Jul 2024 2:10 PM CEST
Budget - ESR-24-22374		Budget document for 27.07.2024	Draft	27 Jul 2024 6:37 PM CEST



# VCV Walkthrough - How to create an ESR study proposal

## Submission Checklist section

29

Open the **Submission Checklist** section, review the listed requirements and verify whether they have been completed

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

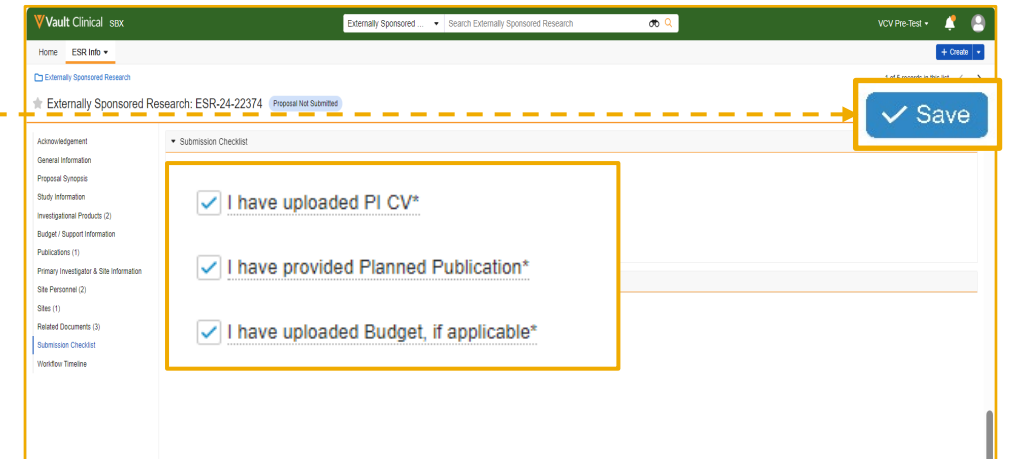
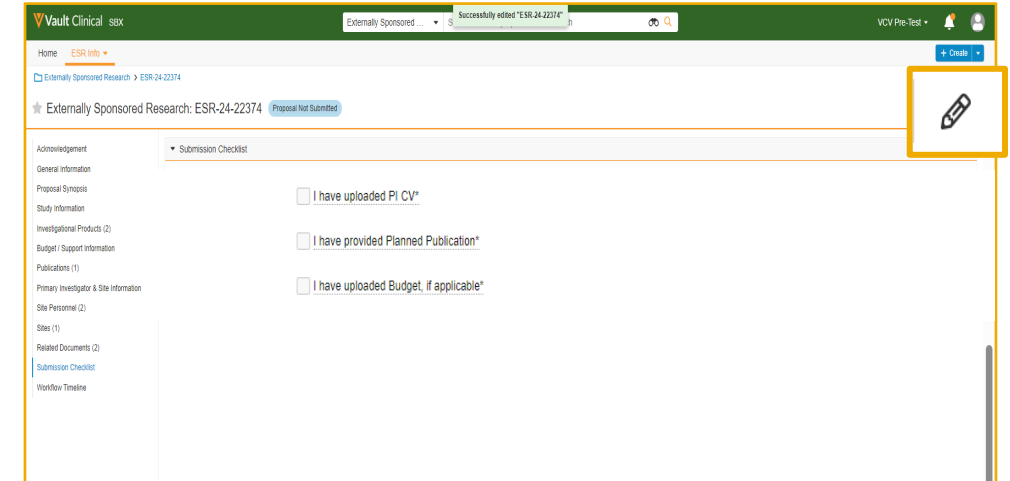
- Upload **Primary Investigator CV**
- Provide at least one **Planned Publication**
- Upload **Budget** (if funding is requested)

To upload CV and Budget, see **Appendix**  
→ [How to upload a document](#)

30

Click the **pencil icon** and tick the boxes from the checklist

Click **Save**



# VCV Walkthrough - How to create an ESR study proposal

## Submit proposal

31

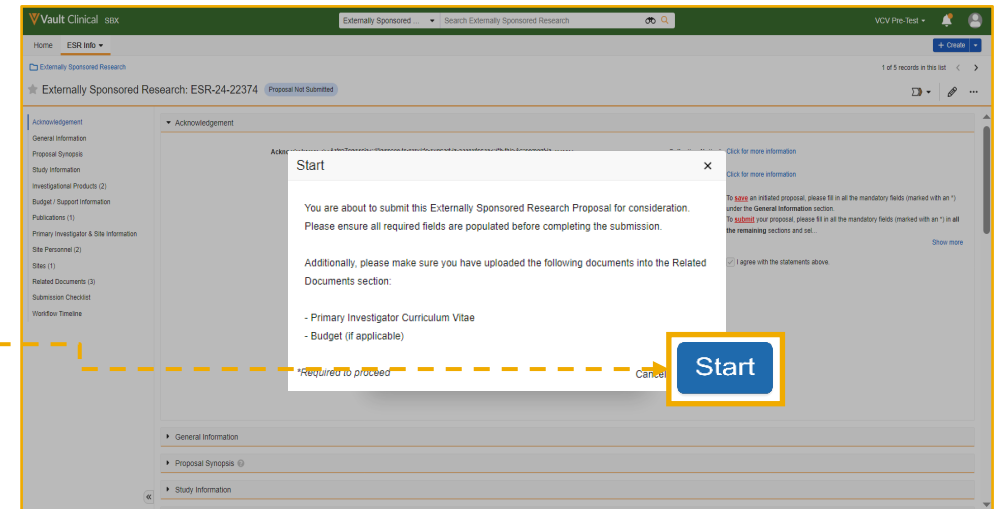
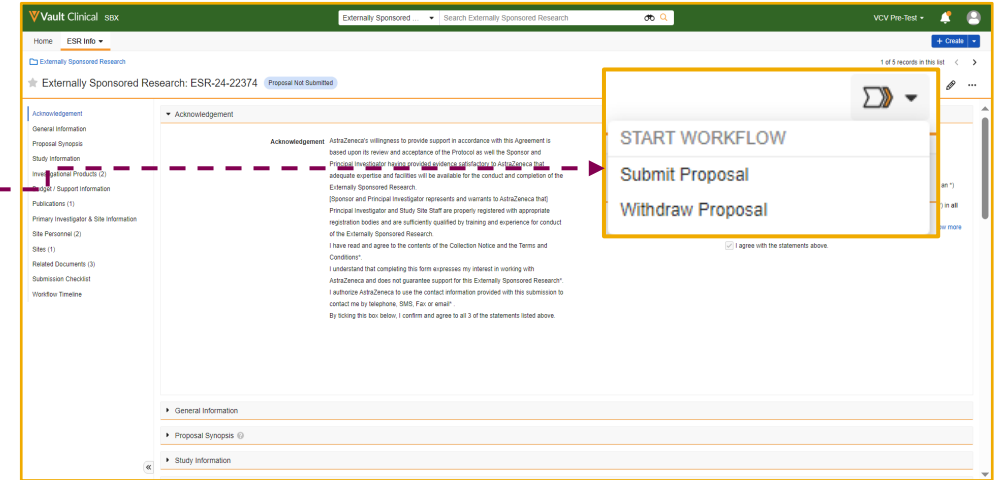
Click on the **Workflow** icon top right and select **Submit Proposal** from the drop-down menu

Allow >1 minute for system to process the submission.

32

Follow the instructions and click **Start**

A pop-up box appears:  
**Start.**



# VCV Walkthrough - How to create an ESR study proposal

## Submit proposal

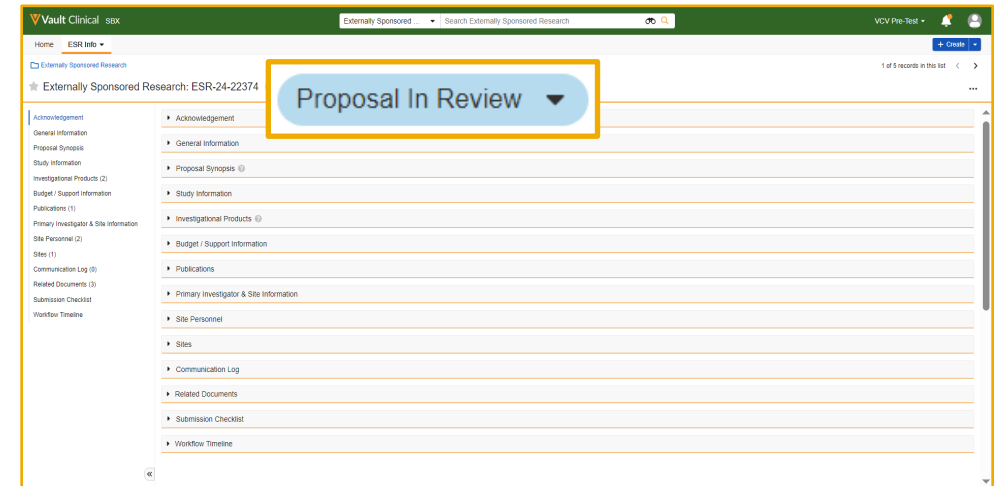
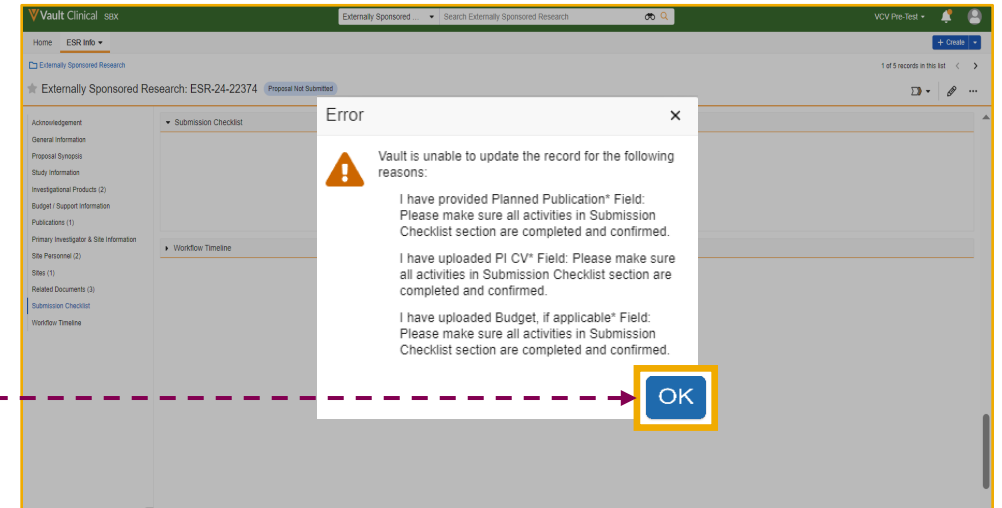
**Please note:** If any mandatory fields are left **incomplete**, a pop-up box will appear listing the fields that need to be filled in.

33

Review the list of missing information, click **OK** and fill in the required fields. Repeat **step 31** to submit the proposal

Once the submission is successfully completed, the study's lifecycle changes to **Proposal in Review**.

After you have submitted the proposal, responsibility for next steps lies with AZ team. AstraZeneca may **accept** or **decline** the study proposal or request **additional information**. The system will notify you via email regardless of the decision.



2

## How to provide Additional Information Requested

for a Proposal/Protocol Quality Check (QC),  
Local Proposal Review or (HQ)  
Proposal/Protocol Review



Click the link to see the training video,  
[How to provide additional information requested](#)

[Return to Contents](#)

A large, stylized yellow 'V' shape that serves as a background for the text on the right side of the slide.

# VCV for ESR

## Externally Sponsored Research



# VCV Walkthrough - How to provide Additional Information Requested

for a Proposal/Protocol QC, Local Proposal/Protocol Review or (HQ) Proposal/Protocol Review

If the Verdict of the QC or review is **Additional Information Requested**, a new task will appear for the External User: **Add Info Requested Proposal/Protocol QC, Local Proposal/Protocol Review or (HQ) Proposal/Protocol Review with Due Date and Instructions**.

Lifecycle of the study changes to **Additional Information Requested**.

1

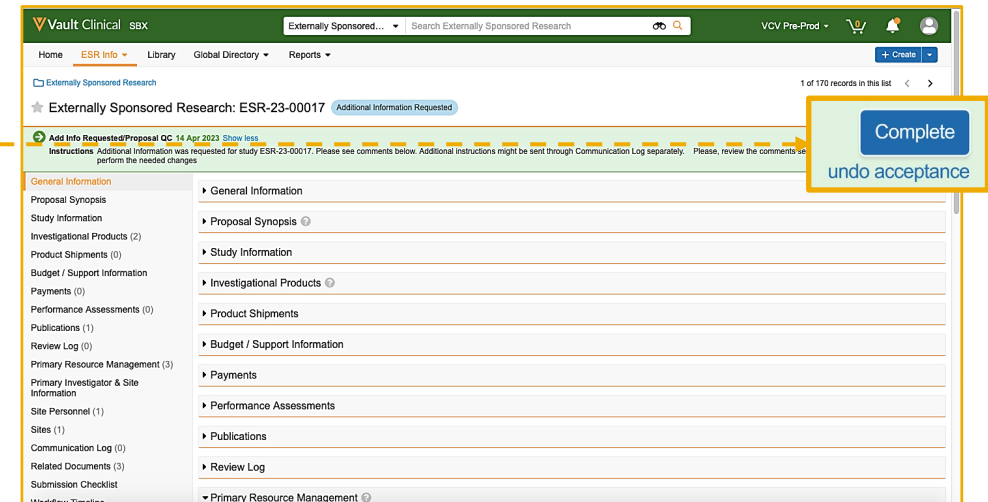
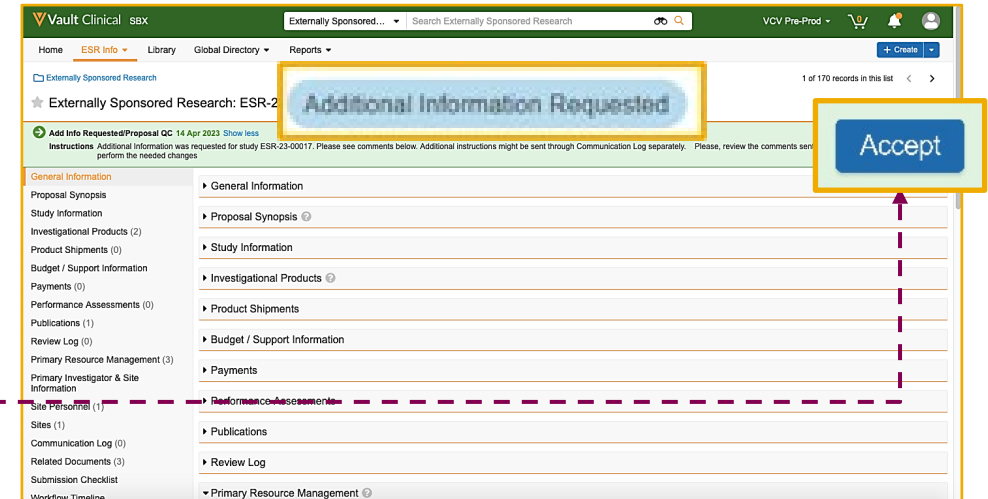
Click **Accept** and follow instructions shared by AstraZeneca

**Please note:** Additional comments/instructions may be sent to you via the **Communication log** or via email.

2

Provide **Additional Information** as requested and click **Complete**

Once the Add Info Requested task is completed, responsibility for next steps lies with AstraZeneca. AZ team may either accept the information provided or request additional information. The system will notify you via email regardless of the decision.



3

# How to submit a Protocol



Click the link to see the training video,  
[How to submit a protocol](#)

[Return to Contents](#)

# VCV for ESR

Externally Sponsored Research





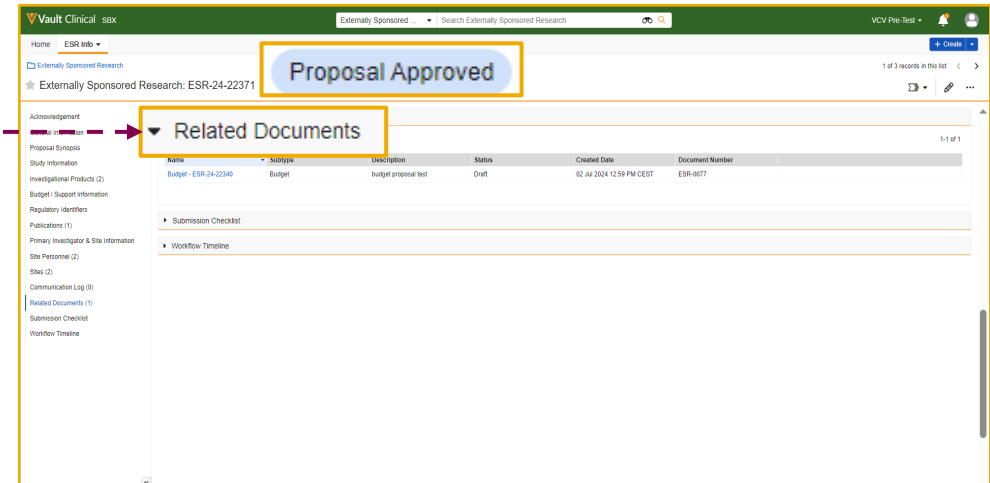
# VCV Walkthrough - How to submit a Protocol

## Protocol submission

When Study's lifecycle shows as **Proposal Approved**, the **Protocol** may be submitted for **QC and Review**.

1

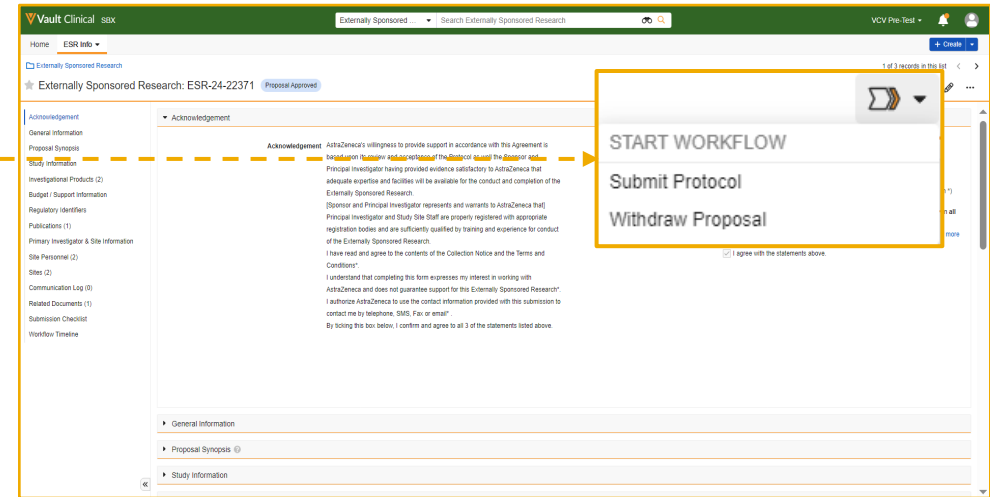
Upload the **Protocol** in the **Related Documents** section (see Appendix → [How to upload a document](#))



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

2

To submit the Protocol, click on the **Workflow icon** and select **Submit Protocol** from the drop-down menu



# VCV Walkthrough - How to submit a Protocol

## Protocol submission

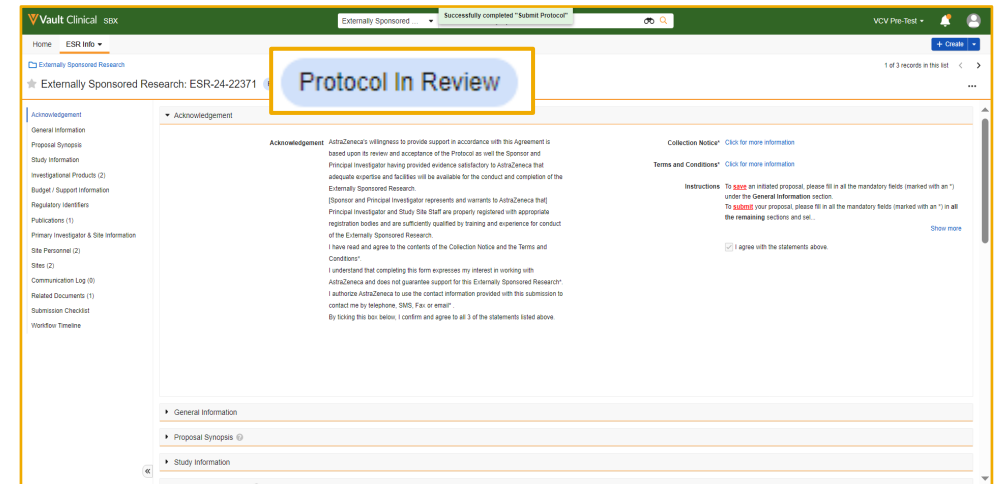
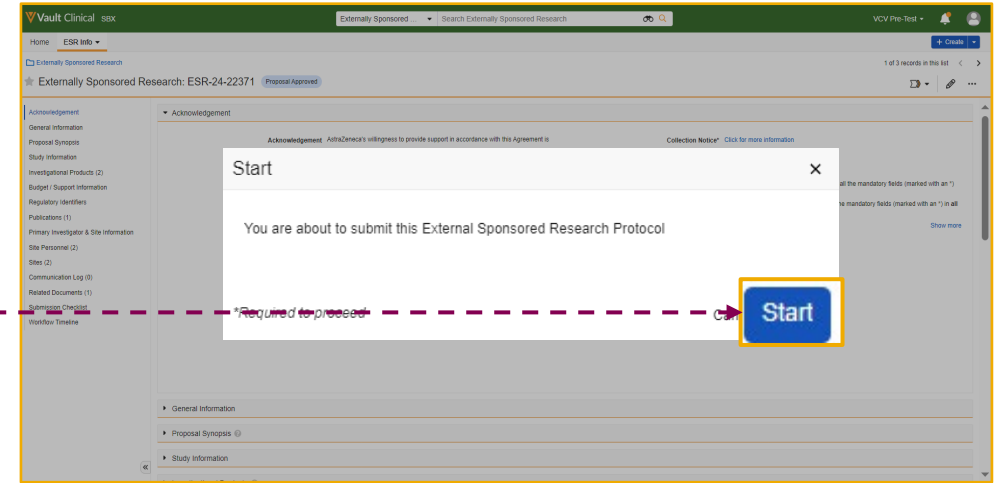
A pop-up box appears:  
**Start.**

3

Click **Start**

Lifecycle of the study changes to  
**Protocol in Review.**

After you have submitted the initial protocol, responsibility for next steps lies with AstraZeneca. AstraZeneca may either accept the provided protocol or request additional information. The system will notify you via email regardless of the decision.



4

## How to provide a Project Status Update (PSU)



Click the link to see the training video,  
[How to provide a project status update](#)

[Return to Contents](#)

# VCV for ESR

Externally Sponsored Research



# VCV Walkthrough - How to provide a Project Status Update

As per the terms outlined in the contract, the Sponsor is required to provide **Project Status Updates**. Reminders are sent to the Sponsor to encourage **PSU submission**.

Additionally, Local Coordinator has an option to **request PSUs** ad hoc at any time during the Study. In such cases, a task will be created for the site personnel.

The task **PSU Requested with Due Date and Instructions** appears in the taskbar.

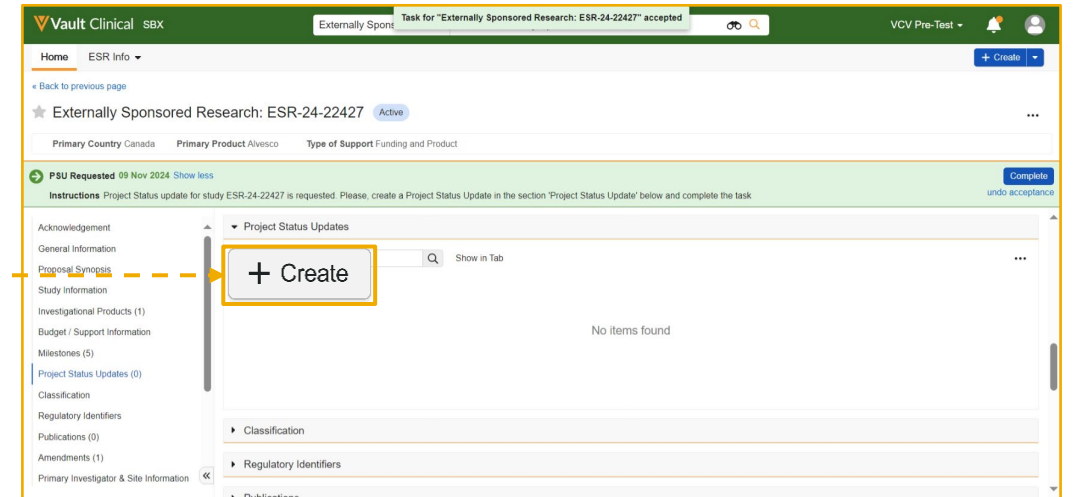
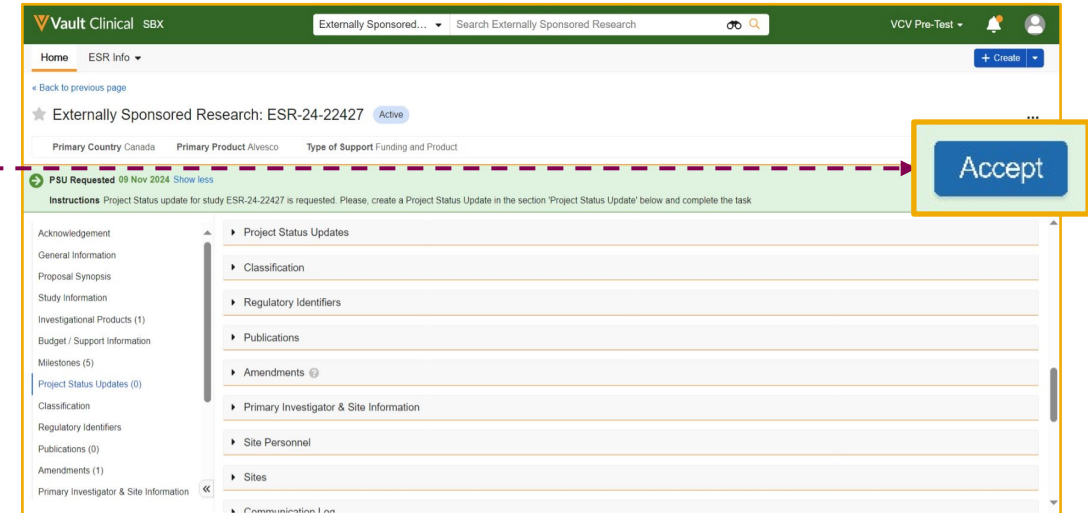
1

Click **Accept**

2

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

**Please note:** Only one PSU can be created per day.



# VCV Walkthrough - How to provide a Project Status Update

New window appears:  
Create ESR Project Status Update.

3

Answer the questions in the **Update Information** sub-section  
Click **Save**

**Updates may consist of:** Milestones, Subject Enrollment, Safety Reporting, Planned Publications and/or Regulatory Updates, depending on the answers provided in the first PSU subsection.

Created PSU record appears as **Saved**. If the answer to:

- **Are there Milestone Updates?** and/or
  - **Are there Subject Enrollment Updates?** and/or
  - **Is there any SAE/AE Information Update?** and/or
  - **Are you planning any study publications?** and/or
  - **Are there Regulatory Updates?**
- was 'Yes', the respective sub-sections show up with **mandatory fields** to fill in before the **PSU submission**.

Externally Sponsored Research ESR-24-22427

Status Update Date 10 Oct 2024

Are there Milestone Updates?  Yes  No

Are there Subject Enrollment Updates?  Yes  No

Is there any SAE/AE Information Update?  Yes  No

Are you planning any study publications?  Yes  No

Are there Regulatory Updates?  Yes  No

Save

ESR Project Status Update: ESR-24-22427-PSU-10Oct2024

Saved

Update Information

Externally Sponsored Research ESR-24-22427

Status Update Date 10 Oct 2024

Are there Milestone Updates? Yes

Are there Subject Enrollment Updates? Yes

Is there any SAE/AE Information Update? Yes

Are you planning any study publications? Yes

Are there Regulatory Updates? Yes

Milestone Update

Subject Enrollment Update



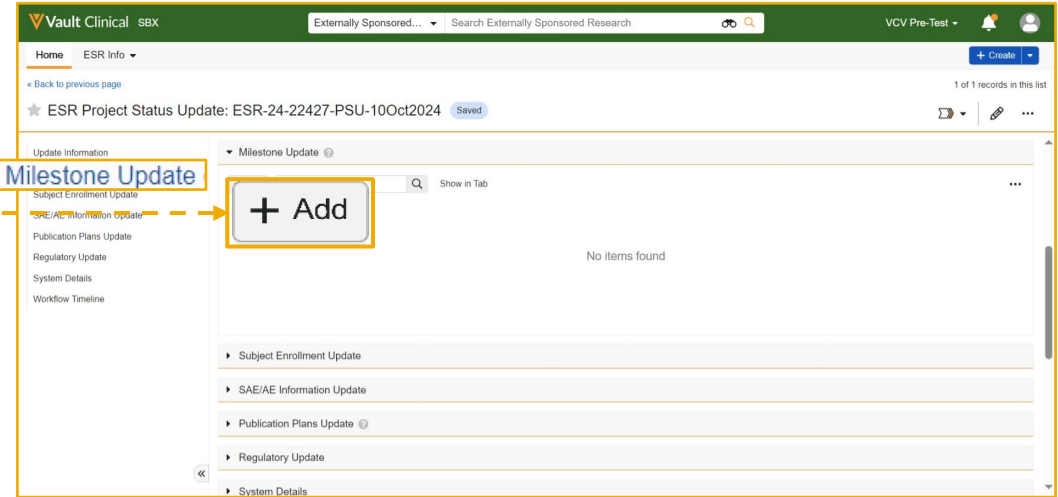
# VCV Walkthrough - How to provide a Project Status Update

## Milestone Update

If the answer to: **Are there Milestone Updates?** was 'Yes', the **Milestone Update** sub-section shows up, where the milestone(s) selected for update should be added.

4

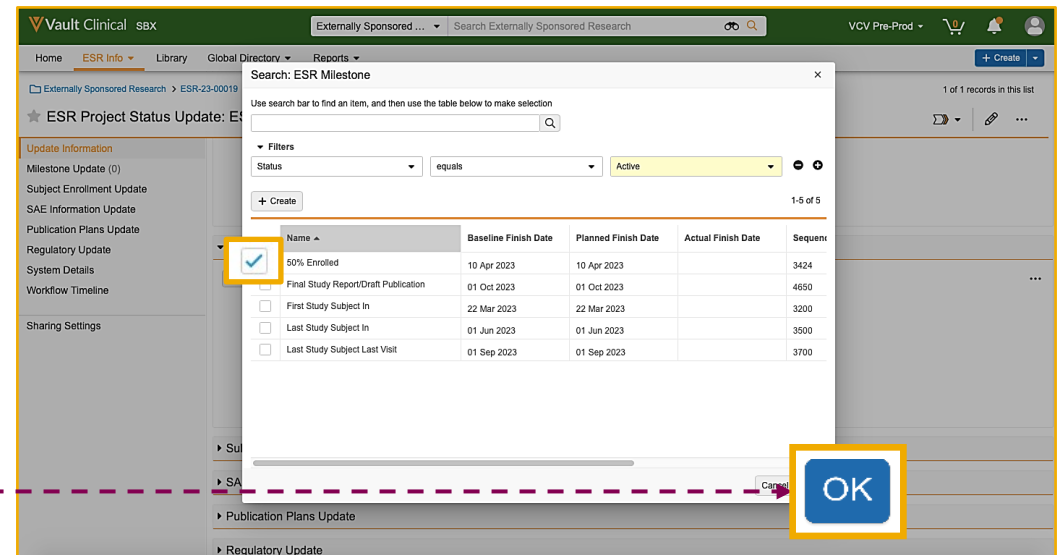
Open the **Milestone Update** sub-section and click **+Add**



A pop-up box appears: **Search ESR Milestone** with all milestones that are set up for this Study.

5

Check the box next to the **Milestone(s)** you wish to update and click **OK**



It is required to add at least one Milestone in the Milestone Update sub-section.



# VCV Walkthrough - How to provide a Project Status Update

## Updates to Milestone

The chosen milestone(s) will appear in the **Milestone Update** sub-section.

6

To update the Milestone, click on the **Milestone Name**

The screenshot shows the 'ESR Project Status Update' page for 'ESR-24-22427-PSU-10Oct2024'. Under the 'Milestone Update' section, there is a table with one record. The 'Name' column contains '50% Enrolled', which is highlighted with a yellow box. A dashed yellow arrow points from this box to the text box for step 6. Other columns include 'Current Planned Finish Date' (Aug 2024), 'Current Actual Finish Date', 'Updated Date', 'Milestone is achieved' (checkbox), and 'Reason for CI'.

New window appears, showing the **details** of the milestone record and its sub-sections with **mandatory fields** to fill in.

7

Click the **pencil icon** top right and navigate to the **Updates to Milestone** sub-section

The screenshot shows the 'Details' page for the milestone 'ESR Selected PSU Milestone: 50% Enrolled'. A pencil icon in the top right corner is highlighted with a yellow box, with a dashed purple arrow pointing to the text box for step 7. The 'Updates to Milestone' section is highlighted with a yellow box and contains fields for 'Current Planned Finish Date' (11 Aug 2024), 'Current Actual Finish Date', 'Updated Date', 'Reason for Change', and 'Milestone is achieved' (checkbox). The 'ESR Milestone' is '50% Enrolled' and the 'ESR PSU Number' is 'ESR-24-22427-PSU-10Oct2024'.



# VCV Walkthrough - How to provide a Project Status Update

## Updates to Milestone

8

Add a new date in the **Updated Date** field

9

Click the **Reason for Change** field and select a value from the dropdown menu

If 'Other' is selected, new mandatory field appears: **If 'Other', reason for change**, where a description of the reason should be provided.

10

Provide an appropriate **description** of the Reason for change

Vault Clinical SBX

Externally Sponsored... Search Externally Sponsored Research

VCV Pre-Test

Home ESR Info

Externally Sponsored Research > ESR-24-22427 > ESR-24-22427-PSU-100c2024

1 of 1 records in this list

★ ESR Selected PSU Milestone: 50% Enrolled Saved Cancel Save

Details

Updates to Milestone

Workflow Timeline

Sharing Settings

Current Planned Finish Date 11 Aug 2024

Updated Date DD MMM YYYY Today

Current Actual Finish Date

Milestone is achieved

Reason for Change

- Contracting negotiation / issue
- COVID-19
- Enrollment on hold - AZ
- Enrollment on hold - sponsor
- Other
- Recruitment not to plan
- Regulatory / Ethics Approval
- Safety signal / Review
- Study Design change

Vault Clinical SBX

Externally Sponsored... Search Externally Sponsored Research

VCV Pre-Test

Home ESR Info

Externally Sponsored Research > ESR-24-22427 > ESR-24-22427-PSU-100c2024

1 of 1 records in this list

★ ESR Selected PSU Milestone: 50% Enrolled Saved Cancel Save

Details

Updates to Milestone

Workflow Timeline

Sharing Settings

ESR Milestone 50% Enrolled

ESR PSU Number ESR-24-22427-PSU-100c2024

Current Planned Finish Date 11 Aug 2024

Updated Date 14 Oct 2024 Today

Current Actual Finish Date

Milestone is achieved

Reason for Change Other

If 'Other', reason for change





# VCV Walkthrough - How to provide a Project Status Update

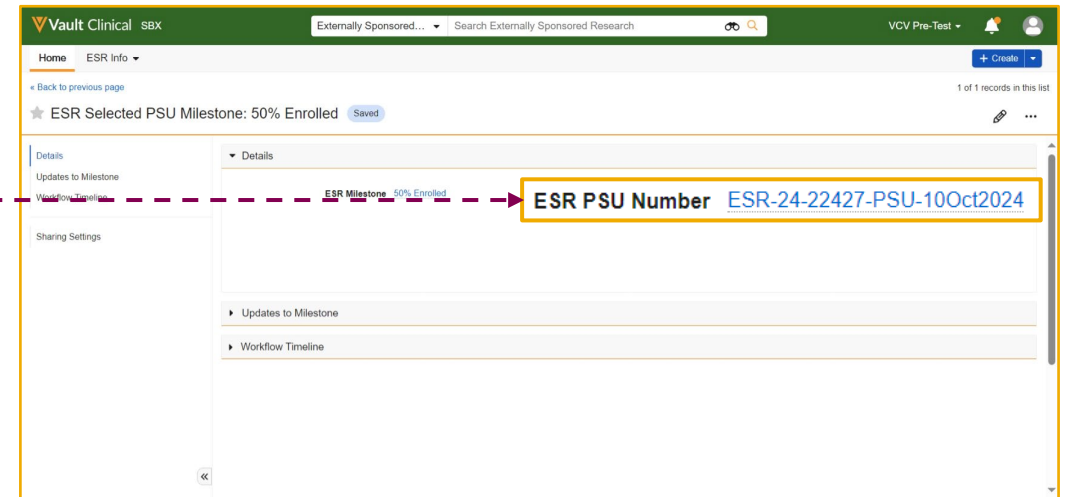
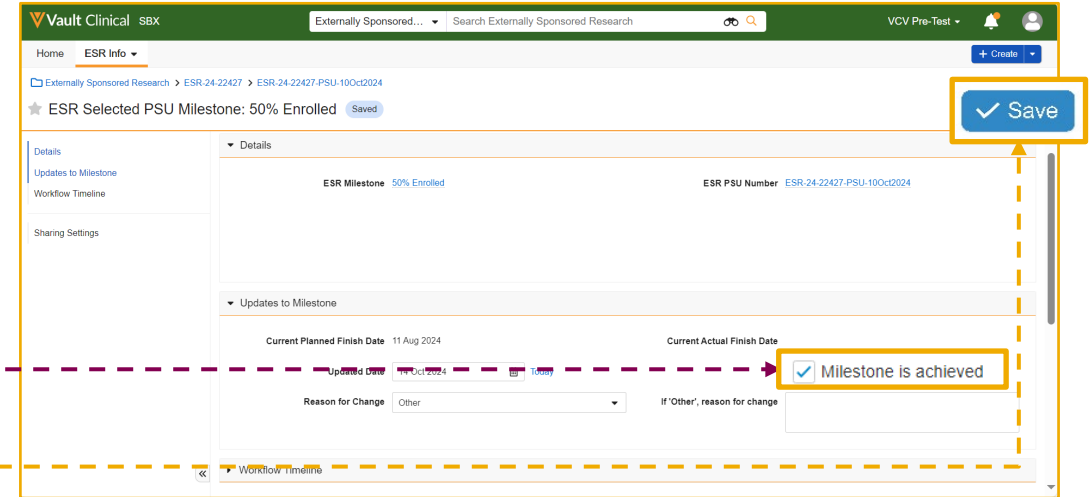
## Updates to Milestone

**11** Check 'Milestone is achieved' if you are providing an actual date for the milestone

**12** Click Save

**13** Go back to the PSU record by clicking the blue-linked PSU Number

Repeat steps 6 – 12 for each of the milestone selected for update.



# VCV Walkthrough - How to provide a Project Status Update

## Subject Enrollment Update

If the answer to: **Are there Subject Enrollment Updates?** was 'Yes', the **Subject Enrollment Update** sub-section appears, containing values provided in the **Study Information** section.

14

Open the **Subject Enrollment Update** sub-section and click **pencil icon** to edit the fields

The screenshot shows the 'ESR Project Status Update' page for ESR-24-22427-PSU-10Oct2024. The 'Subject Enrollment Update' sub-section is expanded, showing a table with columns for 'Current' and 'Updated' values for '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'. A pencil icon is visible in the top right corner of the sub-section, indicating it can be edited.

15

Enter updated number of subjects in the appropriate fields in the right-hand column

The screenshot shows the same 'ESR Project Status Update' page. The 'Updated' columns in the 'Subject Enrollment Update' table are highlighted in yellow, indicating they are the focus for data entry. A blue 'Save' button is visible in the top right corner of the sub-section.

16

Proceed to the next sub-section if available. If not, click **Save**



# VCV Walkthrough - How to provide a Project Status Update

## Serious Adverse Event/Adverse Event Information Update

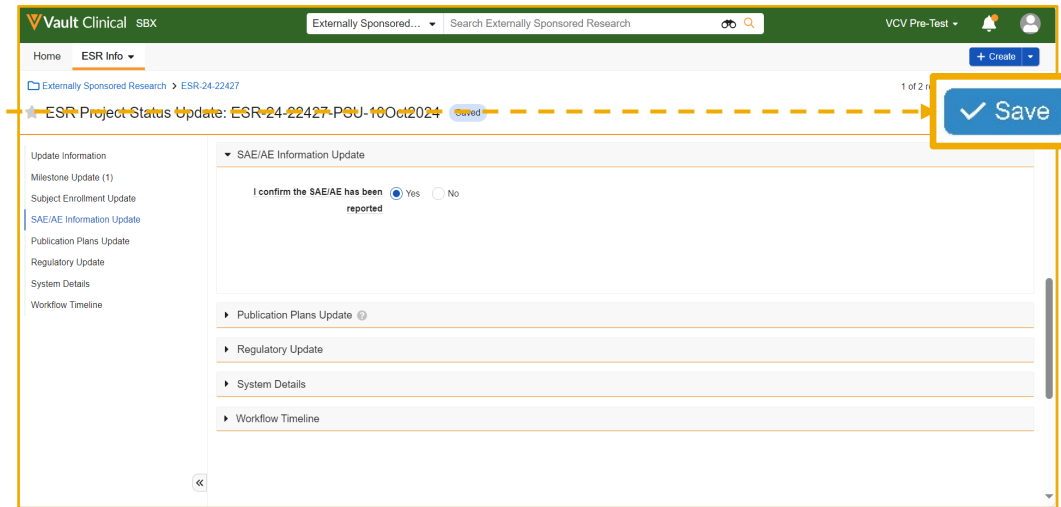
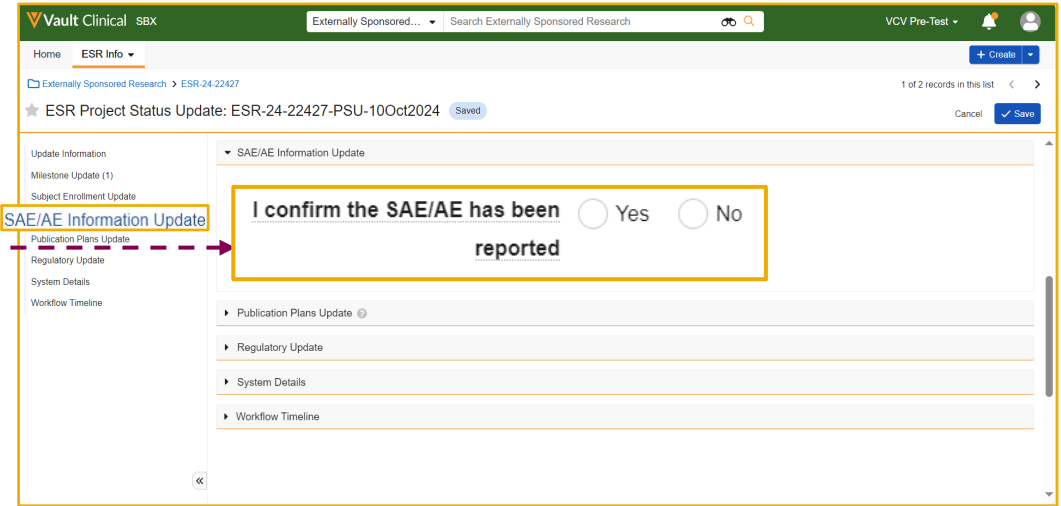
If the answer to: **Is there any SAE/AE Information Update?** was 'Yes', the **SAE/AE Information Update** sub-section appears with mandatory field: **'I confirm the SAE/AE has been reported'**.

17

Open the **SAE/AE Information Update** sub-section and check 'Yes' to confirm that SAEs/AEs have been reported to AZ Company

18

Proceed to the next sub-section if available. If not, click **Save**.



# VCV Walkthrough - How to provide a Project Status Update

## Publication Plans Update

If the answer to: **Are you planning any study publications?** was 'Yes', the **Publication Plans Update** sub-section appears with the field to provide details of publication plans.

Please ensure that updates provided in this sub-section are added to the **Publication node**. Update current planned publications or add new records to reflect the latest plans.

19

Open the **Publication Plans Update** sub-section and fill in the mandatory field

Please provide the **publication type**, approximate **planned publication date**, and **Name of the journal/congress** where it's planned to be published.

20

Proceed to the next sub-section if available. If not, click **Save**

Vault Clinical SBX

Externally Sponsored Research > ESR-24-22427

ESR Project Status Update: ESR-24-22427-PSU-10Oct2024

Update Information

- Milestone Update (1)
- Subject Enrollment Update
- SAE/AE Information Update
- Publication Plans Update**
- Regulatory Update
- System Details
- Workflow Timeline

Please provide likely timing and details

Vault Clinical SBX

Externally Sponsored Research > ESR-24-22427

ESR Project Status Update: ESR-24-22427-PSU-10Oct2024

Update Information

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

Please provide likely timing and details

Please provide the publication type, the approximate planned publication date, and the name of the journal/congress where it's planned to be published/presented

Save



# VCV Walkthrough - How to provide a Project Status Update

## Regulatory Update

If the answer to: **Are there Regulatory Updates?** was 'Yes', the **Regulatory Update** sub-section shows up with mandatory fields: **IRB/EC Approval Date** and **IRB/EC Expiration Date**.

21

Open the **Regulatory Update** sub-section and click the **Calendar** icon next to the field

The screenshot shows the 'Regulatory Update' sub-section in the Vault Clinical interface. The 'IRB/EC Approval Date' field is highlighted with a yellow box, and a calendar icon is visible next to it. A calendar popup is open, showing the date 22. The 'IRB/EC Expiration Date' field is also visible with a calendar icon. The 'Regulatory Update' label is highlighted with a yellow box.

22

Update the **IRB/EC Approval Date** and/or **IRB/EC Expiration Date** and click **Save**

The screenshot shows the 'Regulatory Update' sub-section in the Vault Clinical interface. The 'IRB/EC Approval Date' field is updated to '09 Sep 2024' and the 'IRB/EC Expiration Date' field is updated to '08 Sep 2025'. The 'Save' button is highlighted with a yellow box.



# VCV Walkthrough - How to provide a Project Status Update

After clicking **Save**, all provided updates will be saved under their corresponding sub-sections within the PSU record.

23

Click the blue-linked **ESR Number** to go back to the Study view

The screenshot shows the 'ESR Project Status Update: ESR-24-22427-PSU-16Oct2024' record. The ESR number 'ESR-24-22427' is highlighted in a blue box. The record includes sections for Update Information, Milestone Update, Subject Enrollment Update, SAE/AE Information Update, Publication Plans Update, Regulatory Update, System Details, Workflow Timeline, and Sharing Settings. A confirmation message states 'I confirm the SAE/AE has been reported'. There are also fields for IRB/EC Approval Date (15 Oct 2024) and IRB/EC Expiration Date (04 Nov 2024).

Created PSU record shows up in the **Project Status Updates** section.

24

Complete the task **PSU Requested** by clicking **Complete**

The screenshot shows the 'Externally Sponsored Research: ESR-24-22427' record. The 'PSU Requested' task is highlighted in a green box, and the 'Complete' button is highlighted in a blue box. The 'Project Status Updates' section is expanded, showing a table with columns for PSU Number, Milestone Updates, Subject Enrollment Updates, Regulatory Updates, and any other updates. The table contains one row with the following data:

PSU Number	Are there Milestone Updates?	Are there Subject Enrollment U...	Are there Regulatory Updates?	Is there any f
ESR-24-22427-PSU-10Oct2024	Yes	Yes	Yes	Yes

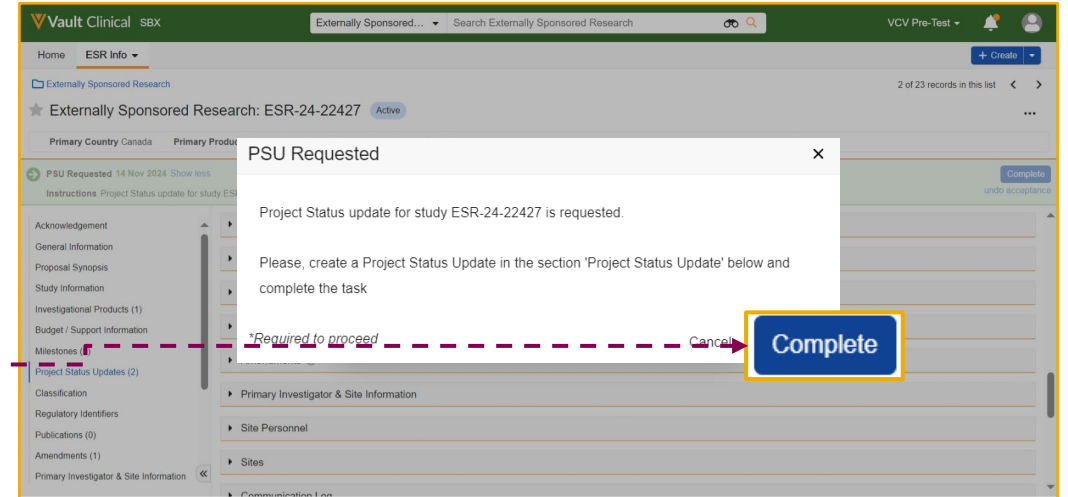


# VCV Walkthrough - How to provide a Project Status Update

A pop-up box appears: PSU Requested.

25

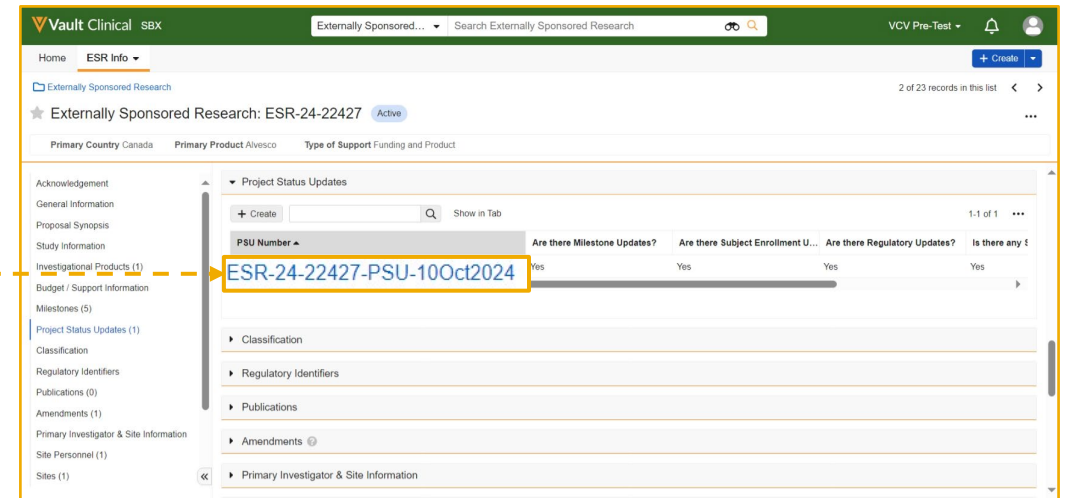
Click **Complete**



Once PSU requested fields are completed and the record was saved, the Investigator should **submit PSU for AZ review.**

26

Go to the **Project Status Updates** section and click the blue-linked **PSU Number**



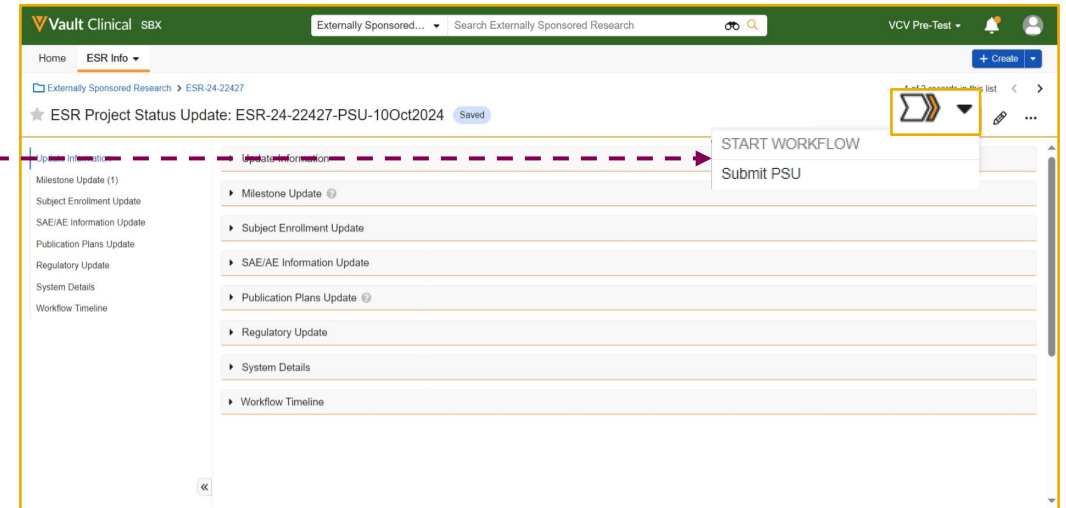
# VCV Walkthrough - How to provide a Project Status Update

## PSU Submission

When PSU has not been submitted for **48 hours** and remains in 'Saved' state, the Investigator will be notified via email about **Pending submission**.

27

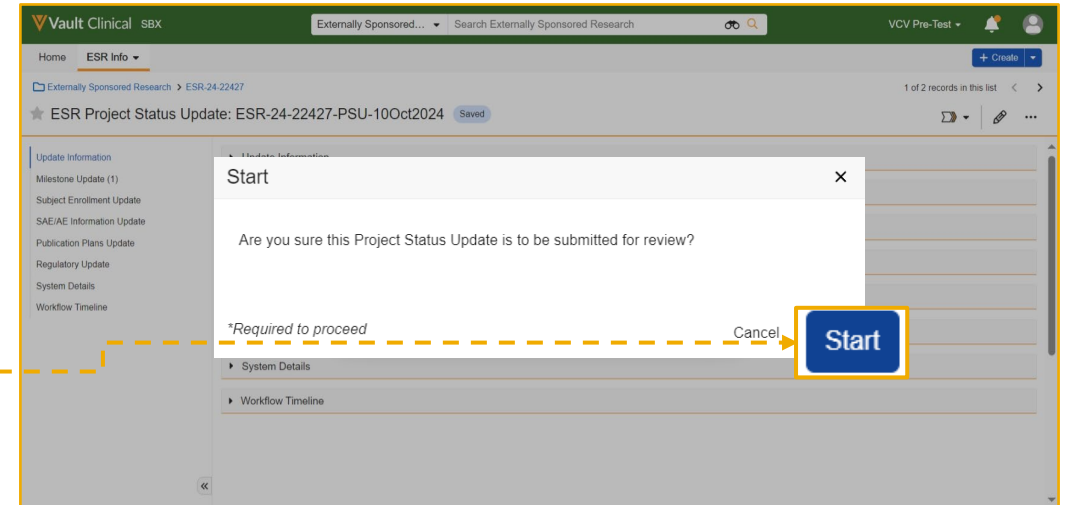
To submit PSU, click the **workflow icon** and select '**Submit PSU**' from the dropdown menu



A pop-up box appears: **Start**.

28

Click **Start** to proceed with the submission and **send PSU for review**





# VCV Walkthrough - How to provide a Project Status Update

## PSU Review

PSU Status changes to **In Review**.  
External users **cannot edit** the record  
in review state.

Local Coordinator reviews the PSU. Depending on the **review outcome**, further tasks may be generated.  
A notification with the review verdict and comments will be sent via email once the review is completed.

If the Verdict is '**Review and Resubmit**', the task **PSU sent for review and resubmit** with **Instructions** will show up under the PSU record.

PSU status has changed to **Review and Resubmit**.

The screenshot shows the Vault Clinical SBX interface. The top navigation bar includes 'Externally Sponsored...' and a search bar. The main content area displays 'ESR Project Status Update: ESR-24-22427-PSU-10Oct2024' with a status badge that reads 'In Review'. A left-hand menu lists various update categories such as 'Update Information', 'Milestone Update (1)', 'Subject Enrollment Update', 'SAE/AE Information Update', 'Publication Plans Update', 'Regulatory Update', 'System Details', and 'Workflow Timeline'. The main content area mirrors these categories with expandable sections.

The screenshot shows the Vault Clinical SBX interface. The top navigation bar includes 'Externally Sponsored...' and a search bar. The main content area displays 'ESR Project Status Update: ESR-24-22427-PSU-10Oct2024' with a status badge that reads 'Review and Resubmit'. Below the header, a green notification banner states: 'PSU sent for review and resubmit. Instructions: Project Status update for study ESR-24-22427 has been sent back for review and has to be resubmitted. Please see comments below.' The left-hand menu and main content area are identical to the previous screenshot.



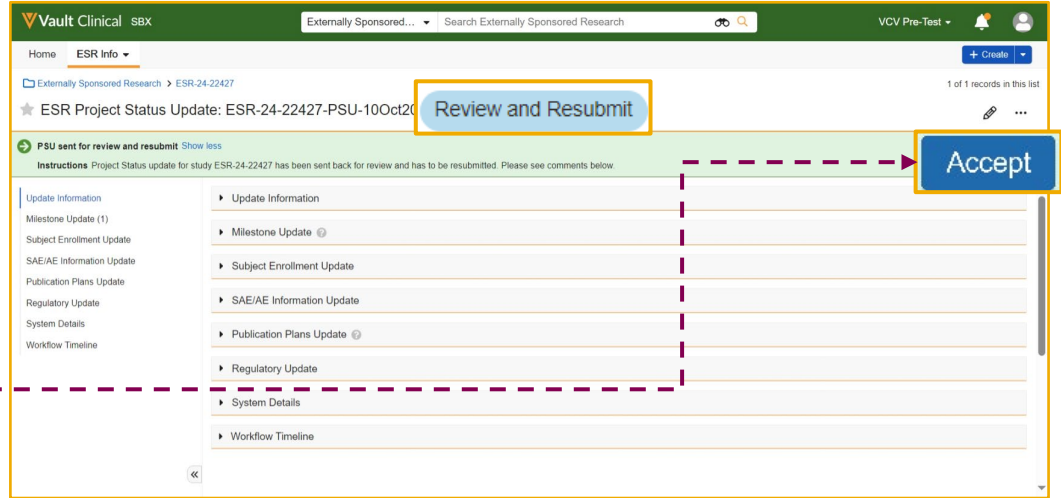
# VCV Walkthrough - How to provide a Project Status Update

PSU sent for review and resubmit

The task can be seen after opening a specific PSU record, and it is **not visible from the main view** of the ESR Study.

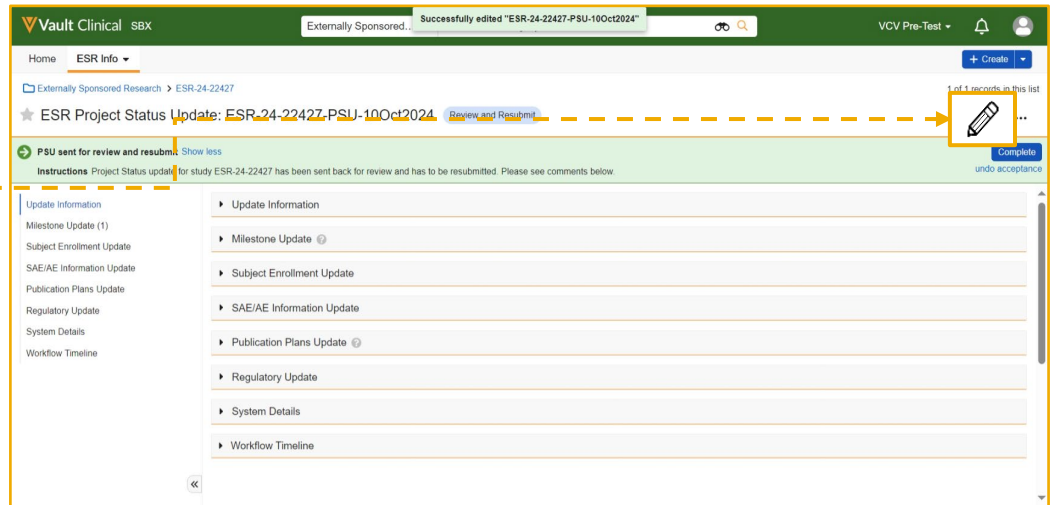
29

Click **Accept** and follow comments from AZ reviewers to update the PSU



30

Click the **pencil icon** to edit the fields and make requested changes



Additional instructions may be sent to you via the **Communication Log**.



# VCV Walkthrough - How to provide a Project Status Update

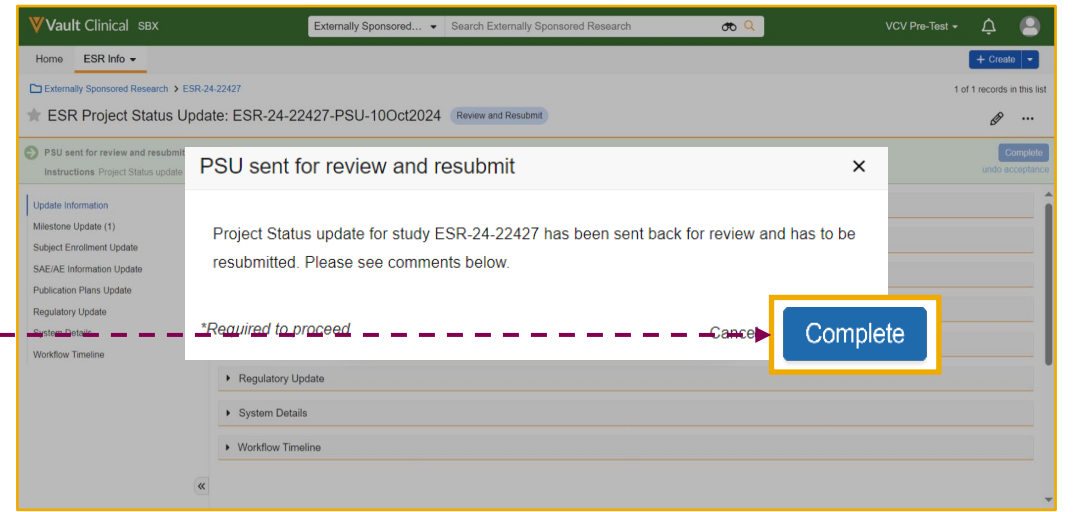
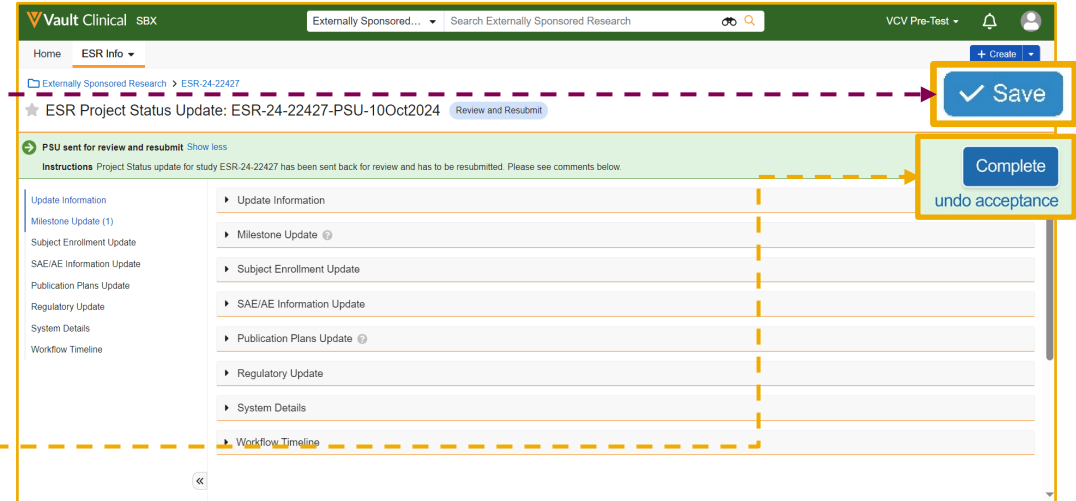
PSU sent for review and resubmit

31 Click Save

32 Complete the task by clicking Complete

33 Click Complete

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

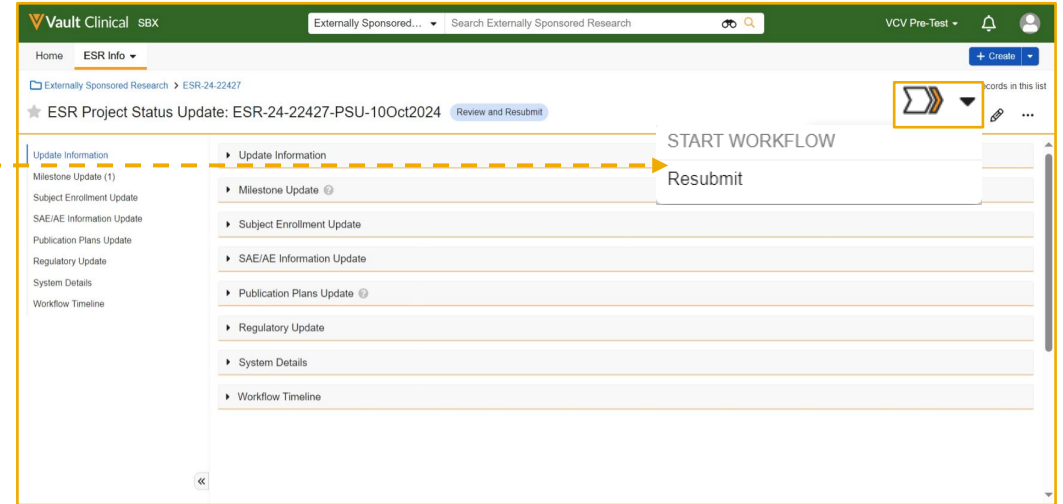


# VCV Walkthrough - How to provide a Project Status Update

## PSU Resubmission

34

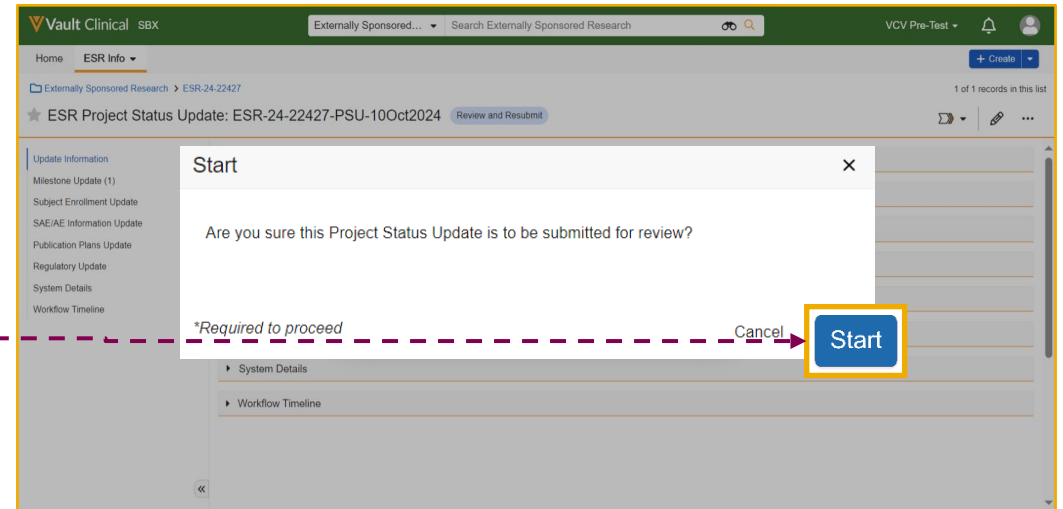
Click the **workflow icon** and select 'Resubmit' from the dropdown menu



A pop-up box appears: **Start**.

35

Click **Start** to proceed with PSU resubmission



# VCV Walkthrough - How to provide a Project Status Update

## Project Status Update Accepted

Status of the PSU record goes back to **In Review**.  
If the Verdict is **Review and Resubmit**, repeat the steps 28 - 35.

If the Verdict is **Accept**, PSU status changes to **Accepted**. Some of the updates will **automatically replace** the information that was previously provided in the **respective sections** of the Study.

If there were updates to **Milestones**, they will be copied over to the **Milestones** section.  
If there were updates to **Enrollment metrics**, they will be copied over to the **Study Information** section.  
If there were updates to **Regulatory dates**, they will be copied over to the **Regulatory Identifiers** section.

The screenshot shows the Vault Clinical SBX interface. The top navigation bar includes 'Externally Sponsored...' and a search bar. The main content area displays 'ESR Project Status Update: ESR-24-22427-PSU-10Oct2024' with a status of 'In Review' highlighted in a blue box. The left sidebar lists update categories like 'Update Information', 'Milestone Update (1)', 'Subject Enrollment Update', etc. The main panel shows a form with fields for 'Status Update Date' (10 Oct 2024) and several yes/no questions: 'Are there Milestone Updates?', 'Are there Subject Enrollment Updates?', 'Is there any SAE/AE information Update?', 'Are you planning any study publications?', and 'Are there Regulatory Updates?'.

The screenshot shows the same Vault Clinical SBX interface as above, but the status of the 'ESR Project Status Update: ESR-24-22427-PSU-10Oct2024' is now 'Accepted', highlighted in a blue box. The form content and layout are identical to the previous screenshot, showing the 'Update Information' section with the same date and questions.



5

# How to create an Amendment

i

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# VCV for ESR

Externally Sponsored Research

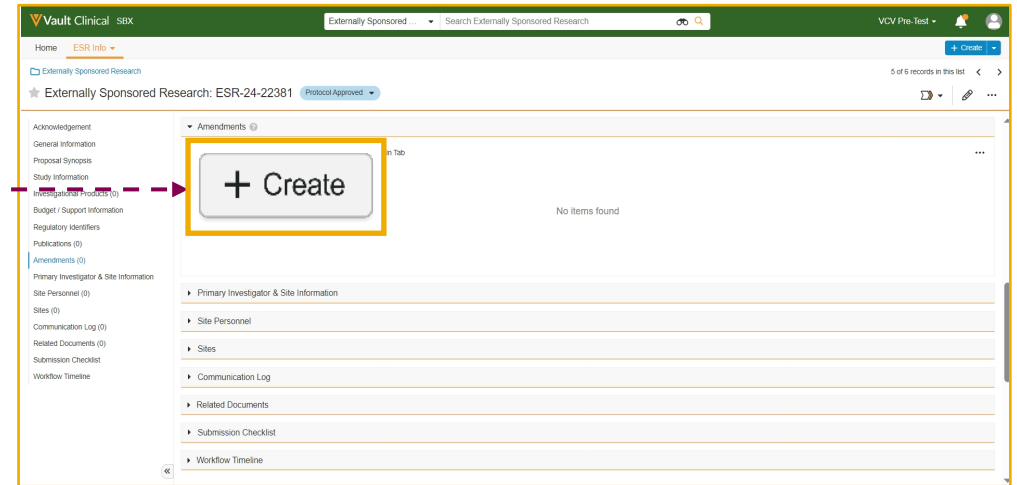


# VCV Walkthrough - How to create an Amendment

An **Amendment** can be created for an ESR Study at any time once the Study Protocol has been quality checked and reviewed by AZ team with an **Approved** verdict.

1

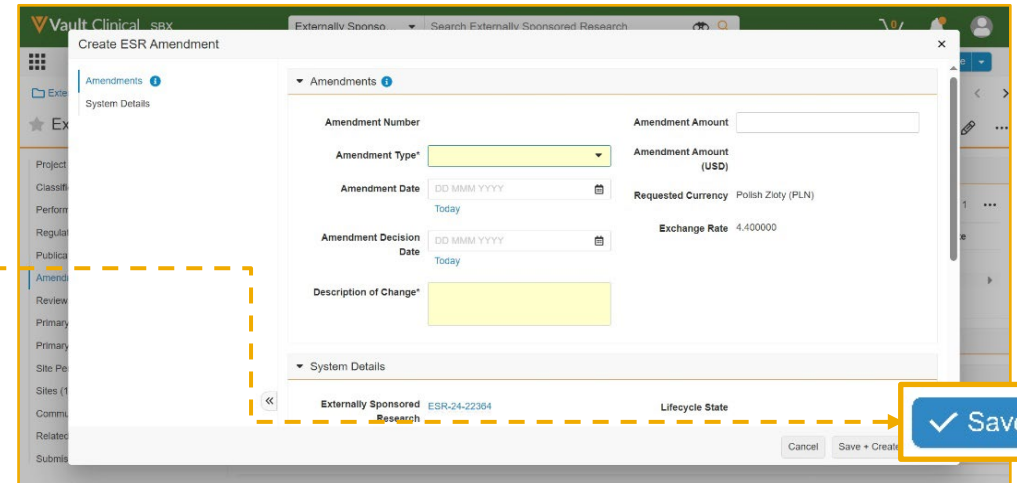
Open the **Amendments** section and click **+Create**



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

2

Complete the mandatory fields and click on **Save**



# VCV Walkthrough - How to create an Amendment

The Amendment Number shows in the Amendments section.

3

Click on the Amendment Number

The Amendment shows as Submitted and is sent to AZ for review.

Externally Sponsored Research

Amendments ?

Amendment Number	Amendment Date	Lifecycle State
ESR-24-22381-Amendme...	25 Jul 2024	Submitted

ESR Amendment: ESR-24-22348-Amendment-000001

Submitted

Amendments

Amendment Number	ESR-24-22348-Amendment-000001	Amendment Amount
Amendment Type	Revised Protocol	Amendment Amount (USD)
Amendment Date	09 Jul 2024	Requested Currency <a href="#">US Dollar (USD)</a>
Amendment Decision Date	09 Jul 2024	Exchange Rate 1.000000
Description of Change	Description of Change	

Related Documents

+ Add

No items found





# VCV Walkthrough - How to create an Amendment

## Uploading the Amendment document

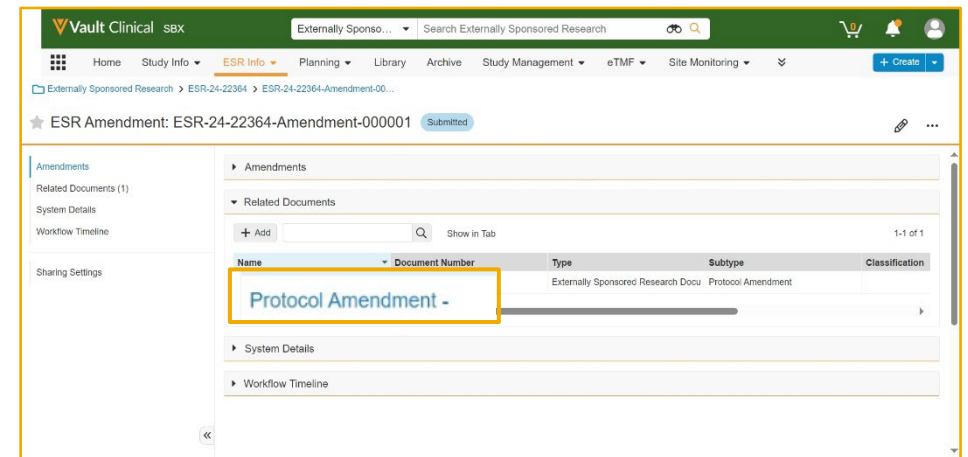
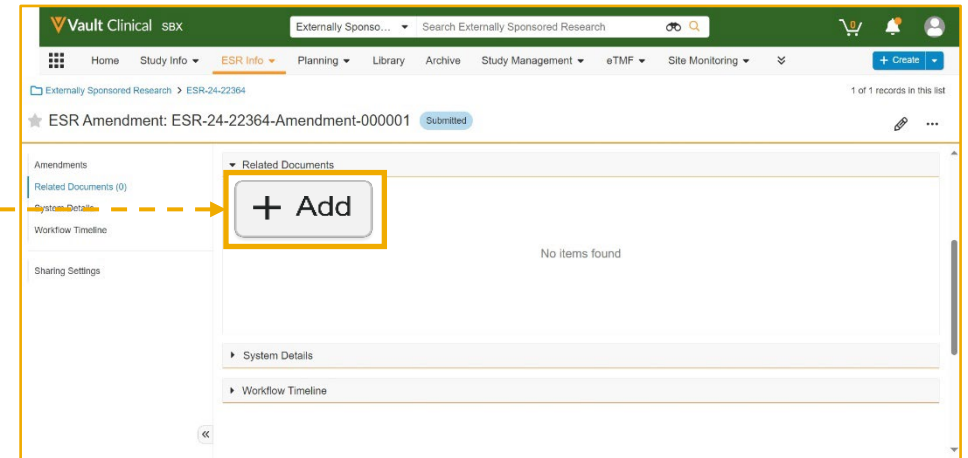
4

Open the **Related Documents** sub-section under the **Amendment record** and click **+Add**

For more details,  
see **Appendix** → [How to upload a document](#).

Please ensure that the updated documents are uploaded under the appropriate subtype - **Protocol amendment**.

Uploaded document appears in the **Related Documents** sub-section after clicking on the **Amendment Number**.



# VCV Walkthrough - How to create an Amendment

## Additional Information Requested for 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.

5

Click **Accept**, provide **Additional Information** and upload the updated document if required

The screenshot shows the Vault Clinical interface for an amendment record (ESR-24-22364-Amendment-000001). A taskbar notification at the top indicates 'Additional Info Requested for Amendment' with a due date of 26 Jun 2024. A blue 'Accept' button is highlighted in the top right corner. The main content area displays amendment details: Amendment Number (ESR-24-22364-Amendment-000001), Amendment Type (Revised Protocol), Amendment Date (26 Jun 2024), Amendment Decision Date (26 Jun 2024), Description of Change (test), Amendment Amount, Amendment Amount (USD), Requested Currency (Polish Zloty (PLN)), and Exchange Rate (4.400000).

6

Click **Complete**

The screenshot shows the same Vault Clinical interface for the amendment record (ESR-24-22377-Amendment-000001). The taskbar notification now indicates 'Additional Info Requested for Amendment' with a due date of 07 Aug 2024. A blue 'Complete' button is highlighted in the top right corner. The main content area displays amendment details: Amendment Number (ESR-24-22377-Amendment-000001), Amendment Type (Revised Protocol), Amendment Date (07 Jul 2024), Amendment Decision Date (07 Jul 2024), Description of Change (test change), Amendment Amount, Amendment Amount (USD), Requested Currency (US Dollar (USD)), and Exchange Rate (1.000000).

**Please note:** The task is visible only after opening a specific **Amendment Record**.



# VCV Walkthrough - How to create an Amendment

## Additional Information Requested for Amendment

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

7

Click Complete

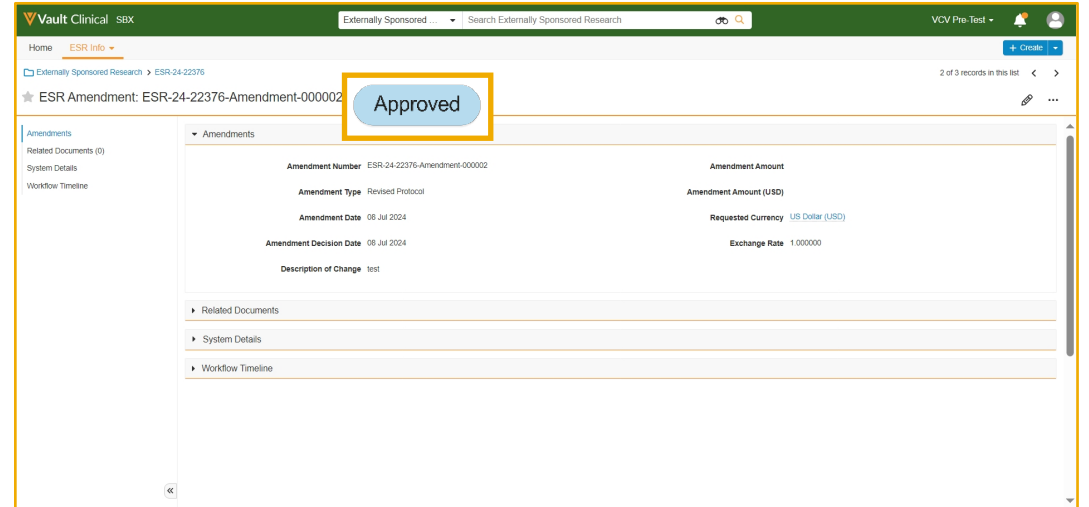
After you have completed the **Additional Info Requested** task, responsibility for next steps lies with AstraZeneca. AstraZeneca may either accept the information provided or request additional information. The system will notify you via email regardless of the decision.

The screenshot shows the Vault Clinical SBX interface. At the top, there's a navigation bar with 'Externally Sponsored Research' and a search bar. Below that, the main content area displays 'ESR Amendment: ESR-23-00019-Amendment-000001' with a 'Submitted' status. A notification banner indicates 'Additional Info Requested for Amendment' on 19 Apr 2023. A sidebar on the left lists 'Amendments', 'System Details', 'Workflow Timeline', and 'Sharing Settings'. The main content area shows a table of amendments with columns for 'Amendment Number', 'Amendment Type', 'Amendment Description', 'Amendment Decision Description', and 'Amendment Document'. A pop-up window is overlaid on the table, displaying the 'Additional Info Requested for Amendment' message and a 'Complete' button. A dashed line connects the 'Click Complete' instruction to the 'Complete' button in the pop-up.



# VCV Walkthrough - How to create an Amendment

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

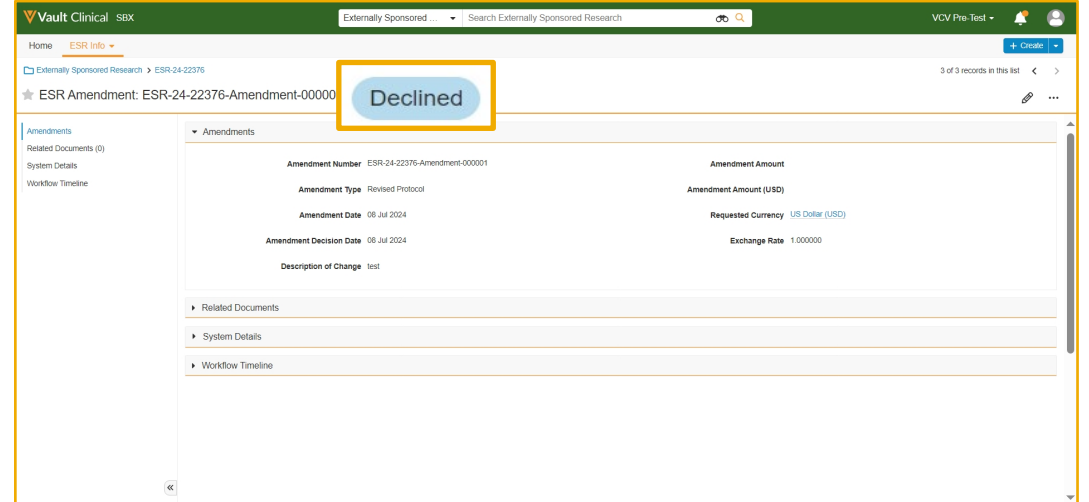


The screenshot displays the 'Externally Sponsored Research' page in Vault Clinical SBX. The breadcrumb trail is 'Home > ESR Info > Externally Sponsored Research > ESR-24-22376'. The main heading is 'ESR Amendment: ESR-24-22376-Amendment-000002', with a blue 'Approved' badge next to it. The left sidebar contains 'Amendments', 'Related Documents (0)', 'System Details', and 'Workflow Timeline'. The main content area shows the following details:

Amendment Number	ESR-24-22376-Amendment-000002	Amendment Amount	
Amendment Type	Revised Protocol	Amendment Amount (USD)	
Amendment Date	08 Jul 2024	Requested Currency	US Dollar (USD)
Amendment Decision Date	08 Jul 2024	Exchange Rate	1.000000
Description of Change	test		

Below the details are expandable sections for 'Related Documents', 'System Details', and 'Workflow Timeline'.

If the Verdict of the Amendment Review is Declined, the Amendment shows as Declined in the Amendment record.



The screenshot displays the 'Externally Sponsored Research' page in Vault Clinical SBX. The breadcrumb trail is 'Home > ESR Info > Externally Sponsored Research > ESR-24-22376'. The main heading is 'ESR Amendment: ESR-24-22376-Amendment-000001', with a blue 'Declined' badge next to it. The left sidebar contains 'Amendments', 'Related Documents (0)', 'System Details', and 'Workflow Timeline'. The main content area shows the following details:

Amendment Number	ESR-24-22376-Amendment-000001	Amendment Amount	
Amendment Type	Revised Protocol	Amendment Amount (USD)	
Amendment Date	08 Jul 2024	Requested Currency	US Dollar (USD)
Amendment Decision Date	08 Jul 2024	Exchange Rate	1.000000
Description of Change	test		

Below the details are expandable sections for 'Related Documents', 'System Details', and 'Workflow Timeline'.



6

# How to provide Final Deliverables



Click the link to see the training video,  
[How to provide final deliverables](#)

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# VCV for ESR

Externally Sponsored Research



# VCV Walkthrough - How to provide Final Deliverables

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

1

Click **Accept**

To upload a document, see **Appendix** → **How to upload a document**

2

Follow the instructions shared by AstraZeneca and provide the requested information. Click **Complete**

The screenshot shows the Vault Clinical interface for 'Externally Sponsored Research: ESR-24-22348'. The status is 'Closing'. A task bar at the top indicates 'Final Deliverables Requested 08 Aug 2024'. A blue 'Accept' button is highlighted in a yellow box. The main content area shows a form with sections for 'Acknowledgement', 'Collection Notice', and 'Terms and Conditions'. The 'Acknowledgement' section contains text about AstraZeneca's willingness to provide support. The 'Collection Notice' and 'Terms and Conditions' sections contain instructions for submitting proposals. A dashed purple line connects the 'Accept' button to the 'Acknowledgement' section.

The screenshot shows the same Vault Clinical interface as above, but with the 'Complete' button highlighted in a yellow box. A dashed yellow line connects the 'Complete' button to the 'Acknowledgement' section. The 'undo acceptance' option is also visible below the 'Complete' button.



# VCV Walkthrough - How to provide Final Deliverables

A pop-up box appears: Final Deliverables Requested.

3

Click Complete

The screenshot shows the Vault Clinical SBX interface for an 'Externally Sponsored Research' record (ESR-23-00019). The 'Acknowledgement' section is active, and a pop-up box titled 'Final Deliverables Requested' is displayed. The pop-up contains the text: 'Study ESR-23-00019 is now ready for submitting final deliverables. Please see the comments below.' and a blue 'Complete' button. A dashed line from the 'Click Complete' instruction points to this button. The background interface shows a navigation menu with 'Home', 'ESR Info', 'Library', 'Global Directory', and 'Reports'. The main content area includes a 'Closure checklist' and a 'Final Deliverables Requested' section with instructions and a 'Complete' button.



# VCV Walkthrough - How to provide Final Deliverables

## Final Deliverables: Additional Information Requested

The Local Coordinator will receive the **Final Deliverables**.

If a **Verdict** of the review is **Additional Information Requested**, a task appears in the taskbar for the Investigator: **Add Info Requested/Final Deliverables** with **Due Date** and **Instructions**.

4

Click **Accept**

Vault Clinical sbx

Externally Sponsored Research: ESR-24-22348

Task for "Externally Sponsored Research: ESR-24-22348" returned to queue

1 of 1 records in this list

Externally Sponsored Research: ESR-24-22348

Add Info Requested/Final Deliverables 08 Aug 2024

Instructions Final Deliverables for study ESR-24-22348 have been sent back for review. Please see comments.

Accept

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.

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... [Show more](#)

I agree with the statements above.

5

Follow the instructions shared by AstraZeneca and provide the requested information. Click **Complete**

Vault Clinical sbx

Externally Sponsored Research: ESR-24-22348

Task for "Externally Sponsored Research: ESR-24-22348" accepted

1 of 1 records in this list

Externally Sponsored Research: ESR-24-22348

Add Info Requested/Final Deliverables 08 Aug 2024

Instructions Final Deliverables for study ESR-24-22348 have been sent back for review. Please see comments.

Complete

undo acceptance

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.

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

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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... [Show more](#)

I agree with the statements above.





# VCV Walkthrough - How to provide Final Deliverables

Final Deliverables: Additional Information Requested

A pop-up window appears: **Add Info Requested/Final Deliverables.**

6

Click Complete

The screenshot displays the Vault Clinical SBX interface. A pop-up window titled "Add Info Requested/Final Deliverables" is centered on the screen. The pop-up contains the text: "Final Deliverables for study ESR-24-22348 have been sent back for review. Please see comments." Below this text, there is a "Cancel" button and a "Complete" button. The "Complete" button is highlighted with a yellow box. In the background, the main interface shows the "Externally Sponsored Research" section for study ESR-24-22348, with a "Complete" button visible in the top right corner of the main content area. A dashed orange line connects the "Complete" button in the pop-up to the "Click Complete" text in the callout box.



# VCV Walkthrough - How to provide Final Deliverables

Whenever the study is ready to be closed, the Local Coordinator selects **Close study** from the workflow icon dropdown menu and the lifecycle state of the study changes to **Closed**.  
Investigators will be notified of the study's closure.

The screenshot shows the Vault Clinical SBX interface. The top navigation bar includes 'Vault Clinical SBX', a search bar for 'Externally Sponsored Research', and a '+ Create' button. The main content area is titled 'Externally Sponsored Research' and shows a list of records. The first record is 'Externally Sponsored Research: ESR-24-22364', which is in a 'Closed' state, as indicated by a blue 'Closed' button highlighted with a yellow box. The left sidebar contains a list of sections: Acknowledgement, General Information, Proposal Synopsis, Study Information, Investigational Products (1), Product Shipments (0), Budget / Support Information, Payments (1), Milestones (7), Contracts, Project Status Updates (1), Classification, and Performance Assessments (1). The main content area displays the 'Acknowledgement' section, which includes text about AstraZeneca's support and the investigator's agreement to the terms and conditions. A 'Collection Notice' and 'Terms and Conditions' section are also visible, along with a 'Show more' link and a checked checkbox for agreement.



7

# How to upload a document

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# VCV for ESR

Externally Sponsored Research

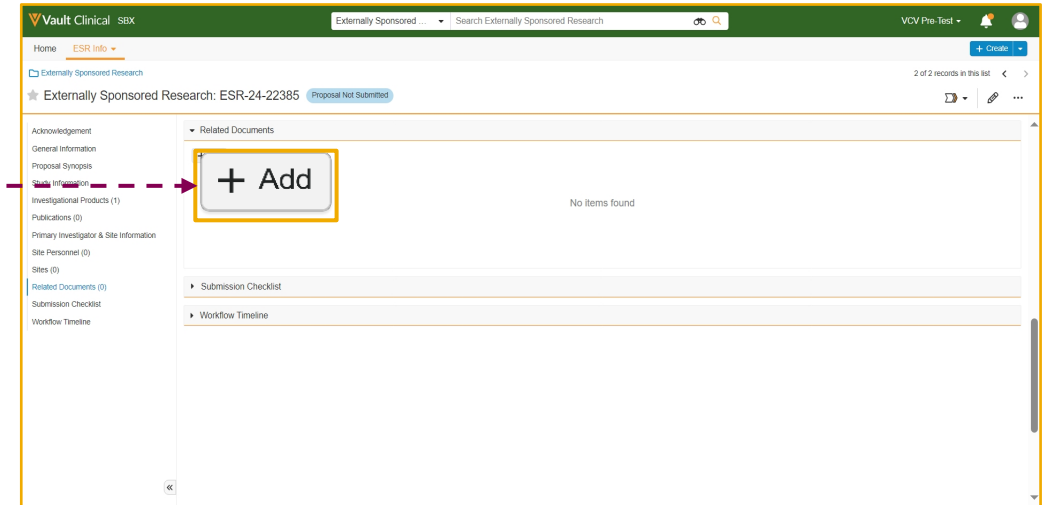


# VCV Walkthrough - How to upload a document

## Related Documents

1

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

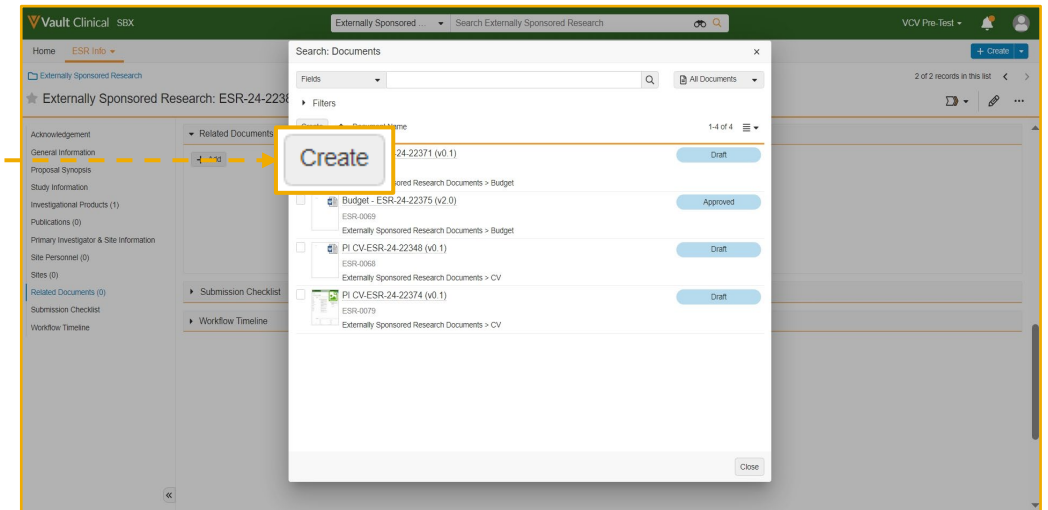


A pop-up box appears:  
**Search: Documents.**

The box shows a **list of documents** the user previously uploaded to VCV, along with those from studies the user is assigned to. From this view, **multiple documents** can be attached to **one study**.

2

Click **Create** to upload a new document



# VCV Walkthrough - How to upload a document

## Related Documents

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

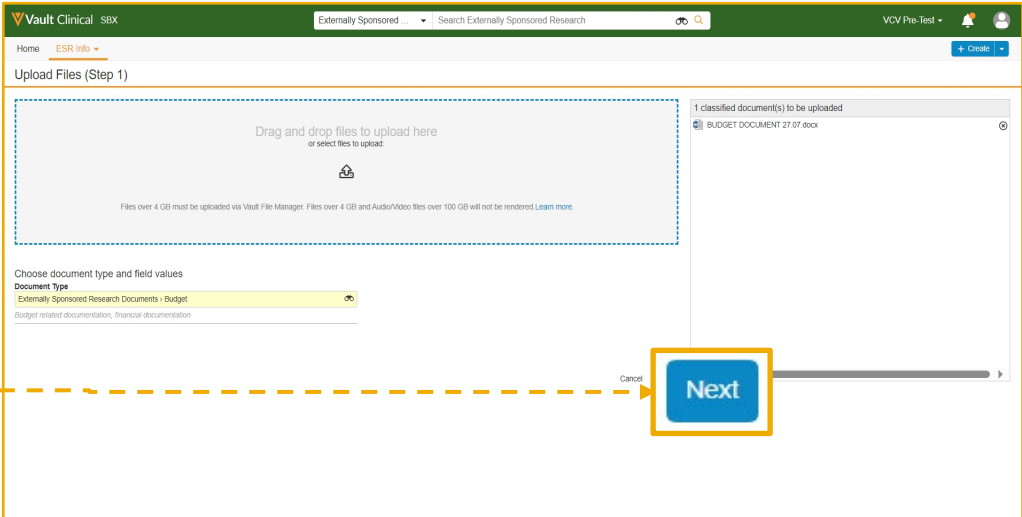
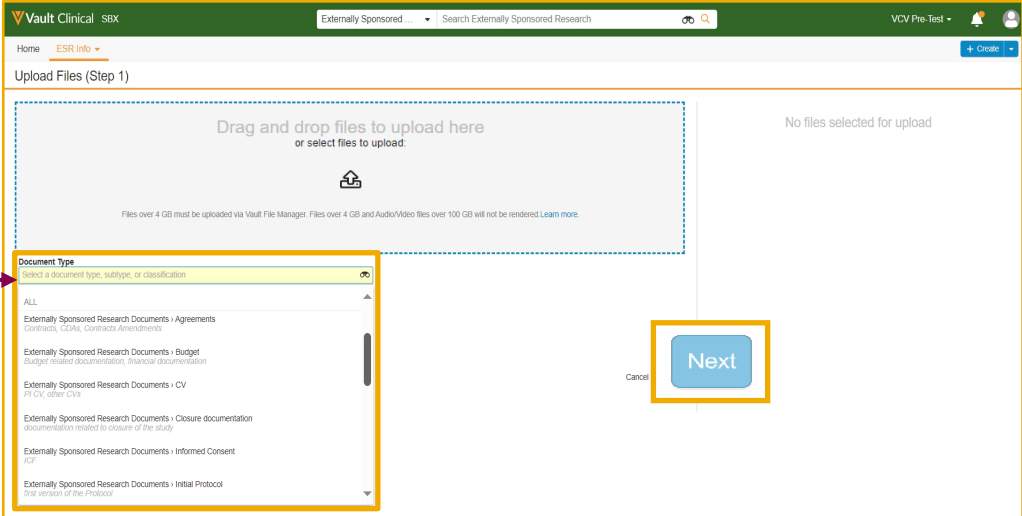
3

Follow instructions to **upload files**.  
Click on the **Document Type** field and select the proper **Type** and **Subtype** from the drop-down menu

**Please note:** A document cannot be created in VCV without uploading a file and selecting **Document Type**.  
The **'Next'** button will become active only after the document is uploaded and its type is selected.

4

Click **Next**

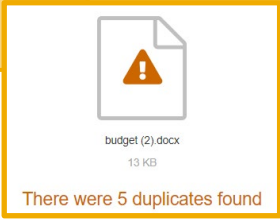


# VCV Walkthrough - How to upload a document

## Related Documents

A new window appears:  
**Upload Files (Step 2).**

If the document is uploaded properly, **“Your file has been successfully uploaded”** information shows up.  
If uploaded file already exists in the system, **“There were duplicates found”** will appear.

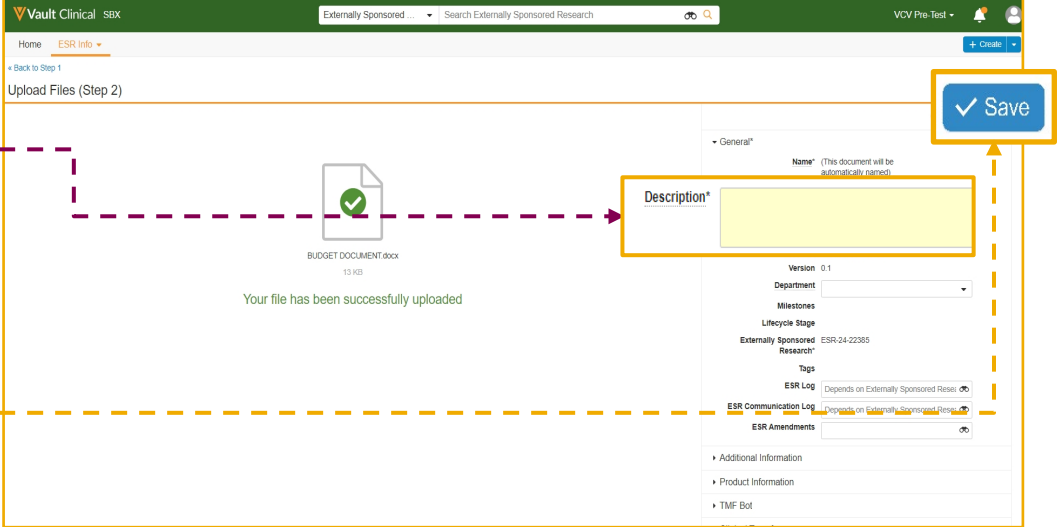
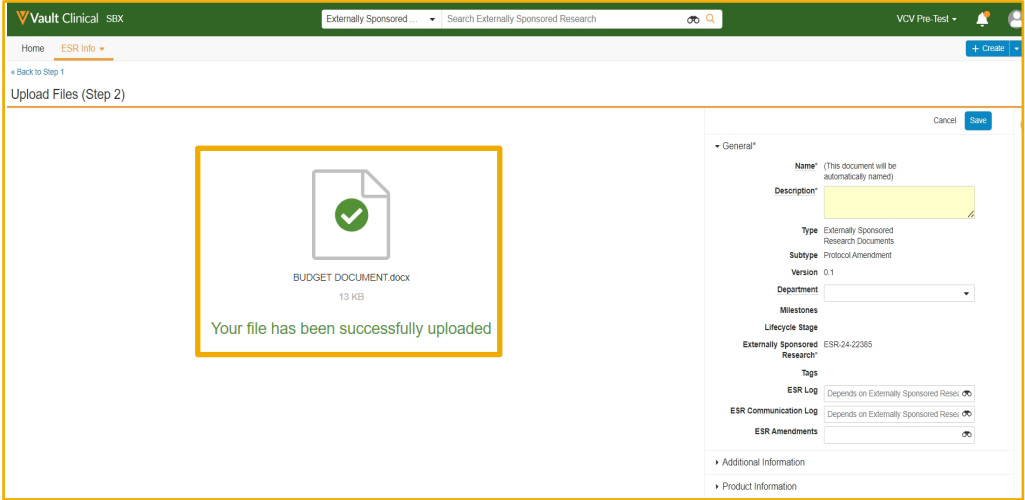


5

Please enter an appropriate **description**, including the document's **name** and **date**, if applicable.

6

Click **Save**



# VCV Walkthrough - How to upload a document

## Related Documents

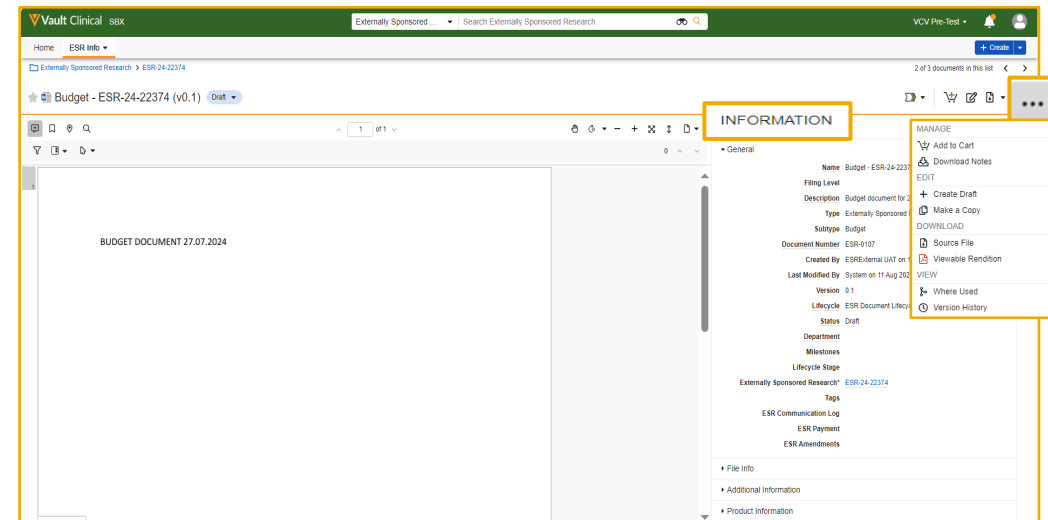
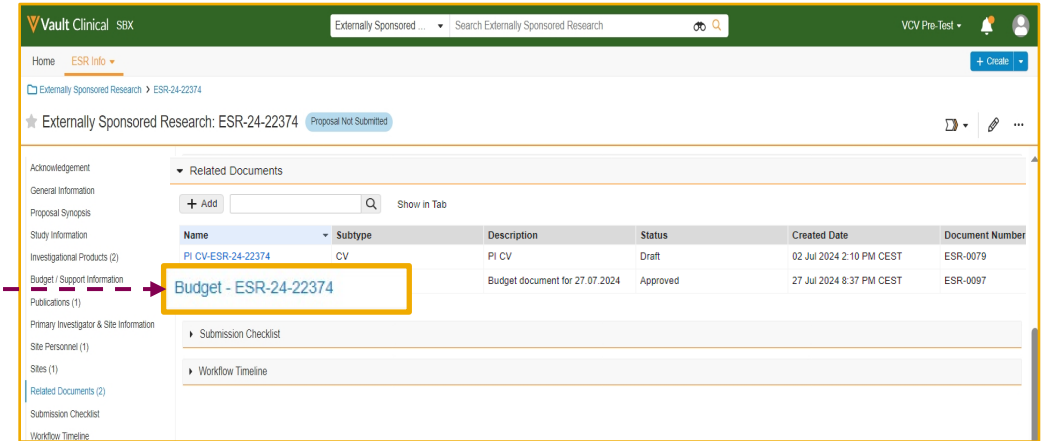
Added document appears in the **Related Documents** section.

7

Click the document **Name** to open the window with detailed record view, where further **actions** can be taken

From the record view all information related to a specific **document** is displayed in the right-hand panel.

Clicking **3 dots** icon top right will display a list of **actions** that can be performed for the document record.



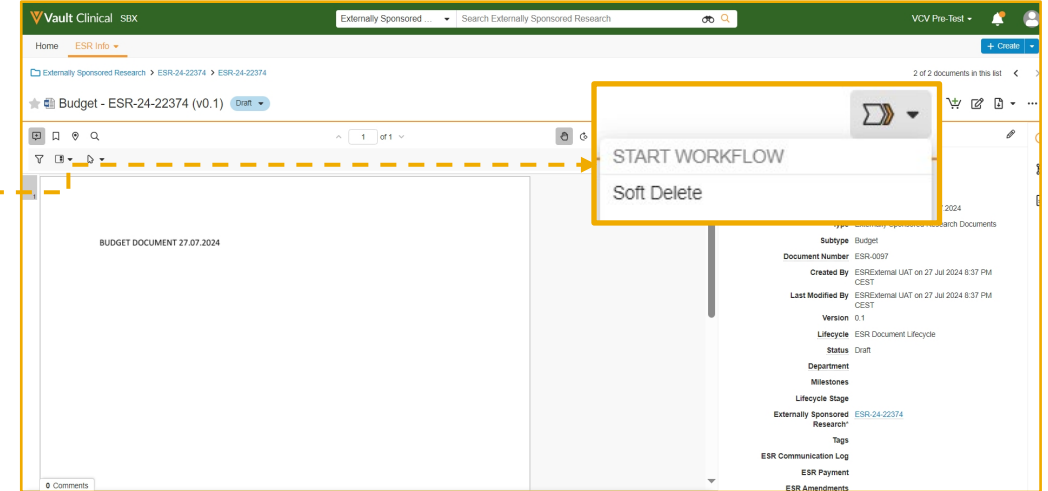
# VCV Walkthrough - How to upload a document

## Document Soft Delete

8

To delete a document, click on the **Workflow icon** and select **Soft Delete** from the drop-down menu

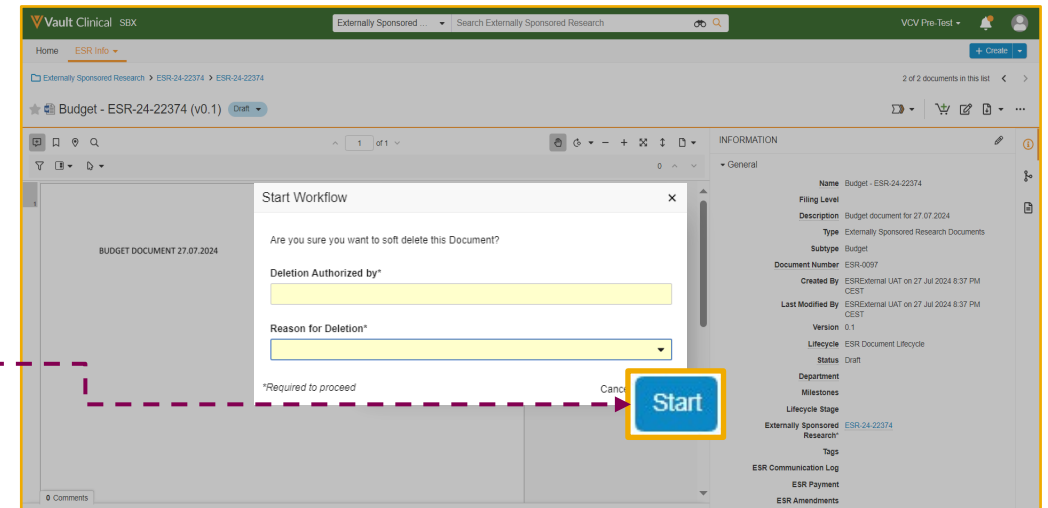
**Please note:** External users can **ONLY** delete their own drafts.



9

Complete the mandatory fields and click **Start**

A pop-up box appears:  
**Start Workflow.**





# VCV Walkthrough - How to upload a document

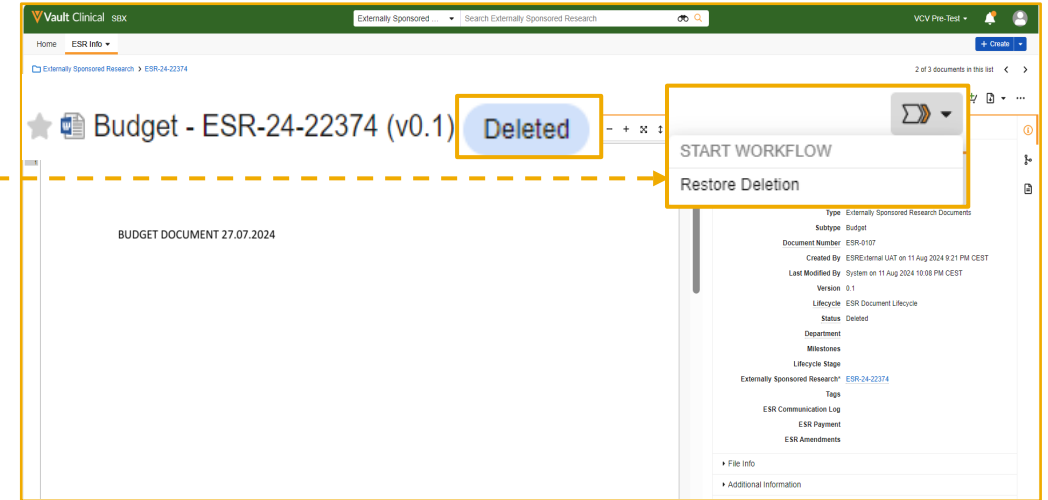
## Document Soft Delete

The document's record shows as Deleted.

After performing **Soft Delete**, the document remains under the Related Documents section. It is **not removed** from VCV and can be **restored** to its previous status.

10

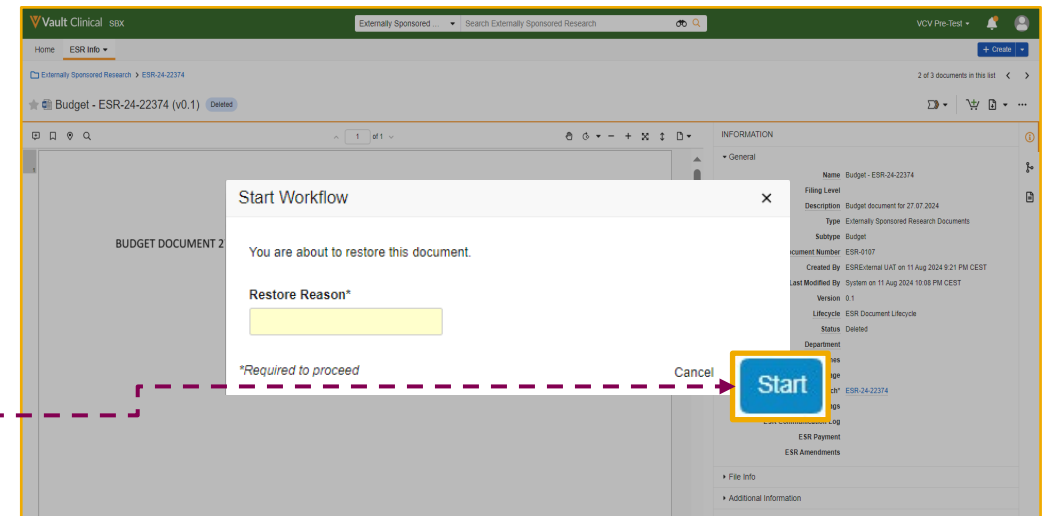
Click on the **Workflow icon** and select **Restore Deletion**



A pop-up box appears: Start Workflow.

11

Provide the **Restore Reason** and click **Start** to undo the document deletion and revert to its previous status



8

# 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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# VCV for ESR

Externally Sponsored Research



# Version History – How to create and manage an ESR study in VCV

Version	Date	Description of change	Author
0.1	13.06.2024	How to create and manage an ESR study in VCV	Paulina Kabaj
0.2	03.07.2024	How to create and manage an ESR study in VCV	Paulina Kabaj
0.3	05.07.2024	How to create and manage an ESR study in VCV	Paulina Kabaj
0.4	12.08.2024	How to create and manage an ESR study in VCV	Paulina Kabaj Maja Žuk

