

# Log Forms Overview

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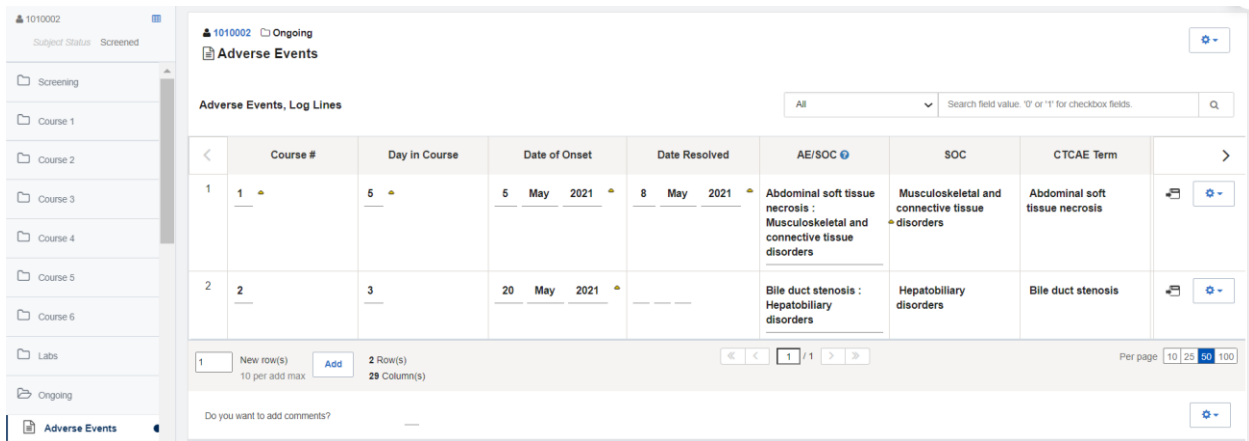
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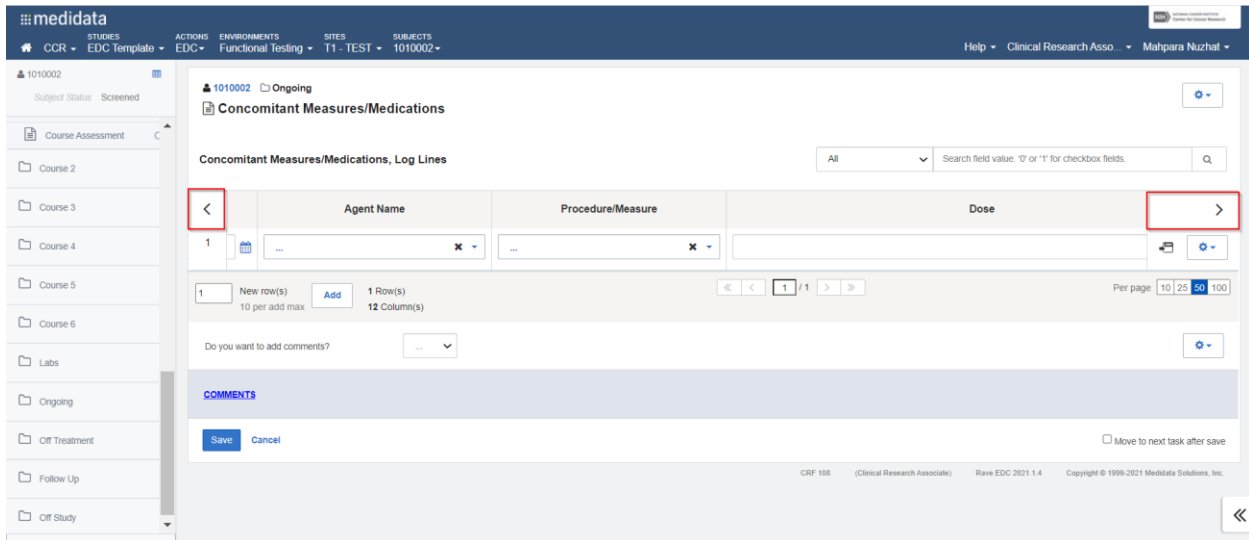
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Log forms can appear in two modes: **Landscape** and **Portrait**. By default, they will be in landscape mode, where all the log records are displayed as individual horizontal rows. An example of a landscape mode layout is shown below.



In landscape mode, all the fields in a log form can be observed by clicking, as needed, on the arrow buttons to the left and right of the header titles.



In contrast, each log line can be viewed on a standard vertical form in portrait mode.

1010002 Ongoing Adverse Events

Adverse Events, Log Lines

Back To Complete View < Previous Line Line 2 of 3 Next Line > Add Another Line

Course # 1

Day in Course 5

Date of Onset 5 May 2021

Date Resolved 8 May 2021

AE/SOC Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders

SOC Musculoskeletal and connective tissue disorders

CTCAE Term Abdominal soft tissue necrosis

Adverse Event Description

Grade 2: Moderate Adverse Event

## Sorting Log Lines

To sort log lines by a specific column, go to landscape mode and click on the relevant column name **once** to sort column values in **ascending** order. To sort the contents of the column in **descending** order, click on the column name **twice**. For example, by clicking on the “Grade” column once, log lines will be sorted in ascending order of “Grade”.

1010002 Ongoing Adverse Events

Adverse Events, Log Lines

All Search field value: '0' or '1' for checkbox fields.

<	Resolved	AE/SOC	SOC	CTCAE Term	Adverse Event Description	Grade	Attribution to Research	Attr	>
1	May 2021	Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	Abdominal soft tissue necrosis		2: Moderate Adverse Event	Adverse Event Unrelated	Advers Unrela	
2		Bile duct stenosis : Hepatobiliary disorders	Hepatobiliary disorders	Bile duct stenosis		1: Mild Adverse Event	Adverse Event Unrelated	Advers Unrela	
3	May 2021	Eczema : Skin and subcutaneous tissue disorders	Skin and subcutaneous tissue disorders	Eczema		2: Moderate Adverse Event	Adverse Event Related	Advers Relate	

1 New row(s) 10 per add max Add 3 Row(s) 29 Column(s) < 1 / 1 > Per page 10 25 50 100

As shown below, all the rows in the log form have now been sorted in ascending order of “Grade”.

The screenshot shows a table titled "Adverse Events, Log Lines" with the following data:

Resolved	AE/SOC	SOC	CTCAE Term	Adverse Event Description	Grade	Attribution to Research	Attr
2	Bile duct stenosis : Hepatobiliary disorders	Hepatobiliary disorders	Bile duct stenosis		1:Mild Adverse Event	Adverse Event Unrelated	Advers Unrela
1	May 2021 Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	Abdominal soft tissue necrosis		2:Moderate Adverse Event	Adverse Event Unrelated	Advers Unrela
3	May 2021 Eczema : Skin and subcutaneous tissue disorders	Skin and subcutaneous tissue disorders	Eczema		2:Moderate Adverse Event	Adverse Event Related	Advers Relate

To sort the rows in descending order, click on the column name again.

The screenshot shows the same table as above, but the "Grade" column header is highlighted with a red box, indicating it is the target for sorting.

The records are now sorted in descending “Grade” order, as demonstrated below.

The screenshot shows the table sorted in descending order of Grade:

Resolved	AE/SOC	SOC	CTCAE Term	Adverse Event Description	Grade	Attribution to Research	Attr
3	May 2021 Eczema : Skin and subcutaneous tissue disorders	Skin and subcutaneous tissue disorders	Eczema		2:Moderate Adverse Event	Adverse Event Related	Advers Relate
1	May 2021 Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	Abdominal soft tissue necrosis		2:Moderate Adverse Event	Adverse Event Unrelated	Advers Unrela
2	Bile duct stenosis : Hepatobiliary disorders	Hepatobiliary disorders	Bile duct stenosis		1:Mild Adverse Event	Adverse Event Unrelated	Advers Unrela

## Entering Data into Log Lines

Data entered into a log line in landscape view can be saved by clicking on the **Save** button.

The screenshot shows the 'Concomitant Measures/Medications, Log Lines' interface. The table has columns for Start Date, Stop Date, Agent Name, and Procedure/Measure. The first row contains the following data: Start Date: 1 Oct 2020; Stop Date: 8 Oct 2020; Agent Name: 9-AC; Procedure/Measure: MRI, Endorectal. Below the table, there is a 'Do you want to add comments?' dropdown menu and a 'COMMENTS' section. At the bottom, there are 'Save' and 'Cancel' buttons, with the 'Save' button highlighted by a red box. A 'Move to next task after save' checkbox is also present.

After entering data in one log line, additional log lines can be added by selecting the **Add** button. The specific number of possible rows to be added can also be entered. The ability to add log lines is dependent on study configuration.

Note: A maximum of 10 log lines can be added at a time.

The screenshot shows the 'Concomitant Measures/Medications, Log Lines' interface. The table has columns for Course #, Day in Course, Start Date, Stop Date, and Agent Name. The first row contains the following data: Course #: 1; Day in Course: 1; Start Date: dd ... yyyy; Stop Date: dd ... yyyy; Agent Name: ... . Below the table, there is a 'Do you want to add comments?' dropdown menu and a 'COMMENTS' section. At the bottom, there are 'Save' and 'Cancel' buttons, with the 'Add' button highlighted by a red box. A 'Move to next task after save' checkbox is also present.

Data can be entered in landscape mode or in portrait mode. To access portrait mode, click on the highlighted icon.

The screenshot shows the Medidata interface in landscape mode. The main content area displays a table titled "Concomitant Measures/Medications, Log Lines". The table has columns for Course #, Day in Course, Start Date, Stop Date, and Agent Name. A red box highlights a small icon in the top right corner of the table row, which is used to switch to portrait mode. The interface also includes a sidebar with navigation options like Course Assessment, Course 2-6, Labs, Ongoing, Off Treatment, and Follow Up. The top navigation bar shows the Medidata logo and various menu items like STUDIES, ACTIONS, ENVIRONMENTS, SITES, and SUBJECTS.

The exact log line would then appear as a standard form.

The screenshot shows the Medidata interface in portrait mode. The main content area displays a form titled "Concomitant Measures/Medications". The form has fields for Course #, Day in Course, Start Date, Stop Date, Agent Name, Procedure/Measure, Dose, and UOM. The interface also includes a sidebar with navigation options like Course Assessment, Course 2-6, Labs, Ongoing, Adverse Events, Concomitant Measures/Medications, Extent of Disease - Lesions C Identification, Extent of Disease - Lesions C Measurements, and Vital Signs. The top navigation bar shows the Medidata logo and various menu items like STUDIES, ACTIONS, ENVIRONMENTS, SITES, and SUBJECTS.

Just like a standard form, any data entered in this mode can be saved by clicking on the **Save** button at the bottom of the page.

This screenshot shows a form for entering Concomitant Measures/Medications. The left sidebar contains a navigation menu with items like Course 1 through Course 6, Labs, Ongoing, Adverse Events, and Concomitant Measures/Medications (which is currently selected). The main form area includes fields for UOM (mg - Milligram), Schedule, Route (PO:Oral), Reason (Acidity), and a Comments text area. At the bottom, there is a 'Back To Complete View' link, navigation for 'Line 1 of 1', a 'Save and Add Another Line' button, a 'Do you want to add comments?' dropdown, and a 'COMMENTS' section. A red box highlights the 'Save' button at the bottom left.

New log lines can also be added in this mode by selecting the **Add Another Line** button.

This screenshot shows the 'Log Lines' section of the Concomitant Measures/Medications form. The left sidebar is similar to the previous screenshot. The main form area is titled 'Concomitant Measures/Medications, Log Lines' and includes a 'Back To Complete View' link, navigation for 'Line 1 of 1', and an 'Add Another Line' button (highlighted with a red box). Below this are fields for Course #, Day in Course, Start Date, Stop Date, Agent Name, Procedure/Measure, Dose, and UOM. Each field has a gear icon for configuration.

We can return to landscape mode by selecting the blue **Back to Complete View** link.

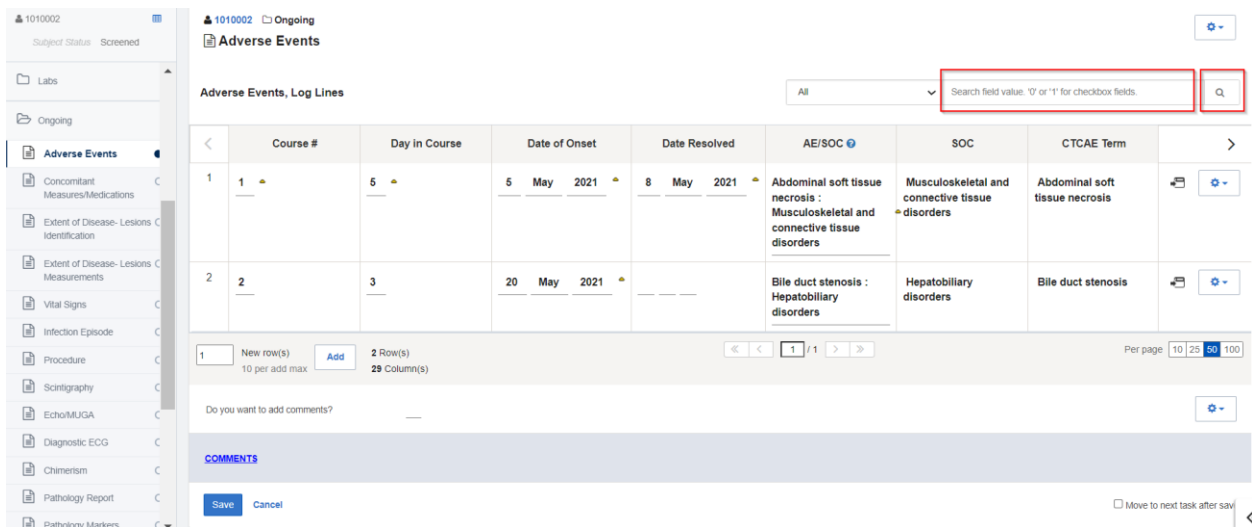
The screenshot shows a web interface for a subject (1010002) with status 'Screened'. The main section is titled 'Concomitant Measures/Medications' and 'Concomitant Measures/Medications, Log Lines'. The current log line is 'Line 1 of 1'. A blue link 'Back To Complete View' is highlighted with a red box. The form contains several fields: Course #, Day in Course, Start Date (dd, --, yyyy), Stop Date (dd, --, yyyy), Agent Name (dropdown), Procedure/Measure (dropdown), Dose, and UOM (dropdown). Each field has a blue 'Reset' icon to its right. A 'Previous Line' and 'Next Line' navigation bar is also visible.

To navigate to other log lines, select the highlighted fields to go back and forth between the portrait view of the log lines.

This screenshot is similar to the one above, but the 'Back To Complete View' link is now blue and the 'Previous Line' and 'Next Line' navigation buttons are highlighted with red boxes. The form fields and their 'Reset' icons remain the same.

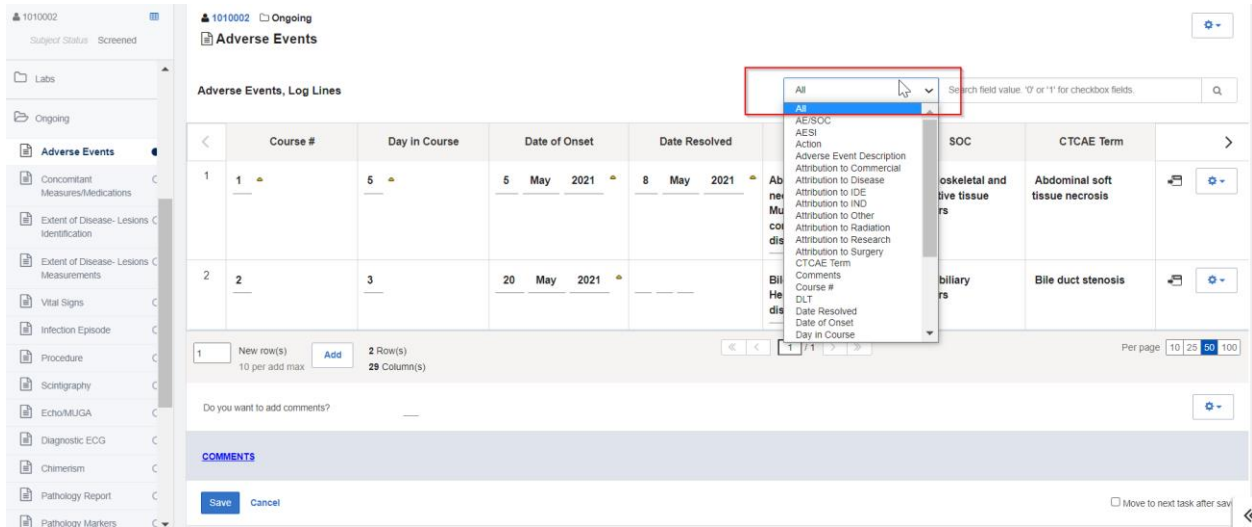
## Searching Log Lines

To search for a value in a log form, enter the relevant term in the search box and click on the magnifying glass “Search” button marked below.



The screenshot shows the 'Adverse Events, Log Lines' interface. At the top right, there is a search bar with the placeholder text 'Search field value: '0' or '1' for checkbox fields.' and a magnifying glass icon. Below the search bar is a table with the following columns: Course #, Day in Course, Date of Onset, Date Resolved, AE/SOC, SOC, and CTCAE Term. The table contains two rows of data. Row 1: Course # 1, Day in Course 5, Date of Onset 5 May 2021, Date Resolved 8 May 2021, AE/SOC 'Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders', SOC 'Musculoskeletal and connective tissue disorders', CTCAE Term 'Abdominal soft tissue necrosis'. Row 2: Course # 2, Day in Course 3, Date of Onset 20 May 2021, Date Resolved, AE/SOC 'Bile duct stenosis : Hepatobiliary disorders', SOC 'Hepatobiliary disorders', CTCAE Term 'Bile duct stenosis'. Below the table, there is a 'COMMENTS' section with a 'Save' button and a 'Cancel' button. A 'Move to next task after save' checkbox is also present.

Optionally, click on the dropdown to the left of the search bar when looking for a value in a specific column and choose the desired column.



The screenshot shows the same 'Adverse Events, Log Lines' interface as above, but with a dropdown menu open over the search bar. The dropdown menu lists the following options: All, AE/SOC, AESSI, Action, Adverse Event Description, Attribution to Commercial, Attribution to Disease, Attribution to IDE, Attribution to IND, Attribution to Other, Attribution to Radiation, Attribution to Research, Attribution to Surgery, Comments, CTCAE Term, Course #, DLT, Date Resolved, Date of Onset, and Day in Course. The 'All' option is currently selected. The search bar and table below are visible but partially obscured by the dropdown menu.



In this example, the term “bile” has been entered into the search bar and the column “CTCAE Term” has been selected from the dropdown. By clicking on the search button, the results of the search are generated.

Adverse Events, Log Lines

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
1	5	5 May 2021	8 May 2021	Ab	oskeletal and	Abdominal soft
2	3	20 May 2021		Bi	iliary	Bile duct stenosis

Adverse Events, Log Lines

1 result(s) for filtering 'bile' with 'CTCAE Term'

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
2	3	20 May 2021		Bile duct stenosis : Hepatobiliary disorders	Hepatobiliary disorders	Bile duct stenosis

To return to the original log view containing all the records in the form, select **Clear Filter**.

Adverse Events, Log Lines

1 result(s) for filtering 'bile' with 'CTCAE Term'

Clear Filter

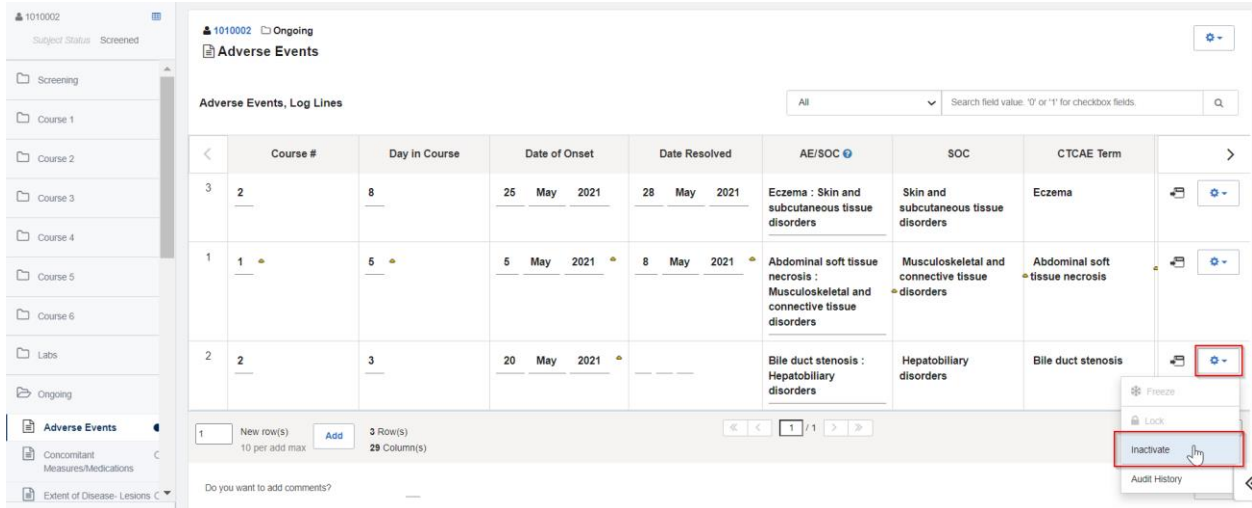
Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
2	3	20 May 2021		Bile duct stenosis : Hepatobiliary disorders	Hepatobiliary disorders	Bile duct stenosis

## Inactivating and Reactivating Log Lines

After successfully saving a log line, it can be inactivated if required. This may be done if a line is entered in error, among other reasons.

**Note:** Log lines cannot be deleted, they can only be inactivated.

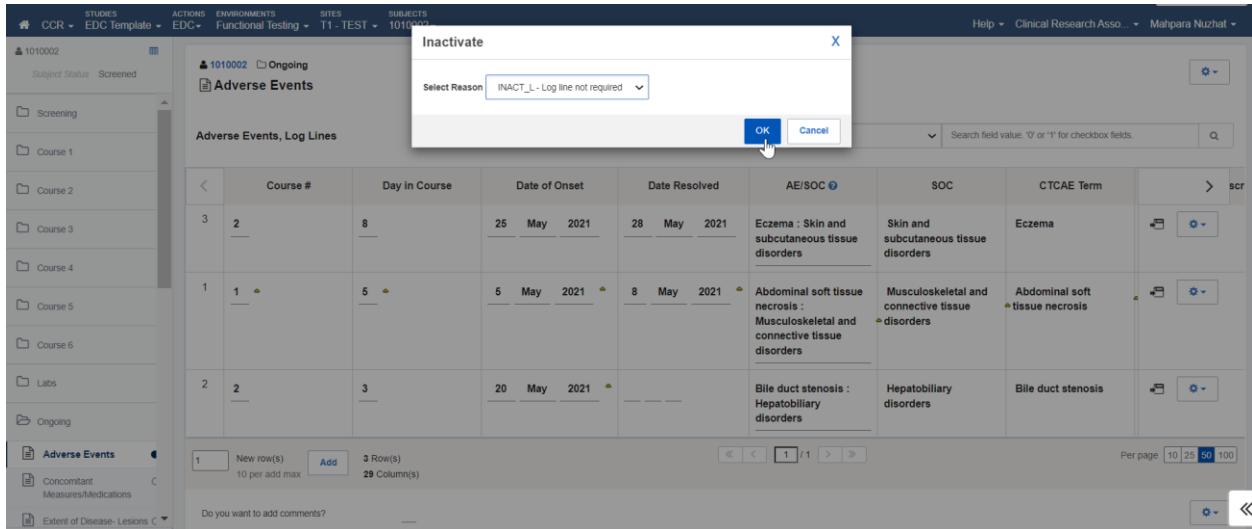
To inactivate a log line, click on the gear icon belonging to that line and select **Inactivate** from the dropdown.



The screenshot shows the 'Adverse Events, Log Lines' table. The table has columns for Course #, Day in Course, Date of Onset, Date Resolved, AE/SOC, SOC, and CTCAE Term. Three rows are visible. The third row (Course # 2, Day 3) is highlighted, and its gear icon dropdown menu is open, showing options: Freeze, Lock, Inactivate (highlighted with a red box), and Audit History.

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
3	2	25 May 2021	28 May 2021	Eczema : Skin and subcutaneous tissue disorders	Skin and subcutaneous tissue disorders	Eczema
1	1	5 May 2021	8 May 2021	Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	Abdominal soft tissue necrosis
2	2	20 May 2021		Bile duct stenosis : Hepatobiliary disorders	Hepatobiliary disorders	Bile duct stenosis

A dialog box will then appear requiring the user's reason for inactivation. Depending on study configuration, this list will normally only consist of one default reason so simply click on the **OK** button.



The screenshot shows the 'Inactivate' dialog box. The 'Select Reason' dropdown menu is open, showing the selected reason: 'INACT\_L - Log line not required'. The 'OK' button is highlighted with a mouse cursor.

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
3	2	25 May 2021	28 May 2021	Eczema : Skin and subcutaneous tissue disorders	Skin and subcutaneous tissue disorders	Eczema
1	1	5 May 2021	8 May 2021	Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	Abdominal soft tissue necrosis
2	2	20 May 2021		Bile duct stenosis : Hepatobiliary disorders	Hepatobiliary disorders	Bile duct stenosis

As shown here, the row has now been inactivated. Inactive lines are marked by strikethrough text and two icons (**Frozen** and **Locked**), highlighted to the right. This means that the line is locked and no longer modifiable.

The screenshot shows a table titled "Adverse Events, Log Lines" with the following data:

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
3	2	25 May 2021	28 May 2021	Eczema : Skin and subcutaneous tissue disorders	Skin and subcutaneous tissue disorders	Eczema
1	1	5 May 2021	8 May 2021	Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	Abdominal soft tissue necrosis
<del>2</del>	<del>-2</del>	<del>20 May 2021</del>		<del>Bile duct stenosis : Hepatobiliary disorders</del>	<del>Hepatobiliary disorders</del>	<del>Bile duct stenosis</del>

The row with Course # 2 is highlighted with a red box, indicating it is inactivated. The text in this row is crossed out, and the "Frozen" and "Locked" icons are visible in the action column.

Based on permissions, inactive log lines can be reactivated if the inactivation was a mistake or if it requires reversing. When a log line is reactivated, it is returned to the state it was in before its inactivation. To reactivate a log line, click on the gear icon of the inactive row and select **Reactivate** from the dropdown.

The screenshot shows the same table as above, but with the gear icon for the inactivated row (row 2) clicked. A dropdown menu is open, showing the following options:

- Unfreeze
- Unlock
- Reactivate** (highlighted)
- Audit History

The "Reactivate" option is highlighted with a red box, indicating it is the correct action to take to reactivate the log line.

Similar to inactivation, a dialog box will then pop up requesting a reason for reactivation. Click on **OK**.

The screenshot shows the Medidata interface with a 'Reactivate' dialog box open. The dialog box contains a 'Select Reason' dropdown menu with the option 'ACT\_L - Log line required' selected. Below the dropdown are two buttons: 'OK' and 'Cancel'. The 'OK' button is highlighted with a red box. In the background, the 'Adverse Events, Log Lines' table is visible, showing columns for Course #, Day in Course, Date of Onset, Date Resolved, AE/SOC, SOC, and CTCAE Term. The table contains three rows of data.

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
2	8	25 May 2021	28 May 2021	Eczema : Skin and subcutaneous tissue disorders	Skin and subcutaneous tissue disorders	Eczema
1	5	5 May 2021	8 May 2021	Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	Abdominal soft tissue necrosis
2	3	20 May 2021		Bile duct stenosis : Hepatobiliary disorders	Hepatobiliary disorders	Bile duct stenosis

The log line then appears as it was prior to inactivation.

The screenshot shows the Medidata interface with the 'Adverse Events, Log Lines' table. The row corresponding to the previously inactivated event is now visible and highlighted with a red box. The table contains three rows of data.

Course #	Day in Course	Date of Onset	Date Resolved	AE/SOC	SOC	CTCAE Term
2	8	25 May 2021	28 May 2021	Eczema : Skin and subcutaneous tissue disorders	Skin and subcutaneous tissue disorders	Eczema
1	5	5 May 2021	8 May 2021	Abdominal soft tissue necrosis : Musculoskeletal and connective tissue disorders	Musculoskeletal and connective tissue disorders	Abdominal soft tissue necrosis
2	3	20 May 2021		Bile duct stenosis : Hepatobiliary disorders	Hepatobiliary disorders	Bile duct stenosis