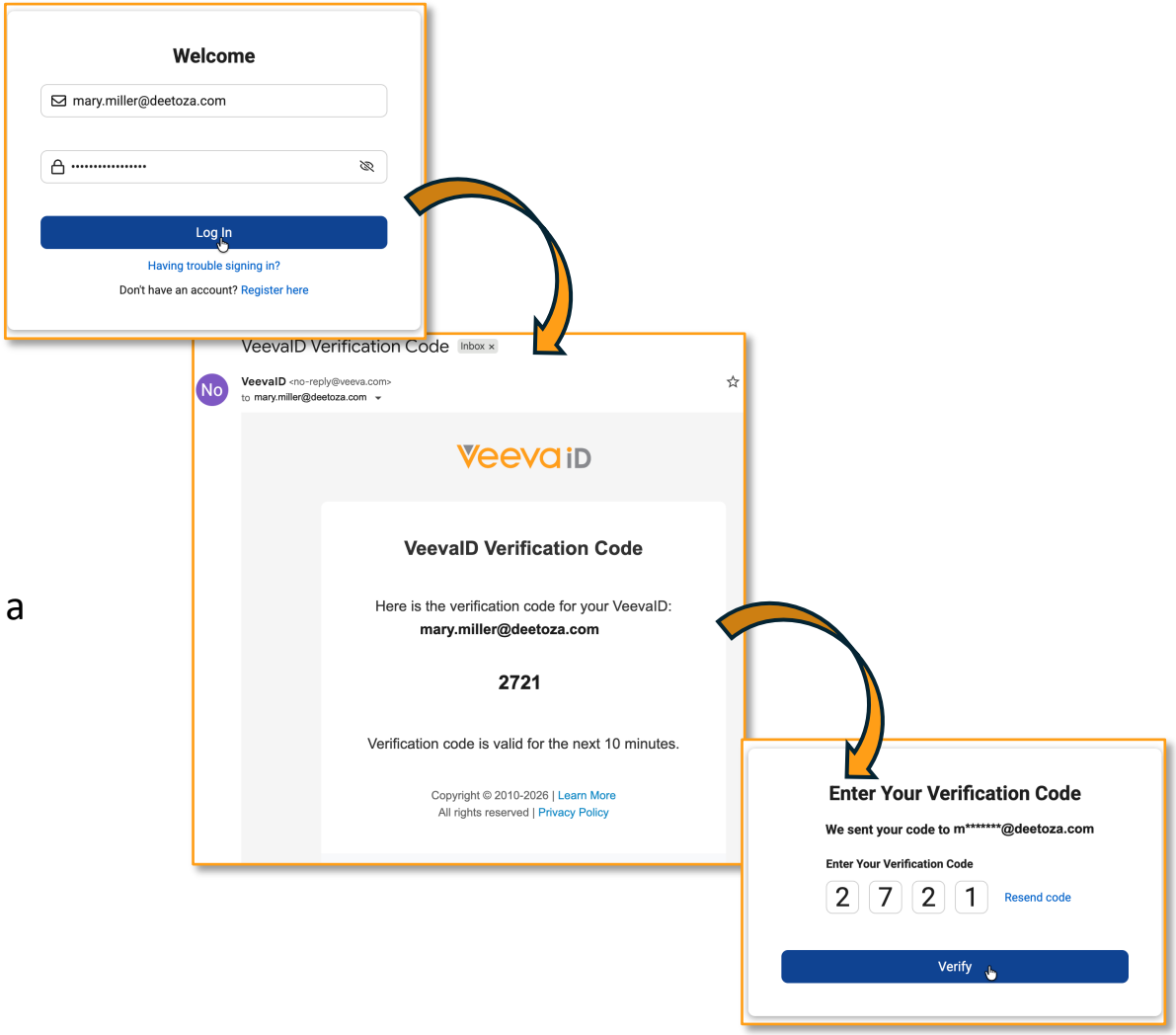
Veeva EDC
Quick Reference Guide

Site user manual

Veeva

Logging in to Veeva EDC

1. Navigate to the VeevaID portal (https://id.veeva.com/login) or to the vault URL shared by your sponsor.
2. (Optional) Select your preferred language from the dropdown.
3. Enter the **Email Address** and **Password** you specified during VeevaID registration.
4. Click **Log In**. The MFA verification page opens and the system sends a verification code to your email address.
5. Enter the 4-digit verification code and click **Verify**.



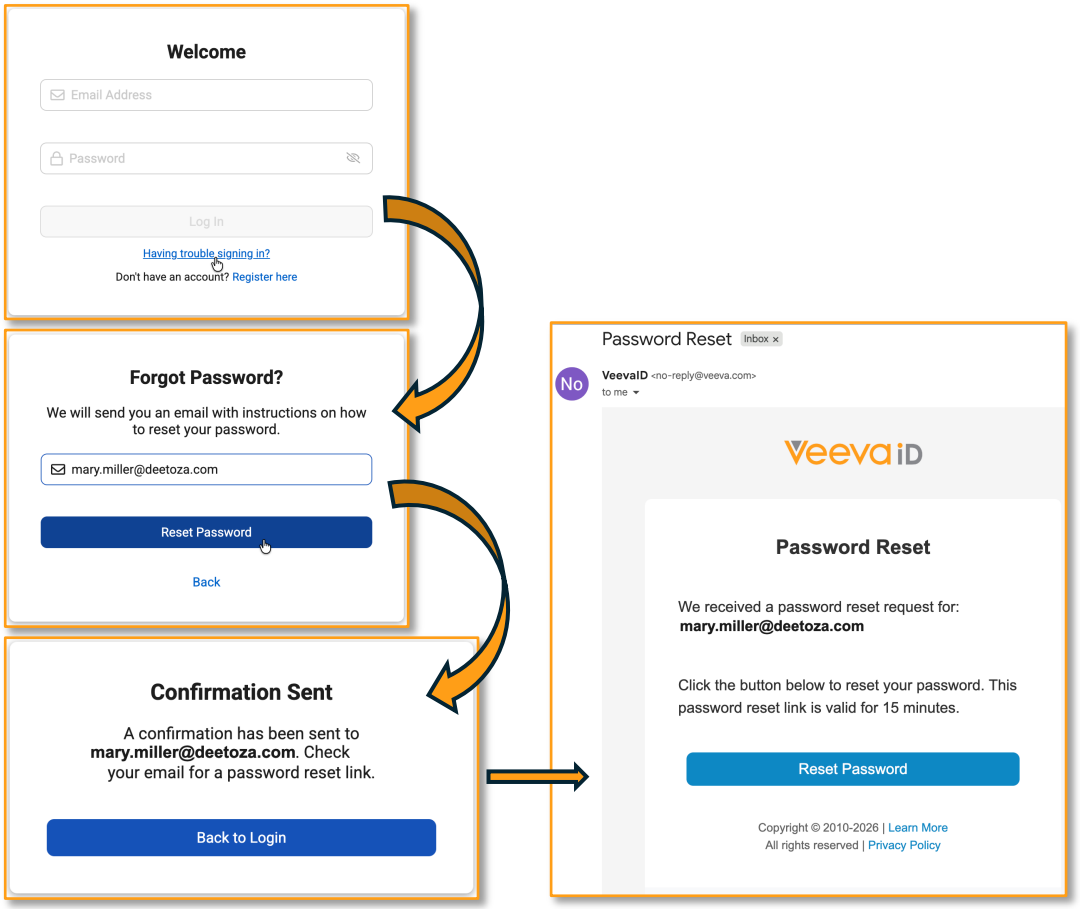
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Resolving Login Issues

If your login fails, we recommend you first attempt to reset your password.

To reset your password:

1. Click **Having trouble signing in?**
2. Enter the **Email Address** you specified during VeevaID registration.
3. Click **Reset Password**.
4. The system will send a confirmation email containing a password reset link to your email address.

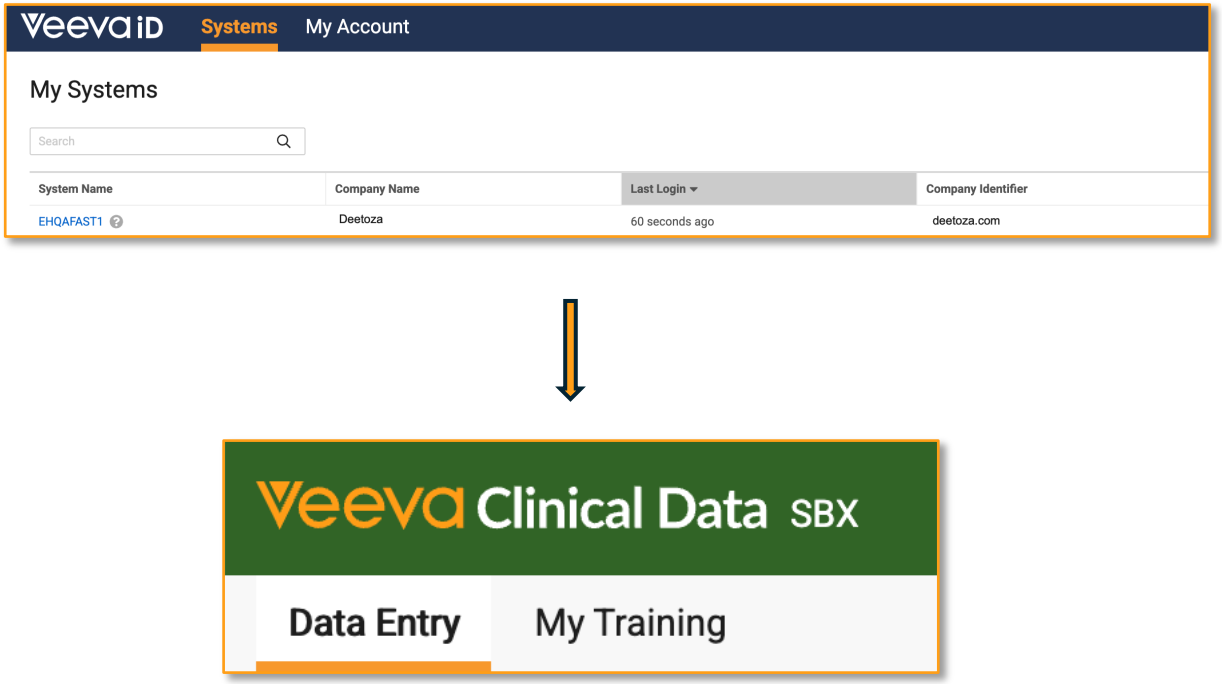


Tip: If your login continues to fail after password reset, we recommend you contact the Veeva Global Service center for assistance: https://www.veeva.com/services/gsc-contact/.

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Accessing a Study

1. (Optional, when logging in via the VeevaID portal) After logging in to your VeevaID portal, navigate to the **Systems** tab.
2. From the Systems tab, click the **System Name** for the sponsor of the study. If you have access to only one *Study*, the Veeva EDC **Data Entry** tab opens directly.
3. (Optional, if you have access to multiple studies) The *Study* list in the Veeva EDC **Data Entry** tab opens. Click the name of the **Study** you want to open.



Tip: If you have access to trials from multiple sponsors and the System Name is the same, check the Company Name or Company Identifier to identify which one you want to navigate to. If it is still not possible to determine which System Name to click, contact your sponsor to confirm.

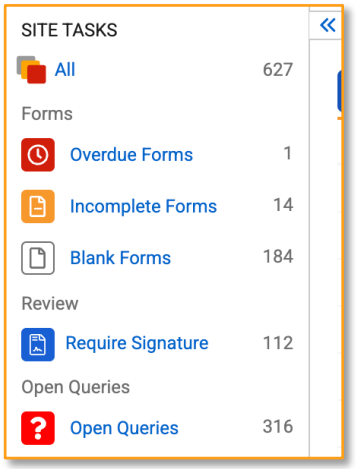
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Site Tasks – Task Types & Icons

The Site Tasks bar helps you quickly identify tasks requiring completion.

The task bar categorizes tasks into the following:

- **Forms**: Overdue *Forms*, incomplete *Forms*, and blank *Forms*
- **Review**: *Forms* that require signature
- **Queries**: Open queries that are ready for you to respond to



Icon	Status	Description
	Incomplete Form	Indicates in progress, incomplete *Forms*.
	Open Query	Indicates that a *Form* has at least one open query for your site to answer.
	Overdue Form	Indicates that a *Form* is overdue.
	Signature Required	Indicates that a submitted *Form* requires your signature.
	Blank	Indicates blank *Forms*.

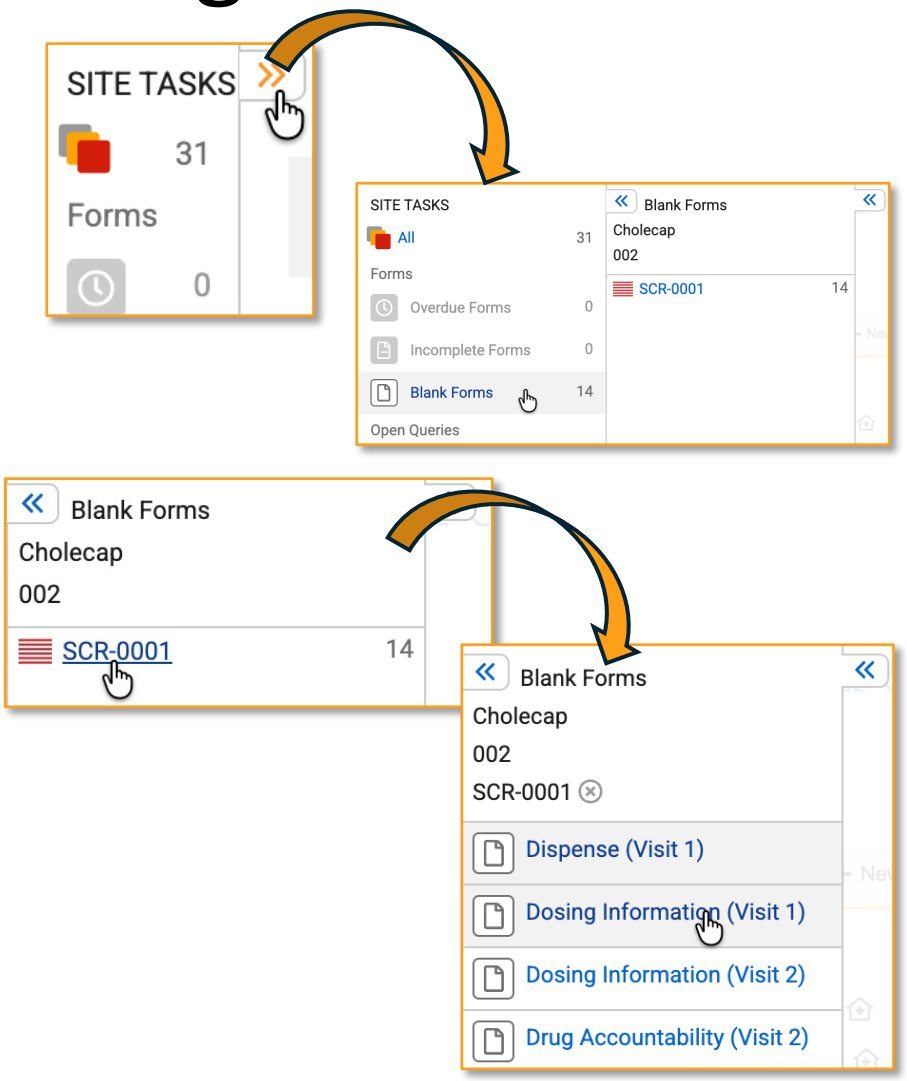
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Site Task Bar – Viewing Tasks

You can expand the Site Tasks bar to view more details about your tasks.

To view tasks on the Site Tasks bar:

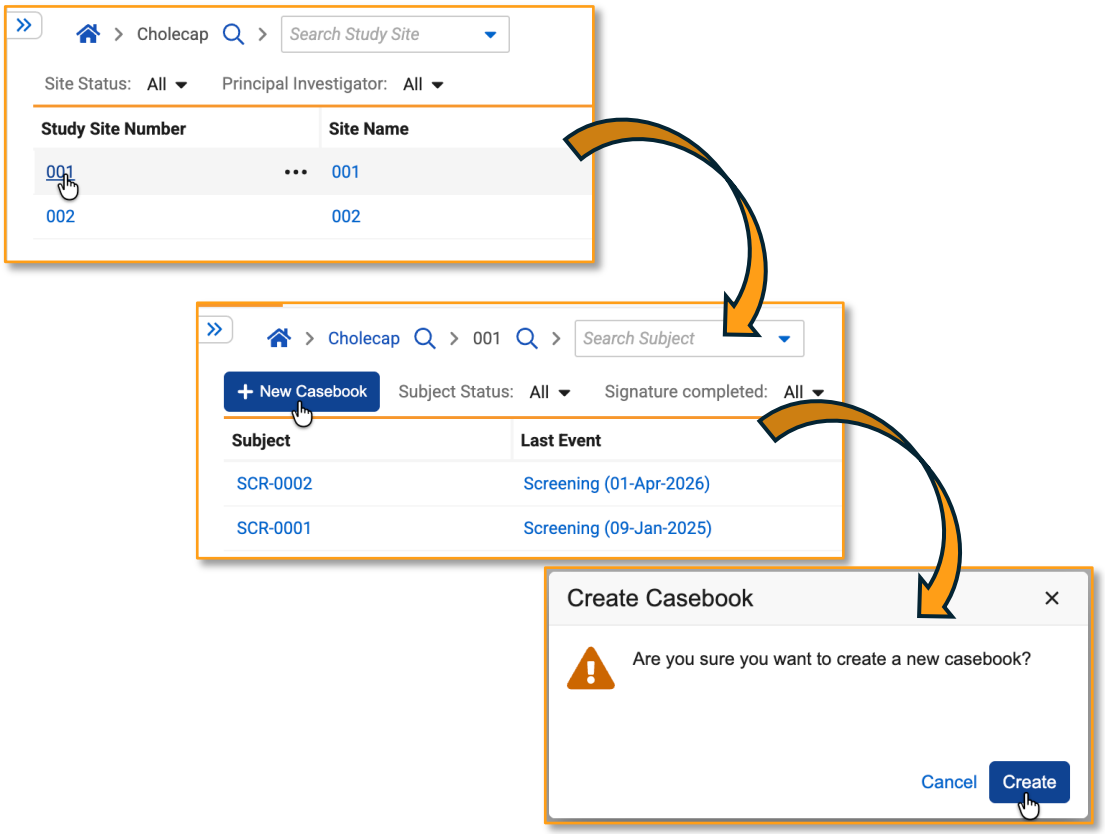
1. Click the **Arrow** tab on the task bar. The task bar expands.
2. Click on a task type. The task bar displays a list of all subjects with a task of that type with a task count for each subject.
3. Click on a subject to view all tasks of the selected type for that subject.
4. Click on a task. Vault opens the area in which you can complete the task.
5. Click the **Arrow** tab again to collapse the task bar.



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Casebooks - Creating a New Casebook

1. From the main page of the *Study* you are working in, click the **Study Site Number** or **Site Name** you want to create a Casebook in. The Casebook listing page opens.
2. Click the **+ New Casebook** button.
3. In the **Create Casebook** dialog, click **Create**.
4. The system creates the new *Casebook* record and opens it.

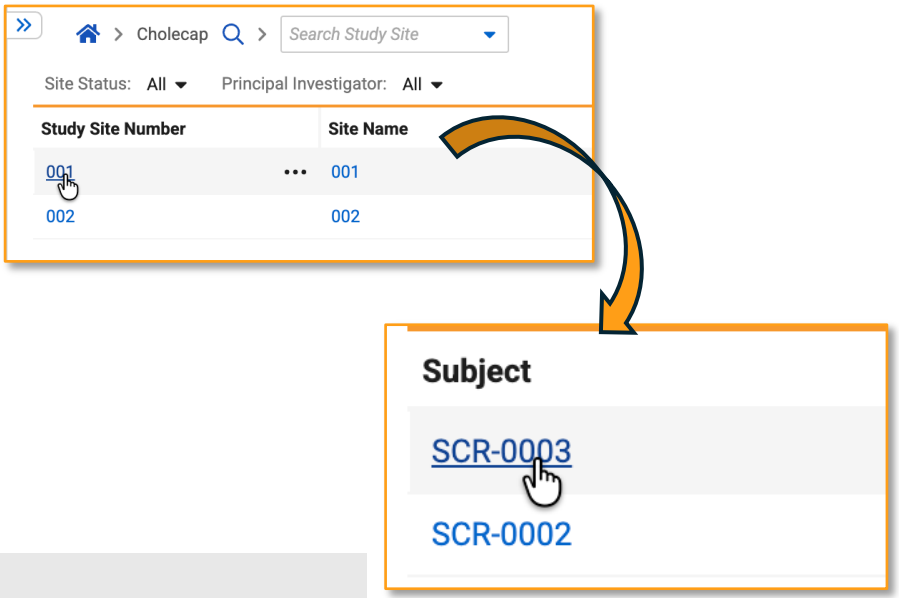


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Casebooks - Viewing a Casebook

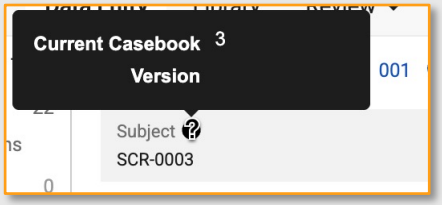
To open a Casebook:

1. From the main page of the *Study* you are working in, click the **Study Site Number** or **Site Name** the *Casebook* you want to view is in. The Casebook listing page opens.
2. Click the *Casebook* in the list to open it. The system opens the *Casebook*.
3. You can now sort the schedule, collapse and expand *Events*, and click into *Forms* to enter data.



Casebook Header

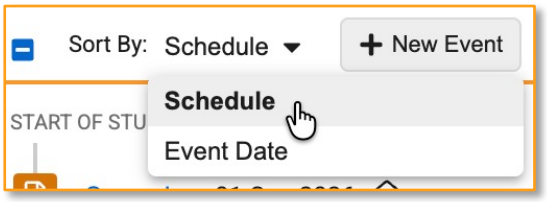
The *Casebook* header typically displays demographic information, like Subject ID, Date of Birth, Gender, Race, and Subject Initials. Fields that populate the header are configured during study design. Hover over the information icon next to the Subject ID to view the current casebook version.



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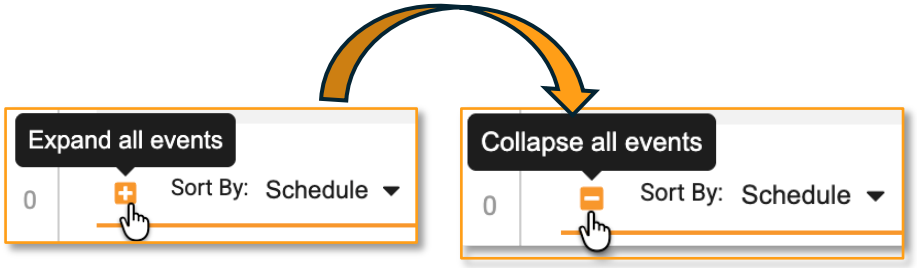
Casebooks - Sorting Events

You can sort the *Events* in the casebook schedule by the *Planned* (from the Study definition) or actual *Event* (user-entered) date. No matter which sorting method you use, the *Event* or *Planned Date* display along with the *Event* in the same manner.



To sort *Events* in a Casebook:

1. From the Casebook's Schedule Header, click to open the **Sort By** dropdown and then select the desired sort order.
2. The system displays the Events in the Casebook according to the selected sort order.
3. (Optional) You can expand or collapse *Events* from the Schedule Header.



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Events - Event Types & Status Icons

There are 3 types of *Events*:

- **Scheduled Events**: Visits scheduled in the study schedule.
- **Unscheduled Events**: Visits that are added outside the study schedule.
- **Common Events**: *Forms* collected outside of a scheduled visit, such including log *Forms* that accept repeated *Forms* throughout the study, such as Adverse Event *Forms*.

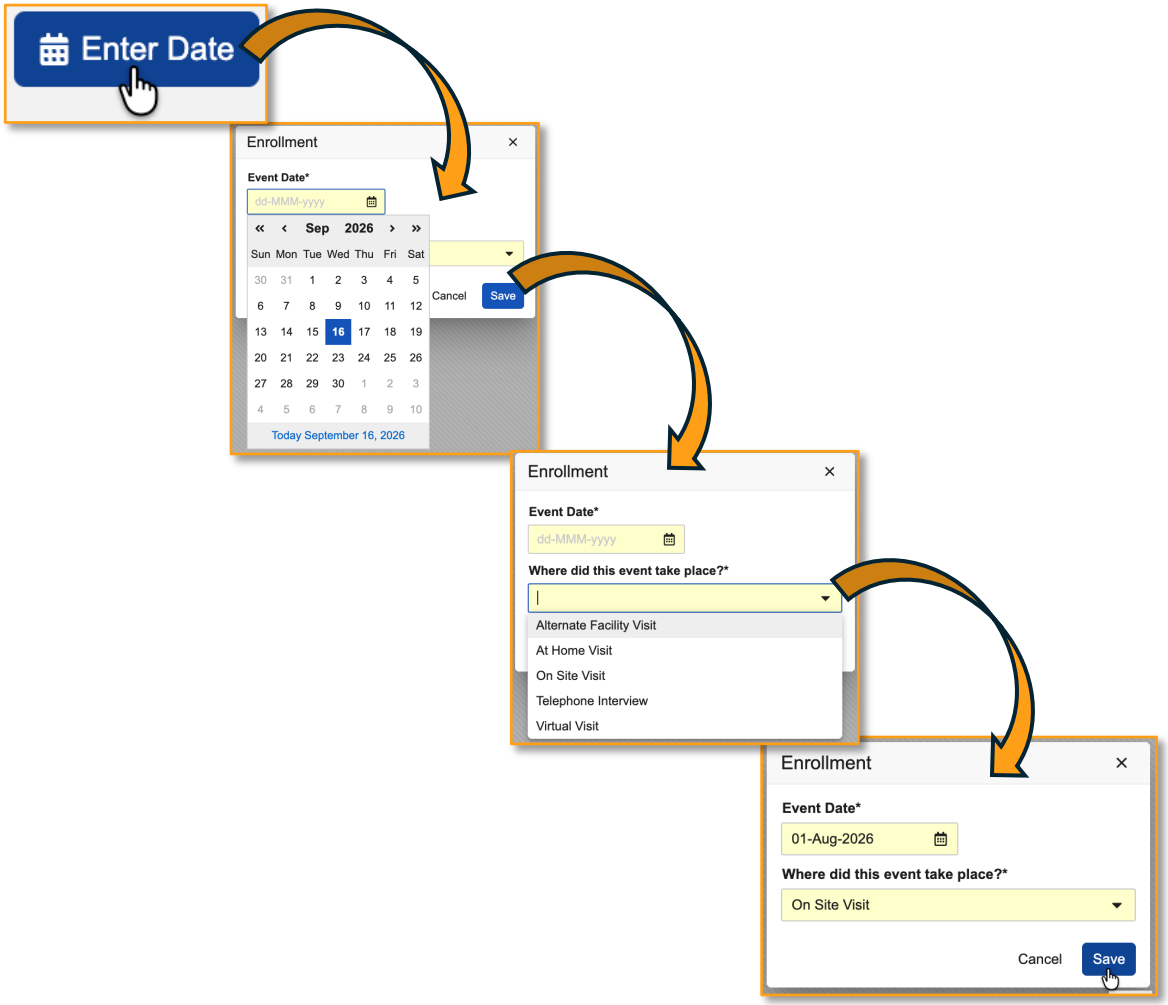
Icon	Status
	Blank
	Did Not Occur
	In Progress
	Submitted
	Planned
	Overdue
	Signed
	Locked
	Frozen
	Marked for Removal
	Open Query
	Answered

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Events - Adding Scheduled Events

To activate a scheduled *Event*:

1. Navigate to the *Casebook* you want to create an Event in.
2. Click **Enter Date**. The *Event* dialog opens.
3. Enter the **Event Date**.
4. (Optional) If your study uses *Visit Method*, select an option for the **Where did this event take place?** Dropdown.
5. Click **Save**. The *Event* is created and *Forms* are automatically added.

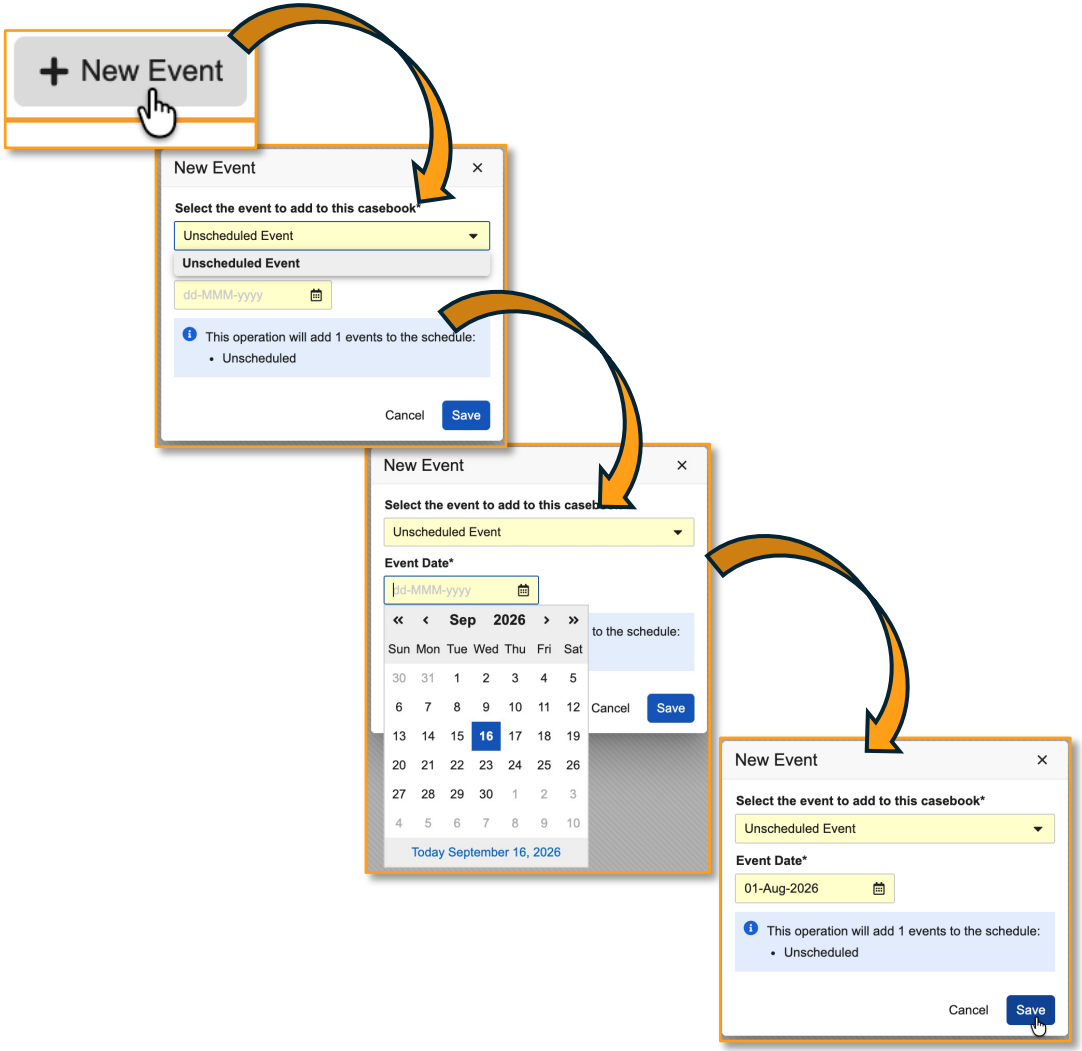


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Events - Adding Unscheduled Events

To add an unscheduled *Event*:

1. Navigate to the *Casebook* you want to create an Event in.
2. Click **+ New Event**. The **New Event** dialog opens.
3. **Select the event to add to this casebook** in the dropdown.
4. Enter the **Event Date**.
5. Click **Save**. The unscheduled *Event* is created and *Forms* are automatically added.



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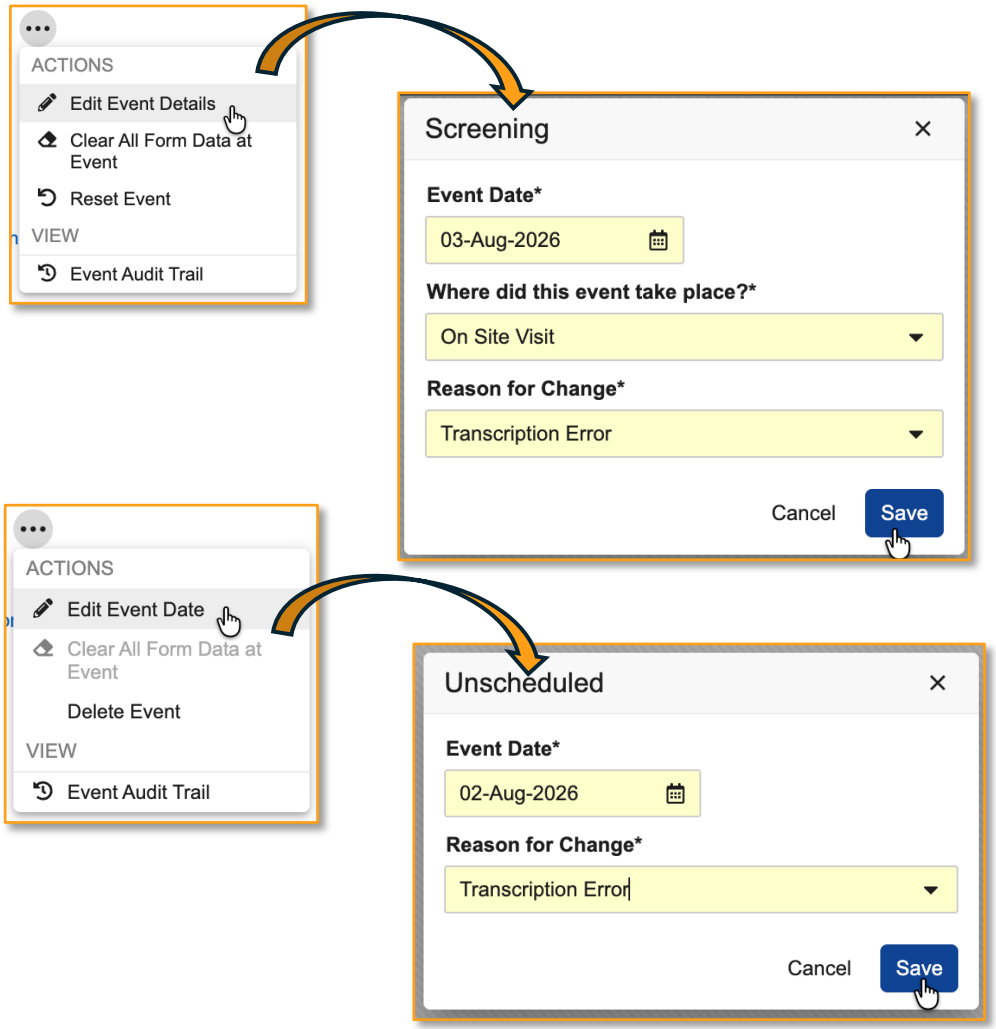
Events - Editing Events

You can edit certain details for scheduled and unscheduled *Events*.
To edit the details of scheduled *Events* with a visit method:

1. From the **Actions (⋯)** menu of the Event, click **Edit Event Details**.
2. Enter the new **Event Date** or select a different visit method.
3. Select a **Reason for Change**.
4. Click **Save**.

To edit the date of unscheduled *Events* or scheduled *Events* without a visit method:

1. From the **Actions (⋯)** menu of the Event, click **Edit Event Date**.
2. Enter the new **Event Date**.
3. Select a **Reason for Change**.
4. Click **Save**.



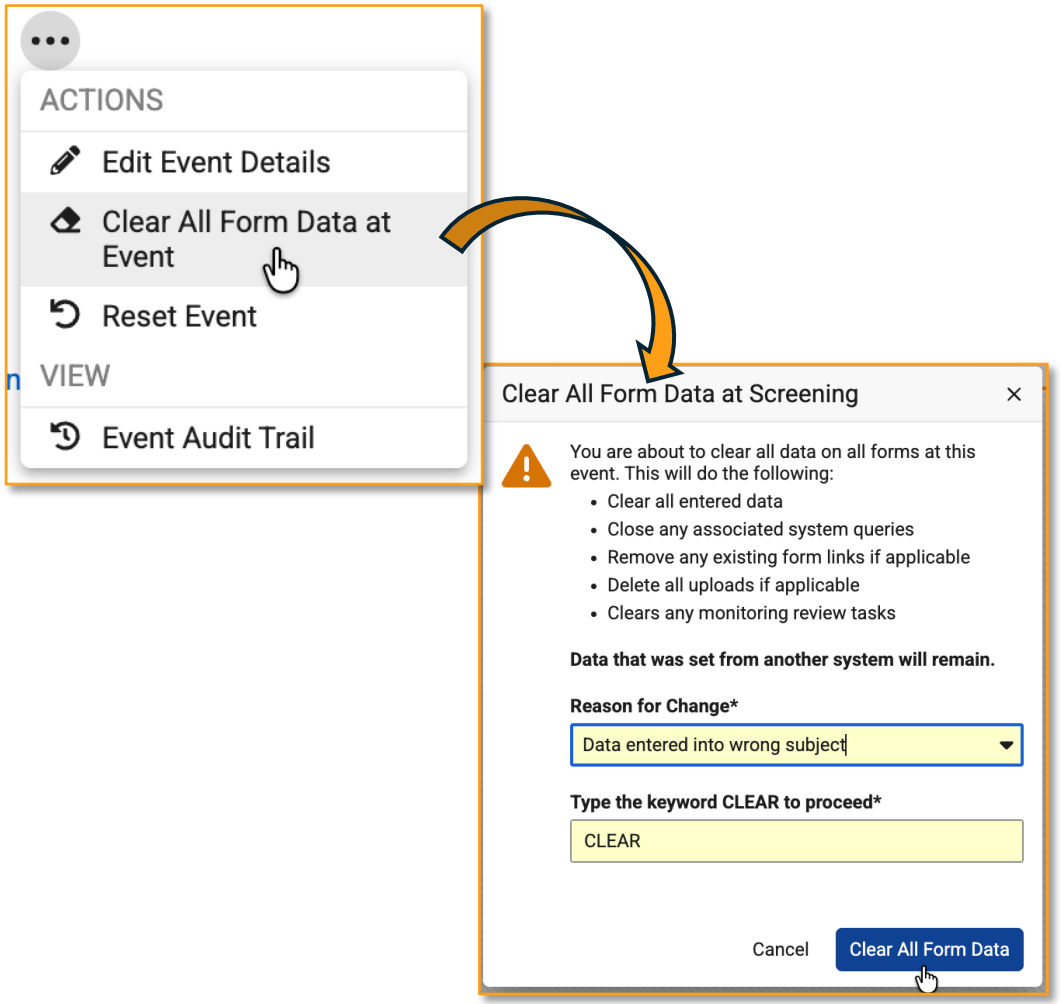
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Events – Clearing Form Data

Clearing form data on an *Event* deletes all entered data, including third party data, closes associated system queries, deletes any Form Links and uploads, and clears any monitoring review tasks. If your *Form* contains third-party data, you must first clear data before you can reset the *Event*.

To clear form data from an *Event*:

1. From the **Actions (⋯)** menu of the Event, click **Clear All Form Data at Event**.
2. In the **Clear All Form Data at [Event]** dialog, select a **Reason for Change**.
3. Type the word **CLEAR** in the keyword text field.
4. Click **Clear**. The system removes all data from the *Event*.

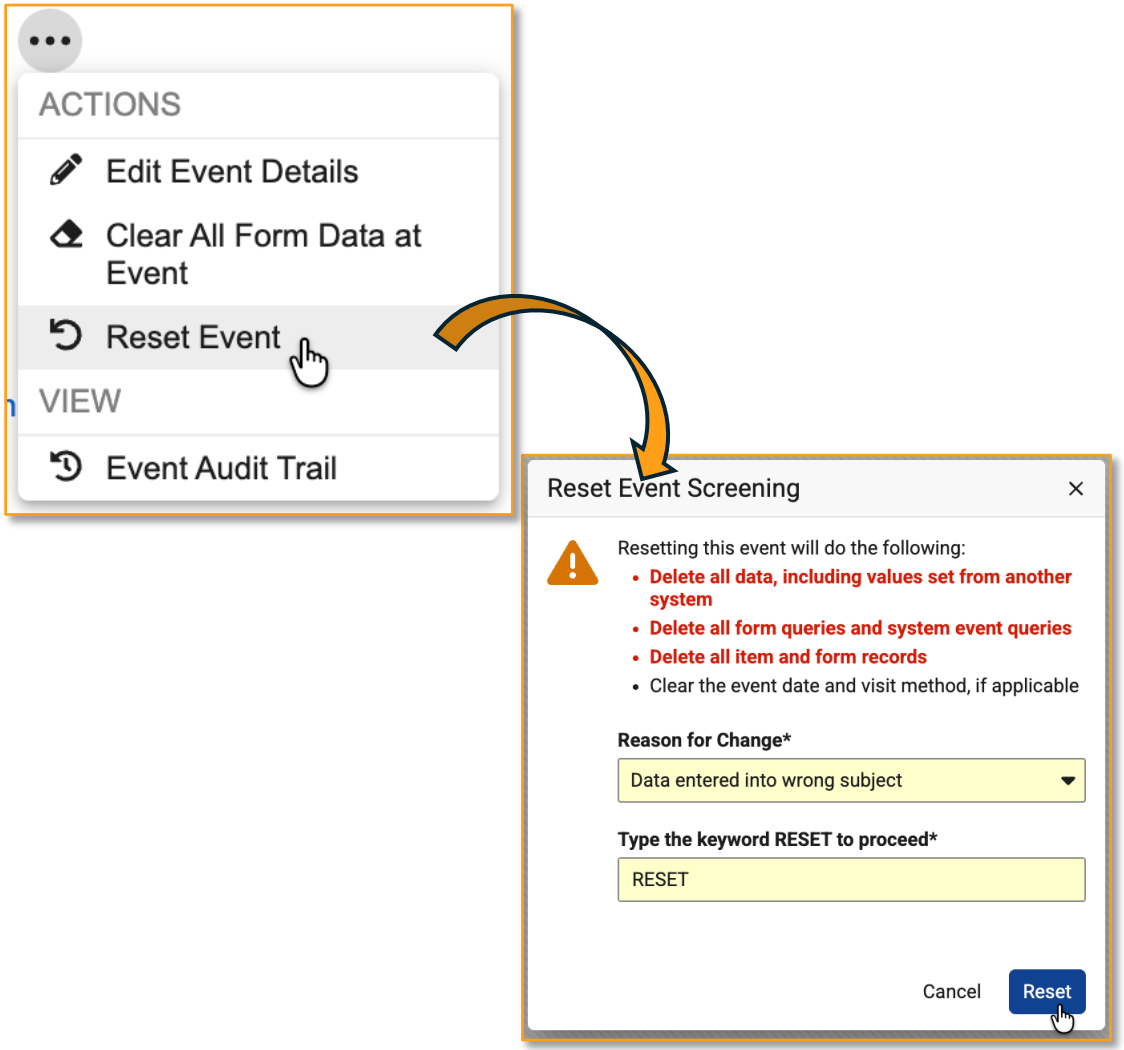


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Events - Resetting Events

Resetting an *Event* deletes all data, *Form* and system *Event* queries, and all *Forms* and *Items* associated with the *Event*. To reset an *Event*:

1. From the **Actions (•••)** menu, click **Reset Event**. The **Reset Event** dialog opens.
2. Select a **Reason for Change**.
3. Type the word **RESET** in the keyword text field.
4. Click **Reset**. The system removes all data from the *Event*.



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Forms - Form Status Icons

Icon	Status
	Blank
	Empty Repeating Form
	Intentionally Left Blank
	In Progress
	In Edit
	Frozen
	Locked
	Marked For Removal

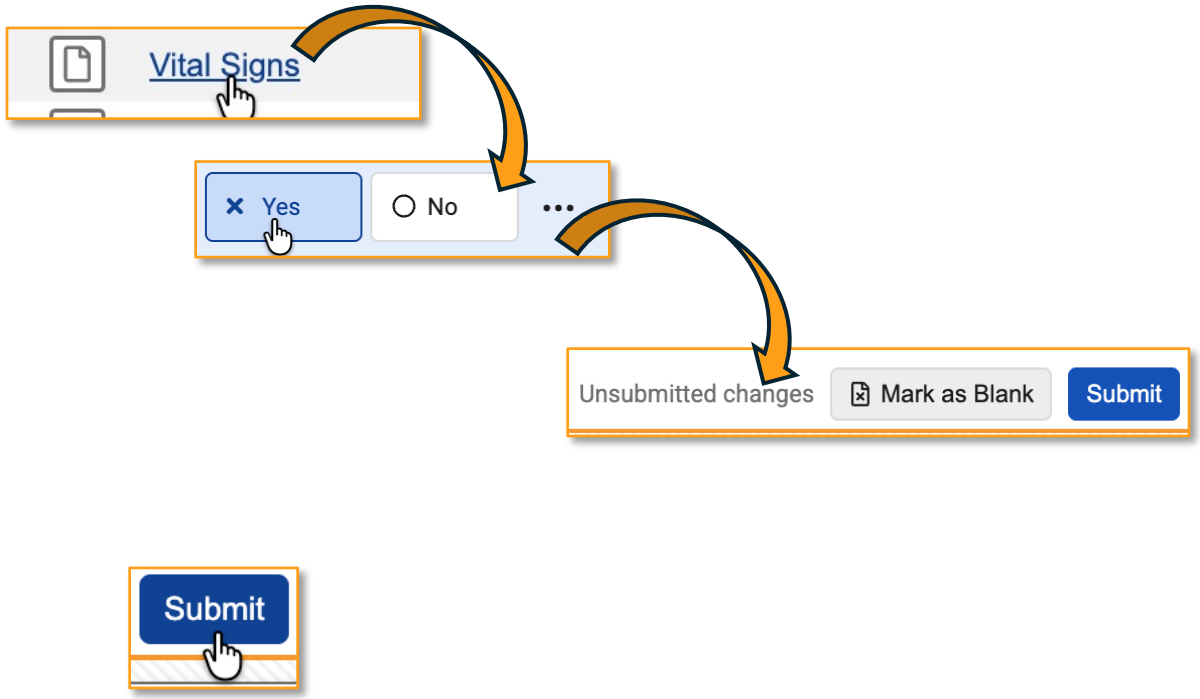
Icon	Status
	Overdue
	Planned
	Signed
	Submitted
	Open Query
	Answered Query
	Data Changed

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Entering and Submitting Data

The system autosaves the data you enter in real time, while you enter it. To fill and submit a *Form*:

1. Navigate to the *Form* within the subject's casebook.
2. Click the **Form** to open it.
3. Enter data in the *Form's* fields. The system automatically saves your changes and displays **Unsubmitted changes** in the header.
4. (Optional) Mark *Items* you did not collect data for as *Intentionally Left Blank*.
5. When finished entering data, click **Submit**. Any further changes to *Form* data will require moving the *Form* into In Edit status and providing a change reason.



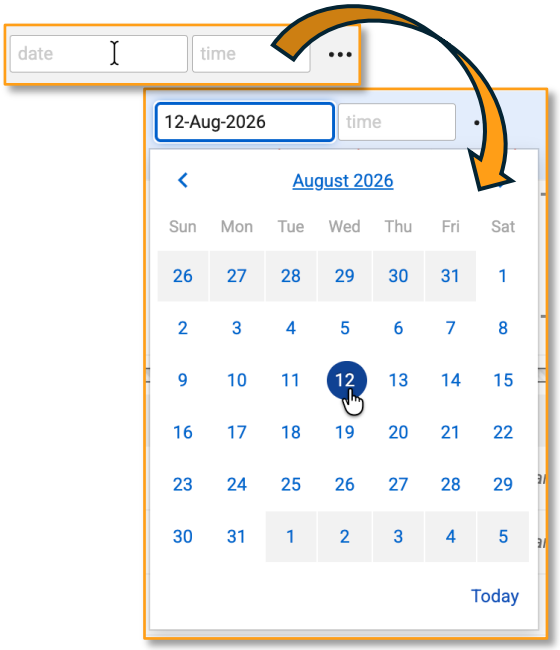
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Entering Data – Using the Calendar

You can use the Calendar to select dates for Date and Datetime *Items*.

To enter dates using the Calendar:

1. Click the **Date** field on the *Item*. The Calendar opens.
2. Select the date and click it. Click **Today** if you want to enter the current date.
3. (If the *Item* is a Datetime *Item*) Enter the **Time**.



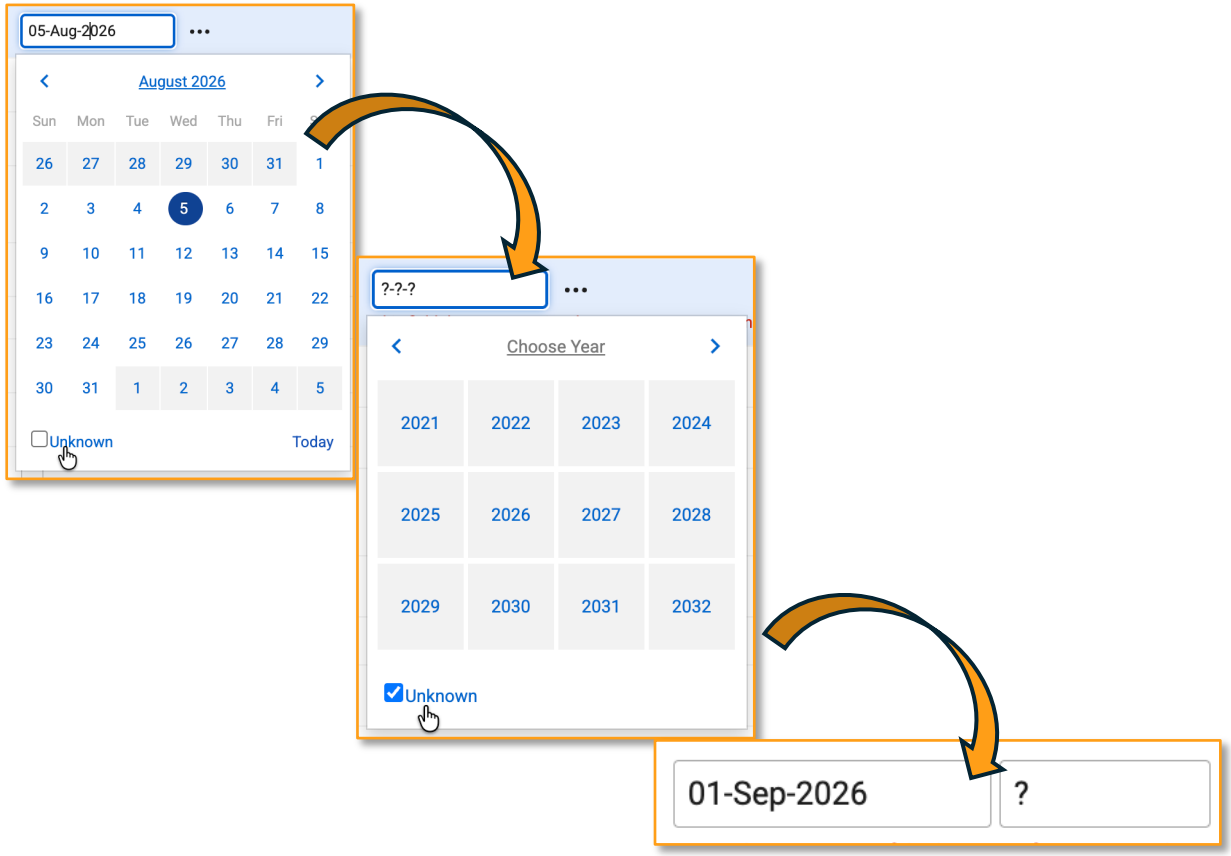
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Entering Data – Entering Unknown Dates

Depending on your *Study's* design, you may be able to mark dates (either the month and day or only the day) and times as unknown.

To enter unknown dates:

1. Click the **Date** field on the *Item*. The Calendar opens.
2. Select the **Unknown** checkbox instead of a date in the calendar.
3. (For Datetime and Time *Items*) To mark a time as Unknown, enter a single "?" (question mark) or "UN:UN" in the **Time** field.



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Entering Data – Adding & Editing Form Links

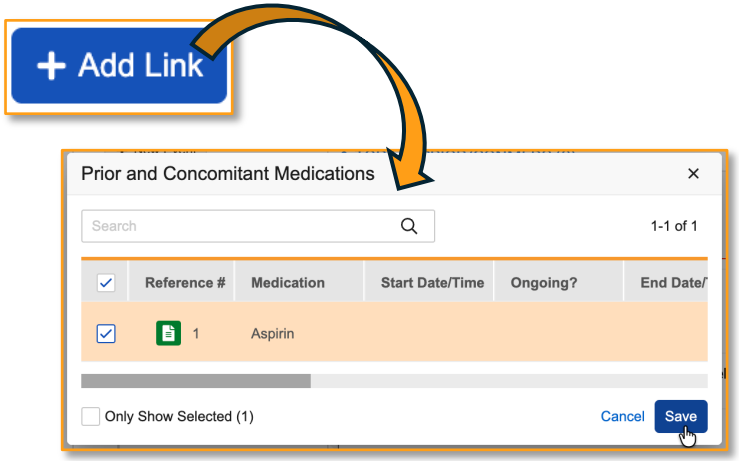
Form Links let you link to other related *Forms* through a jump link.

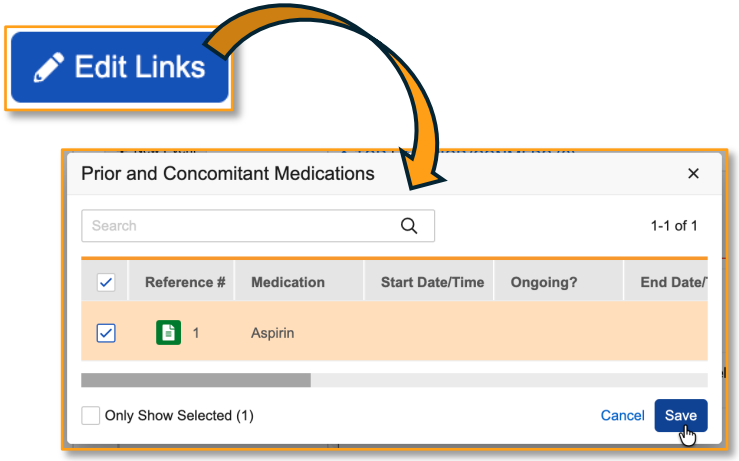
To add a Form Link:

1. Navigate to the *Form* containing the Form Link you want to add.
2. Click the **+ Add Link** button.
3. Select the *Form* you want to link, and click **Save**.

To edit a Form Link:

1. Navigate to the *Form* containing the Form Link you want to edit.
2. Click the **Edit Links** button.
3. Select the *Form* you want to link, and click **Save**.





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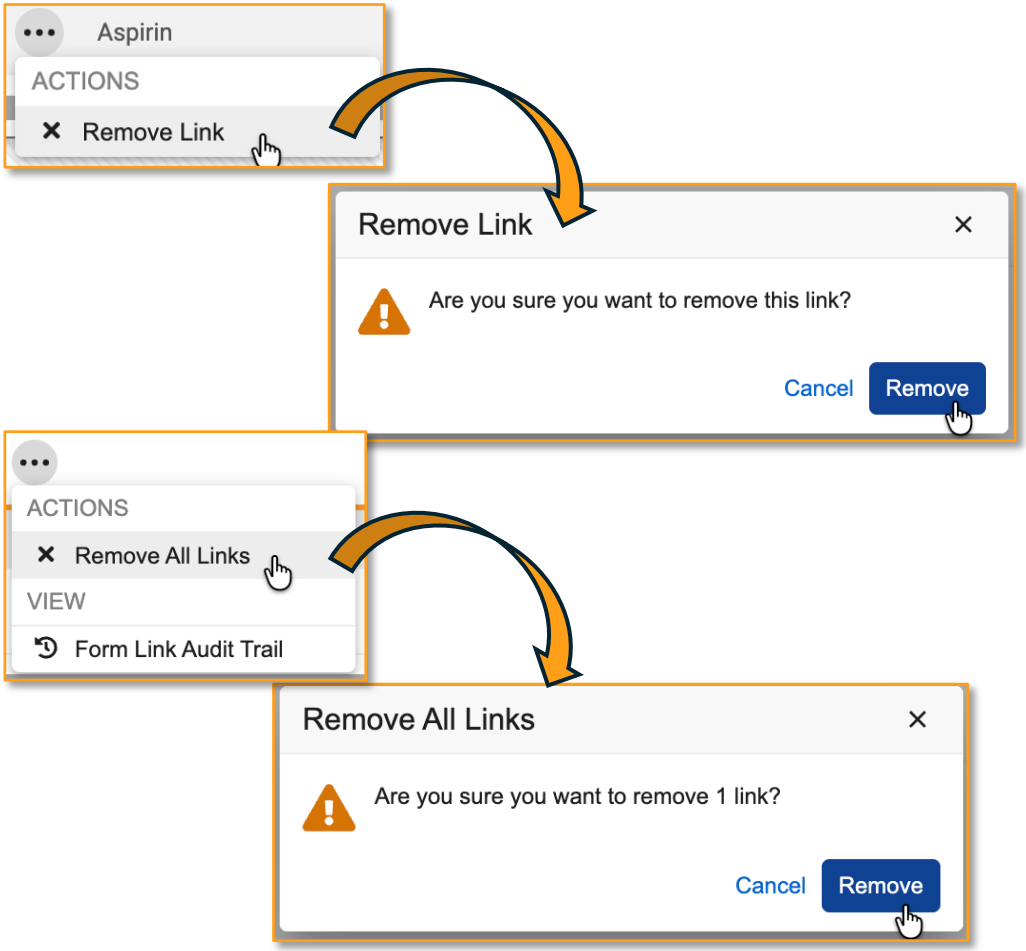
Entering Data – Removing Form Links

To remove a single Form Link:

1. Navigate to the *Form* containing the Form Link you want to edit.
2. In the Form Link *Item*, hover over the *Form's* **Reference #** to display the **Actions** menu.
3. From the **Actions** menu, select **Remove Link**.
4. In the **Remove Link** confirmation dialog, click **Remove**.

To remove all Form Links:

1. Navigate to the *Form* containing the Form Link you want to edit.
2. From the Form Link *Item's* **Actions** menu, select **Remove All Links**.
3. In the **Remove All Links** dialog, click **Remove**.



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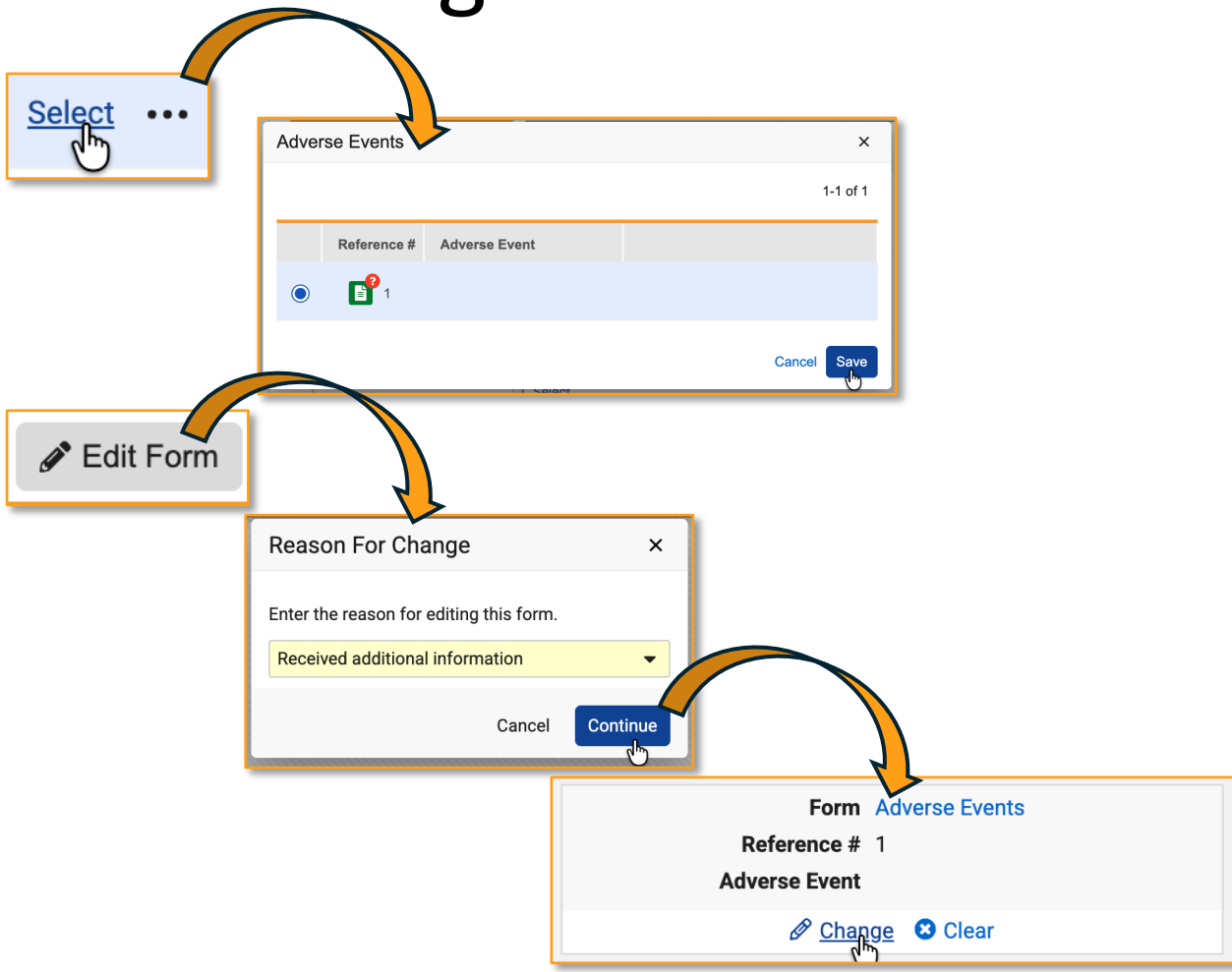
Entering Data – Item Linking

To add an Item-to-Form Link:

1. In the linked *Item*, click **Select**.
2. Select the *Form* to add.
3. Click **Save**.

To edit an Item-to-Form Link:

1. Move the *Form* into Edit mode by clicking **Edit Form** on the upper right of the *Form*.
2. In the **Reason for Change** Dialog, select a reason for editing the *Form*
3. Click **Continue**.
4. In the linked *Item* click **Change**.
5. (Optional) To remove the linked *Item*, click **Clear**.



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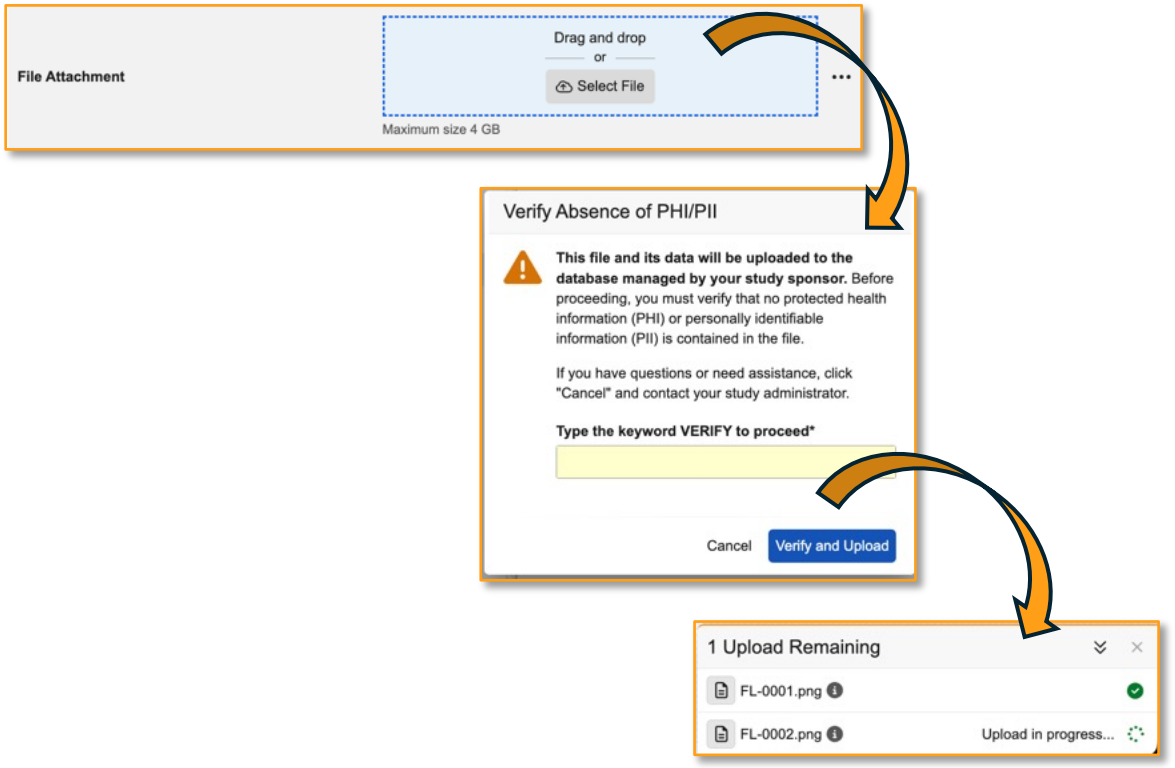
Entering Data – File Attachments

File Attachment Items allow you to upload and download files to a Casebook.

To upload a file attachment:

1. Click **Select File** and browse to select your file. For *Items* that are not displayed in a grid format, you can also drag the file to the **Drag and drop** area.
2. In the **Verify Absence of PHI/PII** dialog, type **VERIFY**.
3. Click **Verify and Upload**.

The system begins uploading the File Attachment to the *Form.* The system also displays an upload drawer that tracks the progress of the file attachment upload.

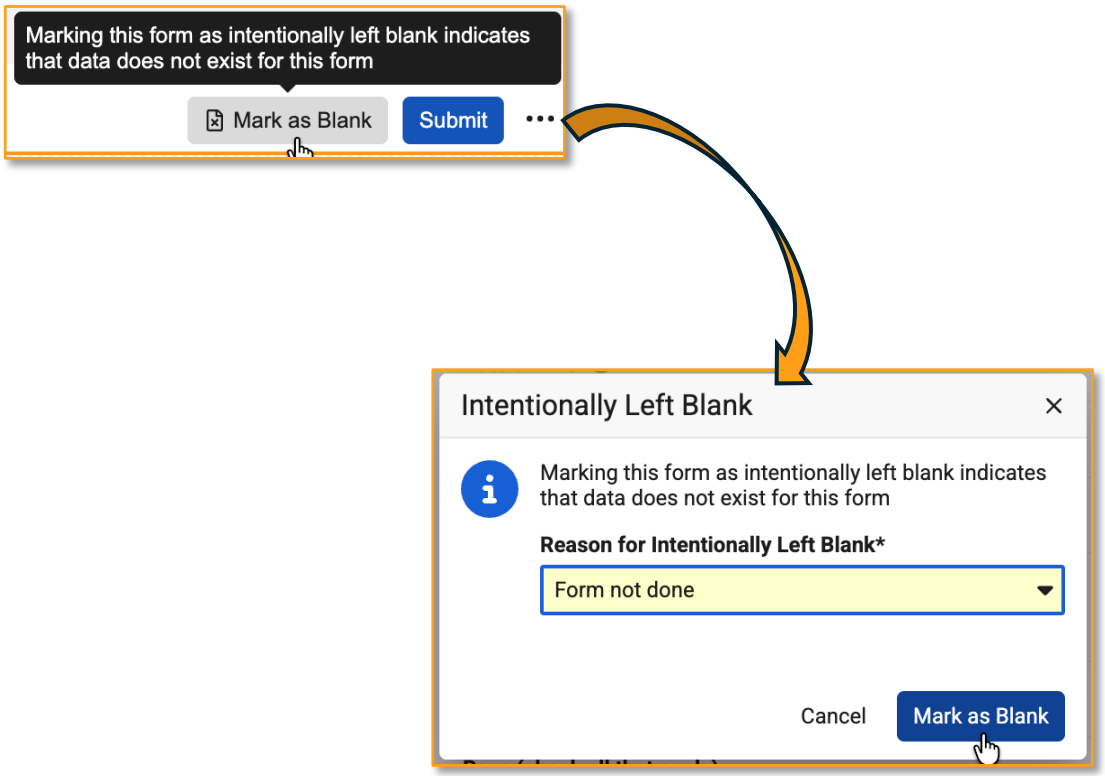


Review File Attachments for PHI/PII: Thoroughly review all files to verify that they do not contain any PHI/PII. If a file contains PHI/PII, do not upload the file and follow your organization's processes for deidentifying the file.

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Entering Data – Marking a Form as ILB

You can mark *Forms* and individual *Items* as *Intentionally Left Blank* to let the sponsor know that the data wasn't collected and why. To mark a *Form* as *Intentionally Left Blank*:



1. Navigate to the *Form* you want to mark as ILB.
2. Click the **Mark as Blank** button on the top righthand corner of the *Form*.
3. In the **Intentionally Left Blank** dialog, select a reason why the data wasn't collected.
4. Click **Mark as Blank**.

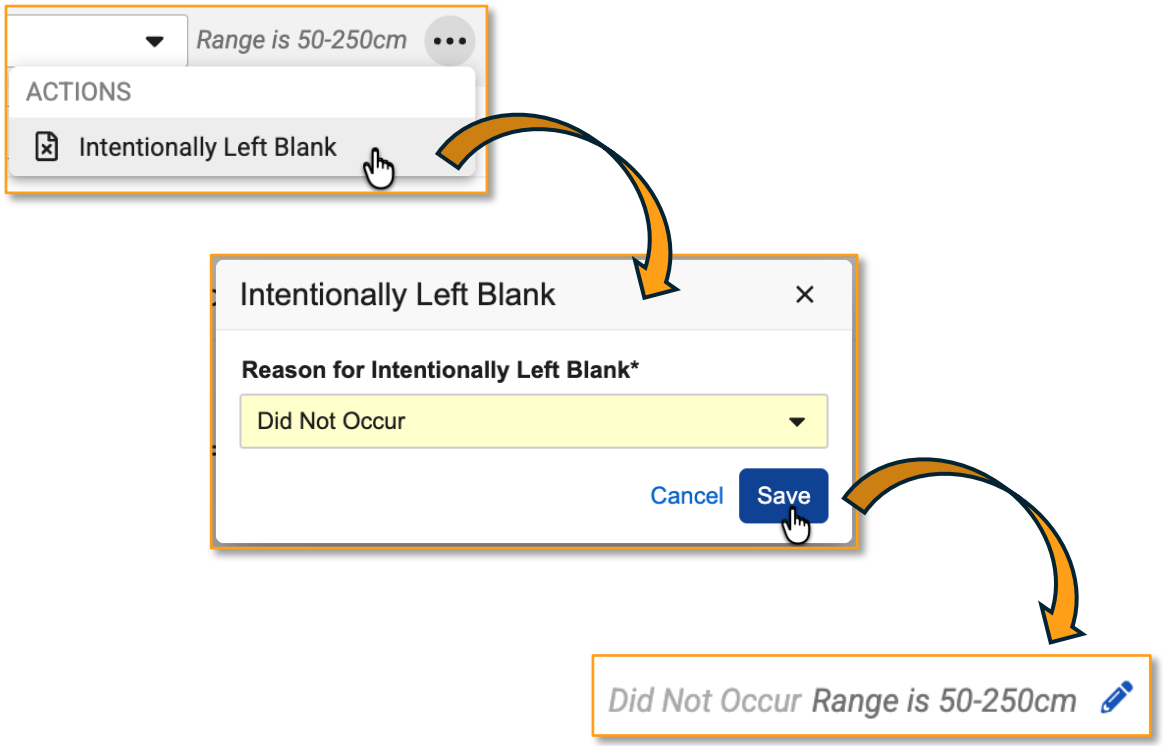
The system marks the *Form* as ILB and displays the ILB icon ( ) next to the *Form* in the *Casebook* schedule.

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Entering Data – Marking an Item as ILB

You can mark *Forms* and individual *Items* as *Intentionally Left Blank* to let the sponsor know that the data wasn't collected and why. To mark an *Item* as *Intentionally Left Blank*:

1. Navigate to the *Form* containing the *Item* you want to mark as ILB.
2. In the **Actions** menu to the right of the Item, click **Intentionally Left Blank**.
3. In the **Intentionally Left Blank** dialog, select a reason why the data wasn't collected.
4. (When marking an Item on a submitted *Form* as ILB) Select a **Reason for Change**.
5. Click **Save**. The system marks the *Item* as *Did Not Occur*.



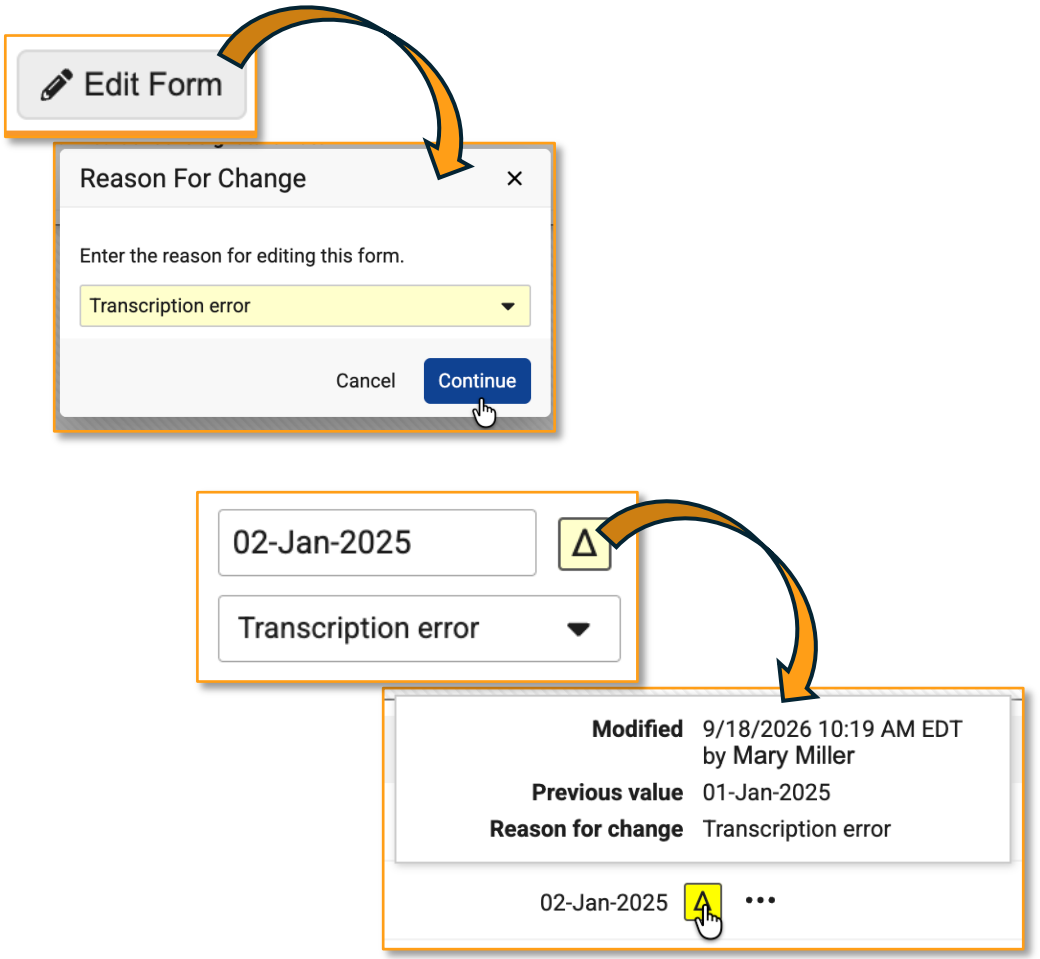
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Editing Data - Editing a Form

To edit a submitted *Form*:

1. Navigate to the *Form* within the casebook.
2. Click the **Form** to open it.
3. Click **Edit Form**.
4. In the **Reason for Change** dialog, select a **Reason for Change**.
5. Click **Continue**.
6. Make your changes. The selected Reason for Change is displayed in a dropdown under edited *Items*.
7. When finished making changes to *Items*, click **Submit**.

The **Data Changed** icon displays on any *Items* that you edited. Hover over this icon to view the *Reason for Change*.

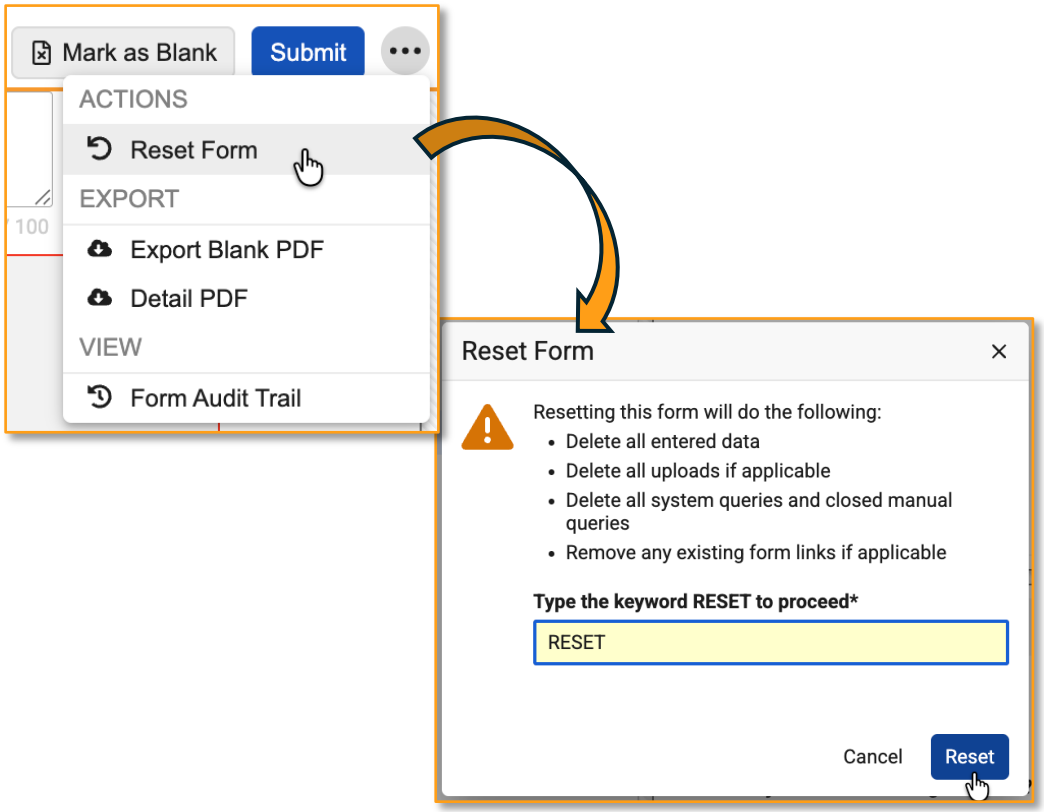


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Editing Data - Resetting a Form

Resetting a *Form* removes all entered data, closes any open system queries, and returns the *Form* to the *Blank* status. Manual queries that are in *Closed* status are deleted, but manual queries that are in *Open* or *Answered* status remain *Open* or *Answered*. The form must be in Edit mode to reset it.
To reset a *Form*:

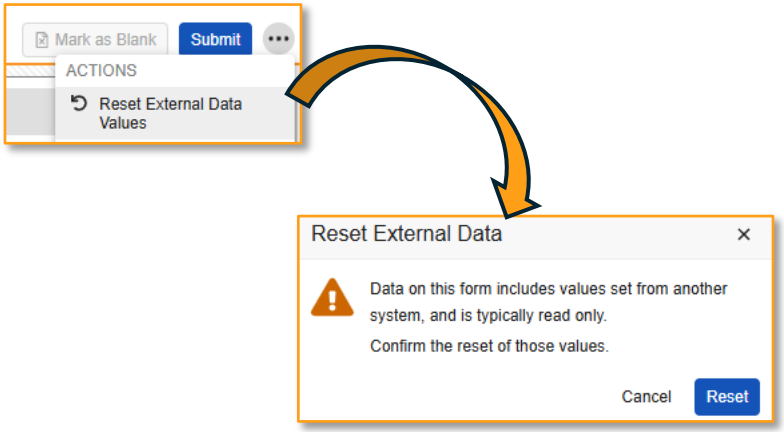
1. Navigate to the *Form* within the *Casebook*.
2. (For submitted *Forms*) Click **Edit**.
3. From the **Actions** menu, select **Reset Form**.
4. In the **Reset Form** confirmation dialog, type **RESET**.
5. Click **Reset**.



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Editing Data - Resetting a Form with External Data

When resetting a *Form* or an *Item Group* in *Form* view, all data is removed except external data, which is read-only in EDC. To remove external data from a *Form*, you must conduct a two-step resetting process.



To reset external data after resetting a form:

1. Navigate to your recently reset *Form* and click on the **Actions** menu.
2. Select **Reset External Data Values**.
3. Click **Reset**.

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Queries - Query Types and Statuses

Veeva EDC has two types of queries: system and manual.

- **System query**: an edit check run by Veeva EDC. The system creates system queries based on data validation rules in your *Study*. After you update data to a value that's in range, Vault automatically closes the query if it's in Open status.
- **Manual query**: a *Query* record that a CRA or Data Manager creates. Once you respond (answer) and perform any updates, the CRA or Data Manager will review your response and close the query.

Query Statuses

Badge	Icon	Name
		*Open Query / Reopened Query*
		*Answered Query*
N/A		*Closed Query*

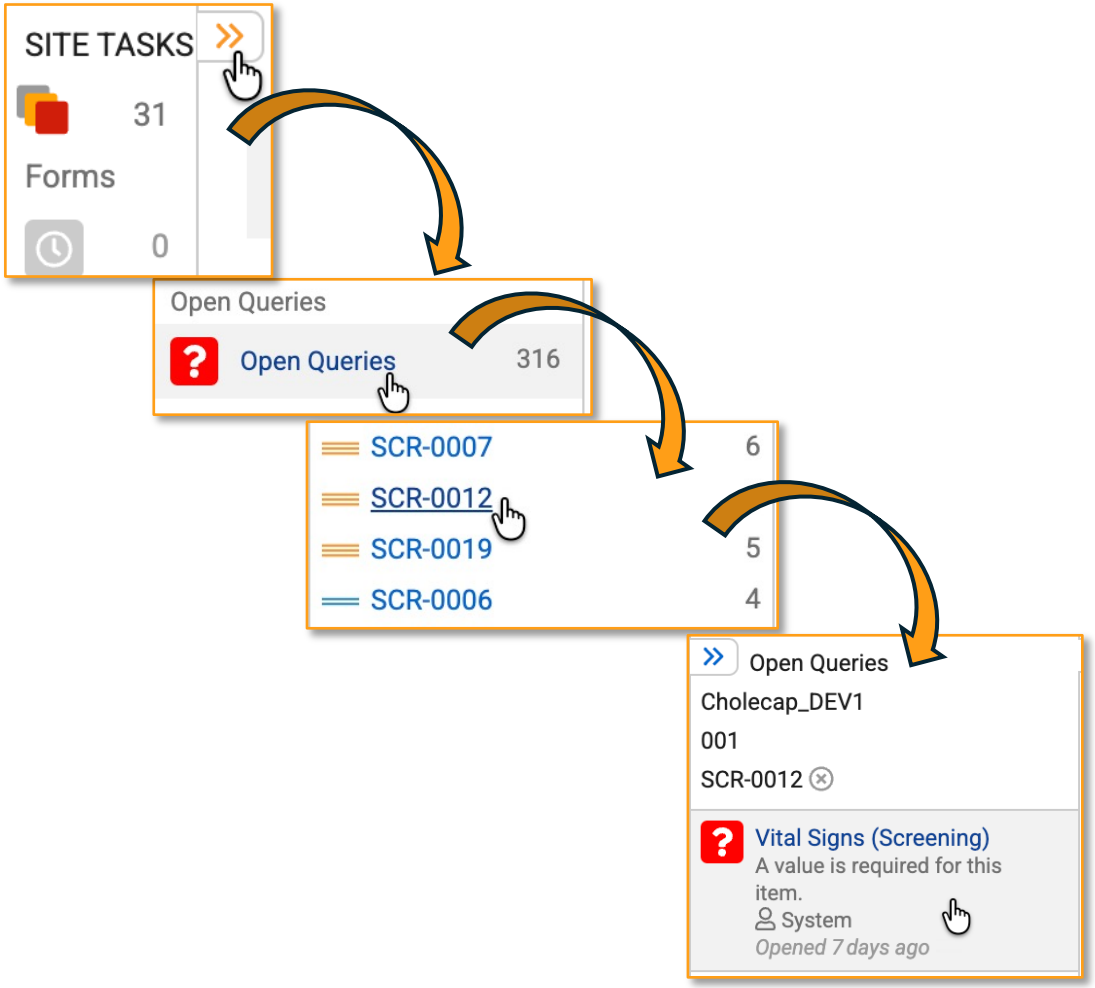
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Responding to Queries - Quick Access

You can view a list of all open queries by using the Site Tasks bar.

To view open queries using the Site Tasks bar:

1. Click the **Arrow** tab on the task bar. The task bar expands.
2. Click **Open Queries**.
3. Click on a subject to view all the *Forms* containing open queries for that subject.
4. Click on a **Form**. The system opens to the location of the first open query on the *Form*.

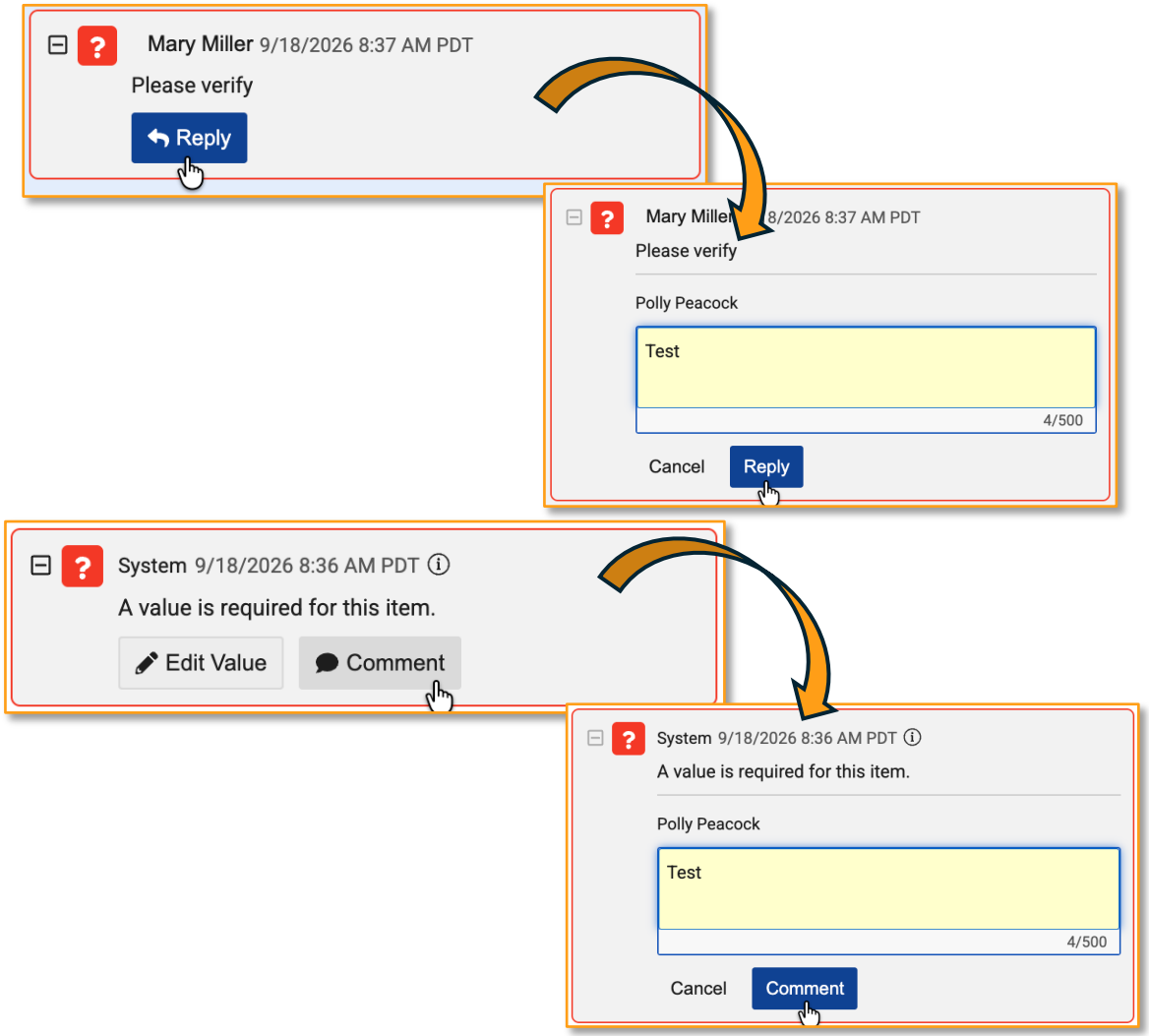


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Responding to Queries – Replying and Commenting

To answer a query:

1. Navigate to the *Event*, *Form*, or *Item* containing the open query.
2. In the query field, Click **Reply** (for manual queries) or **Comment** (for system queries).
3. (Optional) For multi-role users, select a **Query Team**. After saving the response, the *Query Team* becomes read-only.
4. Enter a message and click **Reply** (for manual queries) or **Comment** (for system queries).



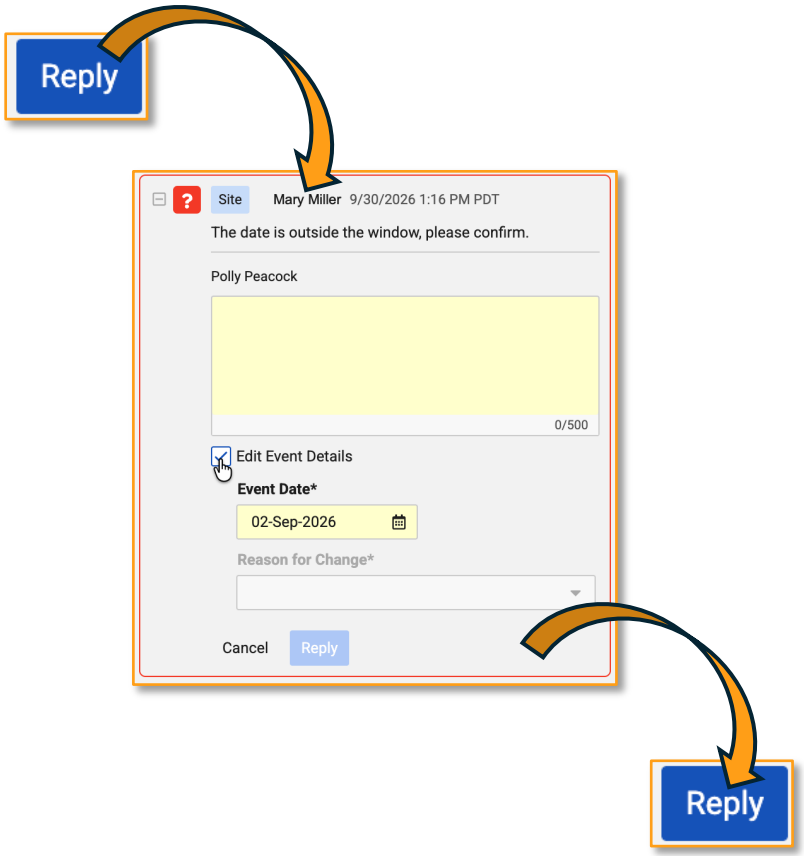
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Responding to Queries – Editing Event Data

To answer a query and change related data:

For *Event* queries:

1. Navigate to the *Event* containing the open query.
2. Expand the *Event* query box.
3. Click **Reply**.
4. Enter a message.
5. Click the **Edit Event Details** checkbox to enter a new **Event Date**.
6. Select a **Reason for Change**.
7. Click **Reply**.

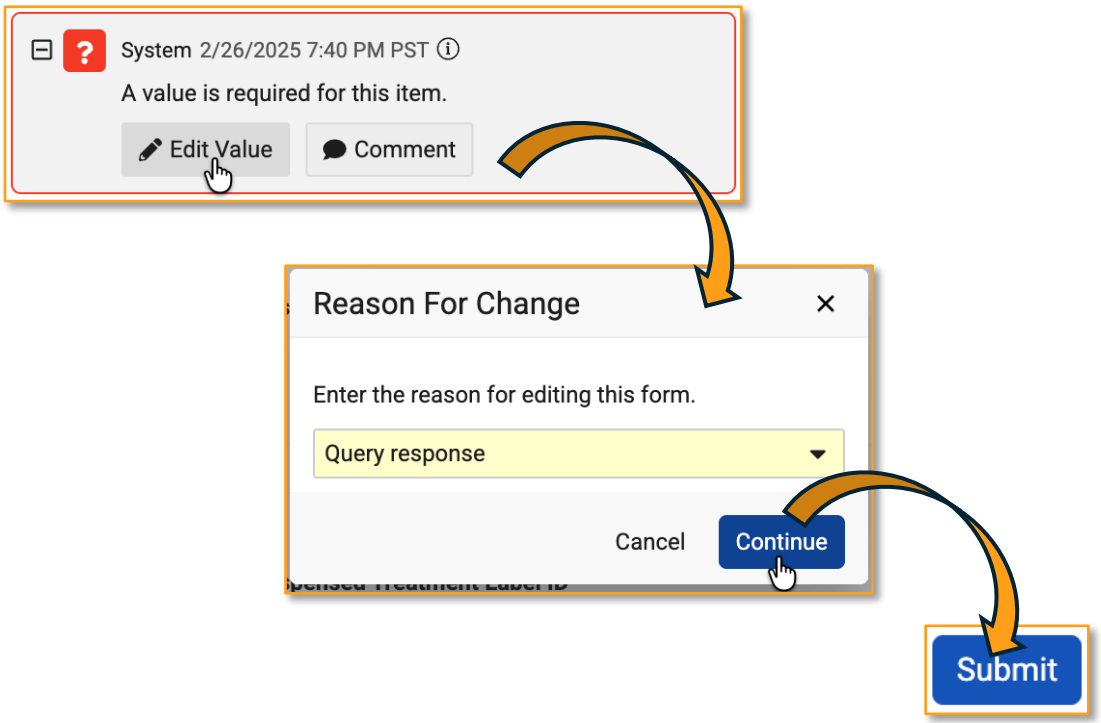


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Responding to Queries - Editing Item Data

To answer an *Item* query and change related data:

1. Navigate to the *Form* containing the *Item* with the open query.
2. Click **Edit Value**.
3. In the **Reason for Change** dialog, select a **Reason for Change**.
4. Click **Continue**.
5. Make your changes to the *Item* data. When you are done editing data, click **Submit** to re-submit the *Form*.



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Signing Data - Conditions

If you have permissions to sign, you can sign and date in EDC by using eSignature. The *CDMS Principal Investigator* role has the *Sign* permission by default. You can sign at the *Form*, *Event*, or *Casebook* level and the signature applies to all eligible *Forms* and *Event* dates. Some actions can break a signature after it is applied.

You can sign a *Form* or *Event* when the following conditions are met:

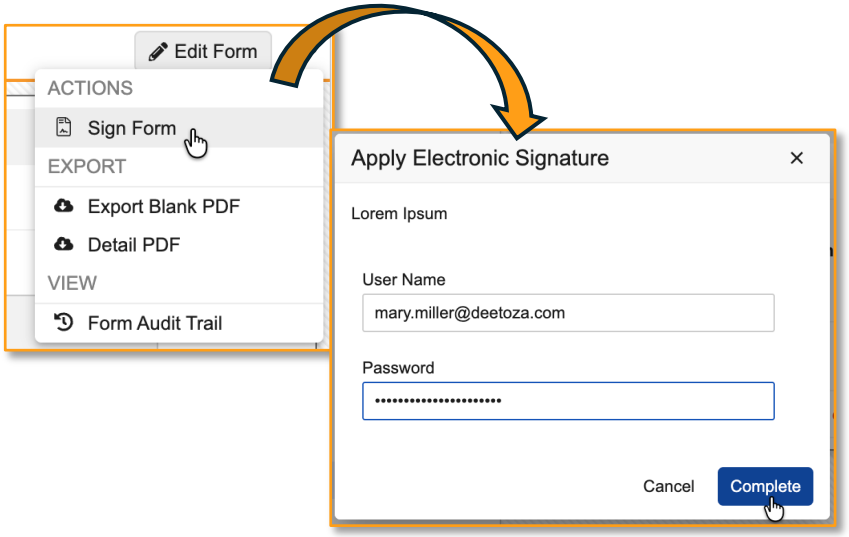
- Any *Forms* are *Submitted*
- The *Form*, *Event*, and *Casebook* are unlocked
- There are no open queries (ability to sign depends on the signature level)

When there is an open query on an *Event*:

- You can't sign *Event Dates* or *Visit Methods* on the *Event*.
- You can sign *Forms* within that *Event*.
- You can sign at the *Casebook* level, but Vault only applies your signature to *Event Dates* with no open queries. Vault then applies your signature to all *Forms*, including those in the *Event*.

When there is an open query on an *Item*, but there is no open query on the *Event Date*:

- You can't sign a *Form* with an open query.
- You can sign at the *Event* level, but Vault only applies your signature to *Forms* with no open queries.



Actions that can break a Signature:

Actions in **Data Entry** that can break a signature include:

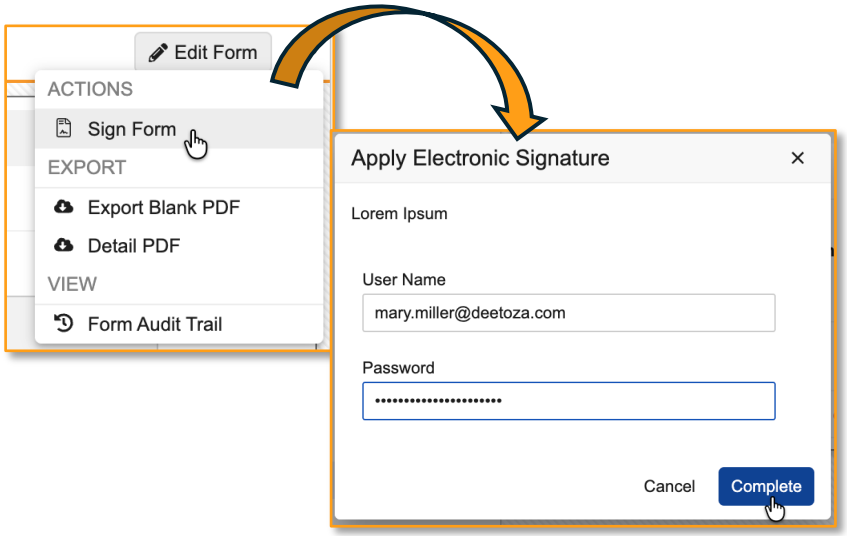
- Editing a *Form*, which involves changes to *Item* data (breaks signature for the *Form*)
- Resetting a *Form* (breaks signature for the *Form*)
- Resetting an *Event* (breaks signature for the *Forms* in the *Event*)
- Editing an *Event Date* (breaks signature for the *Event Date*)
- Editing a *Visit Method* (breaks signature for the *Visit Method*)

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Signing Data – Signing Forms

To sign an individual *Form*:

1. Navigate to the *Form* you want to sign.
2. From the Actions menu of the *Form*, click **Sign Form**.
3. In the Apply Electronic Signature dialog, enter your **Username** and **Password.**
4. Click **Complete**.

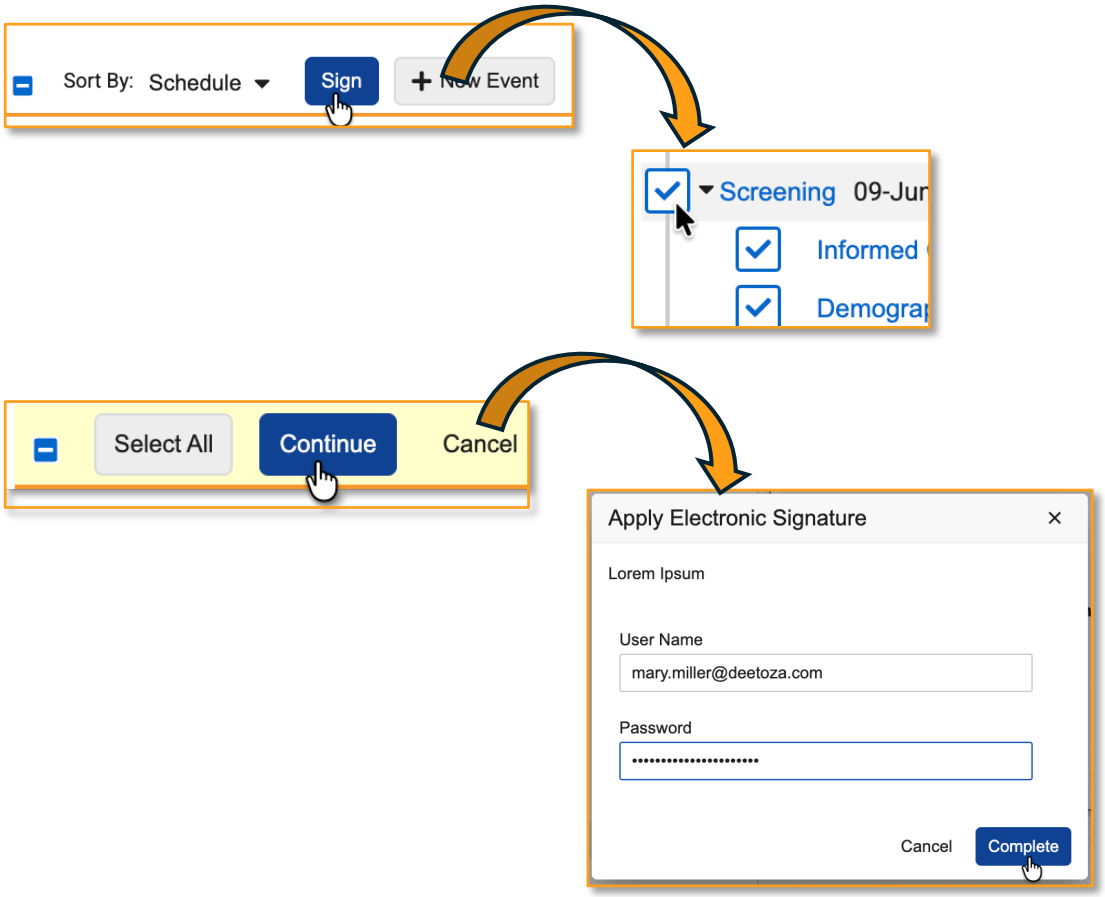


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Signing Data – Signing Events

Signing at the *Event* level applies your eSignature to all eligible *Forms* and *Event* dates. To sign an *Event*:

1. Navigate to the Casebook you want to sign.
2. At the top of the Casebook Schedule panel, click **Sign**.
3. Select one or more Events you want to sign. You can also click **Select All** to select all *Events* and *Forms* in the *Casebook*.
4. Click **Continue**.
5. In the Apply Electronic Signature dialog, enter your **User Name** and **Password**.
6. Click **Complete**.



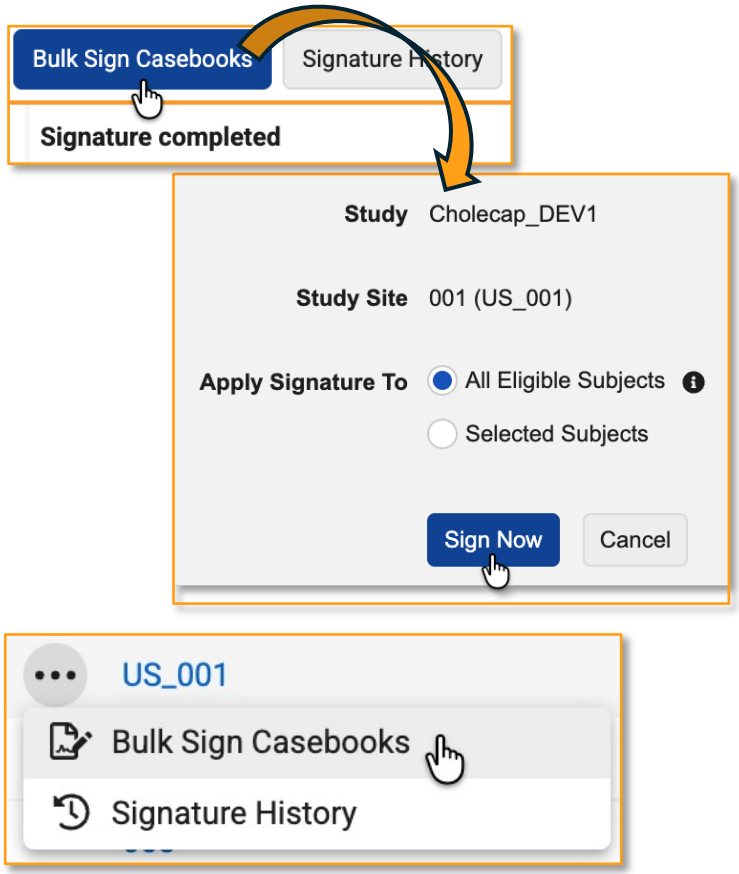
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Signing Data – Bulk Casebook Signature

If **Bulk Casebook Signature** is configured for your site, you can bulk sign all eligible Casebooks at the site.

To bulk sign casebooks at your site:

1. Navigate to the Casebook listing page.
2. Click the **Bulk Sign Casebooks** button on the top right corner of the page. The **Sign Casebooks** page opens.
3. Select where to apply the signature: **All Eligible Subjects** or **Selected Subjects**.
4. (Optional) When choosing **Selected Subjects**, select the checkbox next to each *Subject* you want to sign.
5. Click **Sign Now**.
6. You can also bulk sign from the *Site* listing page by selecting **Sign Casebooks** from the *Site*'s **Actions** menu.

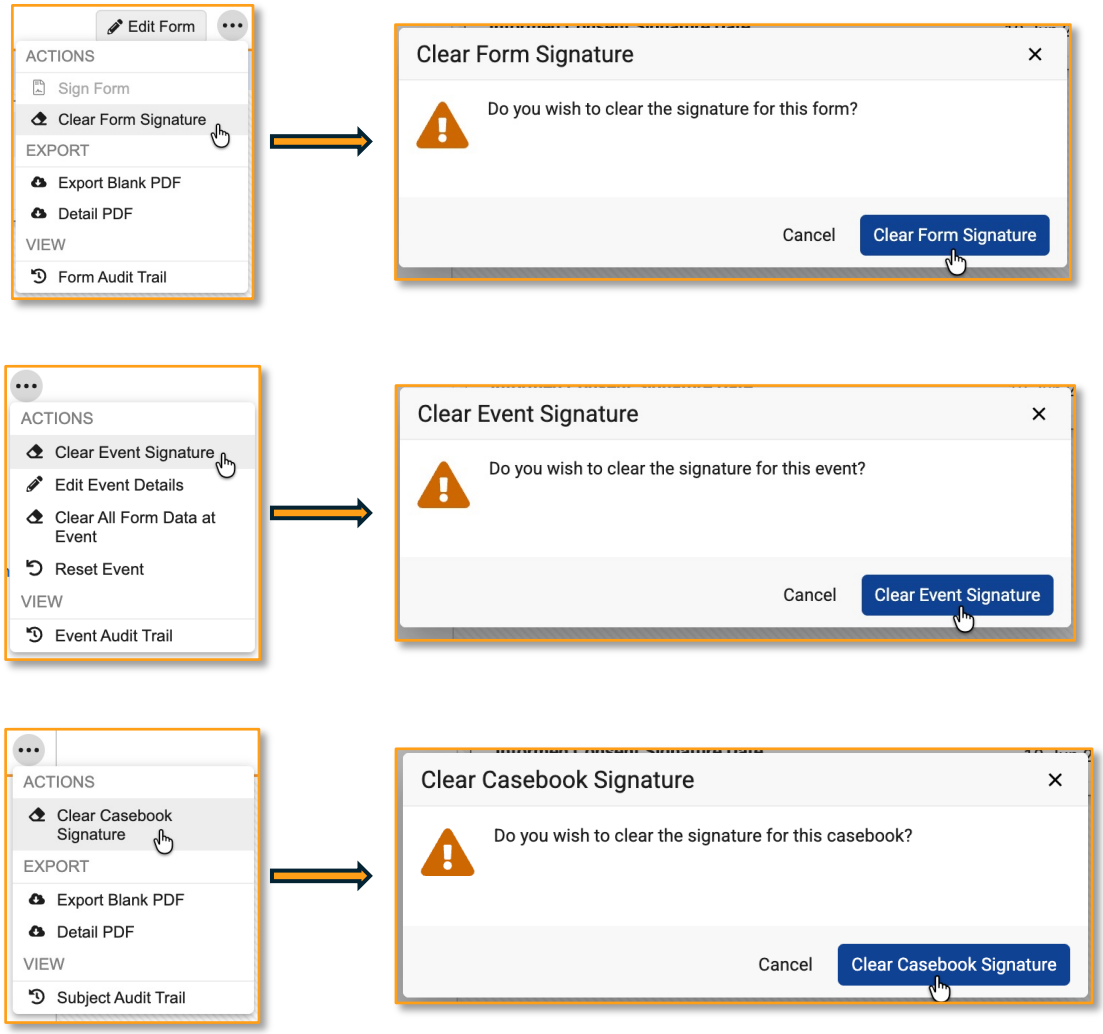


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Signing Data - Clearing Signatures

Clearing an eSignature removes the signature from the objects the action is performed on. To clear an eSignature:

1. Navigate to the *Form*, *Event,* or *Casebook* you want to clear the signature from.
2. Select the **Clear Signature** action:
   - For a *Form*, open the *Form* and click **Clear Signature** from the *Form's* **Actions Menu**.
   - For a *Casebook* click **Clear Casebook Signature** from the *Casebook's* **Actions Menu**.
   - For an *Event*, click **Clear Event Signature** from the *Event's* **Actions Menu**.
3. In the **Clear Signature** dialog, click **Clear Signature**.



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Veeva EDC Glossary

Term	Definition
Casebook	The digital record containing all clinical trial data, visits, and forms for a single study participant.
Event	A specific visit or timepoint in a study, categorized as scheduled (protocol visit), unscheduled (extra visit), or common (ongoing log forms like Adverse Events).
Form	A structured page within an event used to collect related clinical data items. Also known as an eCRF.
Item	An individual data field or question located on a form.
Site Tasks Bar	A side panel that categorizes and displays your pending work, such as incomplete forms, open queries, and required signatures.
Intentionally Left Blank (ILB)	A status applied to a form or item to document that required data was not collected and record the reason why.
In Edit	A temporary status activated when modifying previously submitted form data, which requires entering a reason for change before re-submitting.
Reason for Change	A required dropdown selection explaining why previously submitted data or dates are being updated.
Form Link / Item-to-Form Link	An interactive connection that links related records across different forms, such as connecting a concomitant medication to an adverse event.
File Attachment	An uploaded document attached to a form field, requiring verification that no Personal Health Information (PHI) or Personally Identifiable Information (PII) is included.
System Query	An automated alert generated by Veeva EDC when entered data violates configured validation rules or acceptable ranges.
Manual Query	A specific question or clarification request created directly by Monitor or Data Manager regarding entered data.
Frozen	A status set by study reviewers that temporarily locks data from site edits while it undergoes quality review.
Locked	An administrative status applied after review that permanently prevents further edits or additions to a form, event, or casebook.
eSignature / Signature	An electronic signature applied by authorized site personnel (such as the Principal Investigator) to certify the completeness and accuracy of submitted data.
Audit Trail	A permanent background log that records every data entry, modification, timestamp, and user action taken within the system.
Reset (Form / Event)	A function that completely wipes all entered data, items, and system queries from a form or event to return it to a blank status.
External Data	Data automatically populated from external sources that is read-only and cannot be manually edited in EDC.

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