

Designer Users Guide

v 5.0

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Getting Started

Setting up Your Browser

Screen Resolution

Designer is designed for screen resolutions of **1280 X 1024**. If your screen resolution is less than this, some Designer pages may not fit on your screen.

Multiple Browser Windows

Open Designer in one browser window only. When you open Designer in a browser, a session is created between the browser and the database. Opening Designer in more than one browser window may cause Designer to send or receive the wrong information.

Browser Add ons

Using browser add ons, such as browser extensions or toolbars, may interfere with your ability to use hot keys for navigation and data entry in Designer.

Browser Security Settings

To use Designer, your browser security settings cannot prompt for a username and password when accessing the local intranet.

To change your browser security settings:

1. Start Internet Explorer.
2. On the Tools menu, click Internet Options. The Internet Options dialog box appears.
3. Click the Security tab.
4. Click Local Intranet.
5. Click Custom Level. The Security Settings dialog box appears.
6. Scroll to the User Authentication section.
7. Ensure that Prompt for Username and Password is not selected.
8. Click OK.
9. Click OK.

Accepting Cookies

Your browser must accept cookies in order to log into Designer. Therefore your Privacy level can be set to no higher than Medium High in Internet Options.

To change your privacy level to accept cookies:

1. Start Internet Explorer.
2. On the Tools menu, click Internet Options. The Internet Options dialog box appears.
3. Click the Privacy tab.
4. Move the slider bar to one of the following settings:
 - Medium
 - Medium High
5. Do not select any of the following settings:
 - Accept All Cookies
 - Block All Cookies
6. Click OK.

Logging in to Designer

Designer is a web application. In order to log in to Designer, you must have the following:

- An Internet connection
- Internet Explorer 7.0 or 8.0
- A Designer username and password
- The website address of the Designer application

To log in to Designer

1. Start Internet Explorer.
2. In the Address field at the top of your browser, enter the address of the Designer application.
3. Press Enter. Designer prompts you for your username and password.
4. In the **Username** field, type your username in one of the following formats:

username

domainname\username

username@domain

Example: If the domain is "vialithival" and your Username is "Nrichards1", you could enter your username as `vialithival\Nrichards1` or `Nrichards1@vialithival`.

5. In the **Password** field, type your password.

The Designer Home page appears.

Possible Error Messages When Logging In

You will not be able to log in to Designer if one or more of the following occurs:

- You enter an incorrect username and/or password
- Your account is locked
- Your password has expired

Please contact your System Administrator for more information.

The Designer Home Page

The Designer Home Page shows a list of studies you can view and work with. From the Home Page, users can create and import new studies and use filters to search for the specific study they want to work with.

From the Home Page, administrators can use the Administration link to access features for managing Designer users and user roles.

The screenshot shows the DataLabs Designer interface. At the top, the header displays 'DataLabs Designer' and 'Welcome, Miles Massey | Log Out'. Below the header is a toolbar with a 'Home' button. A breadcrumb trail shows 'Home'. An 'Actions' palette on the left lists 'Create New Study', 'Create Study from Existing', and 'Import Study'. The main content area displays a table of studies with columns for Client/Sponsor, Study Name, Study Label, Protocol, Therapeutic Area, Study Drug Name, and Last Active. Below the table is a page navigation bar with a 'Page size' dropdown set to 10 and a '4 items in 1 pages' indicator.

Client/Sponsor	Study Name	Study Label	Protocol	Therapeutic Area	Study Drug Name	Last Active
Sponsor1	ENT	ENT	JAS289756	Otolaryngology	Drug Name	06-Apr-2010 07:03:07 PM UTC
Sponsor2	Urology	Urology	PDY204857	Urology	Drug Name	06-Apr-2010 06:55:28 PM UTC
Sponsor3	Allergy	Allergy	KEF385967	Allergy	Drug Name	06-Apr-2010 03:54:51 PM UTC
Sponsor4	Transplant	Transplant	TIR948392	Transplant	Drug Name	06-Apr-2010 03:40:47 PM UTC

Note: All dates and times within Designer are displayed in European format: DD-MMM-YYYY HH:MM:SS.

The Designer Header

The Designer Header shows the name of the study you're currently working with and the name of the user currently logged into Designer.

The Designer Header also provides a link to log you out of Designer.

Toolbar Buttons

The toolbar buttons provide a way for you to quickly access the basic components of a study. Toolbar buttons are organized, from left to right, to follow the typically used to design a study.

Note: If only the Home button appears on the toolbar, a study has not been selected. The full toolbar is only available when you've selected the study you want to work with.

Breadcrumbs

Breadcrumbs show your current "path" in Designer. You can click any of the links on this bar to go back to a previous page in your path.

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Administration Link

The Administration link is displayed only for users who have been assigned the role of Administrator in Designer. This link allows you to access the Administration page.

Actions Palette

The Actions Palette allows you to create a new study, verify and publish an existing study, and to view the status of study-related jobs.

The Actions Palette is dynamic and changes based on the page you're currently viewing.

Page Selected	Actions Available	Description of Action
Home Page	Create New Study	Opens the Study page where you can create a new study.
	Create Study from Existing	Allows you to create a new study by copying an existing study.
	Import Study	Allows you to import an existing study XML file into Designer. (Only studies created in Designer 4.x and greater can be imported.)
Study Page	View Study Jobs	Opens the Study Management Jobs page where you can view the progress of study import, verification, and publication jobs.
	Verify Study	Verifies that all relationships between the study components are properly defined and complete for the current study.
	Publish Study	Creates a .zip file that contains an XML file of the design data for the current study.
	Study Level Edit Checks	Allows you to define the default messages for edit checks and range checks.
Question Properties Page	Question Prompts	Allows you to navigate to the Question Properties page for the selected Question Prompt.

Grid Links

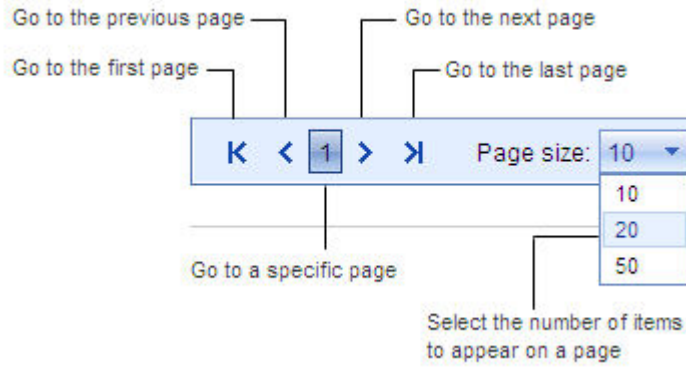
On pages that contains grids, you can use the **Show/Hide Filter** link to toggle between showing and hiding filters on the grid. You can use the **Refresh** link to refresh the information displayed in the grid.

Studies Grid

The Studies Grid shows a list of all studies available for you to view and work with. You can access a study by clicking the Study Name or Study Label.

Page Navigation

The page navigation controls allow you to navigate through information that spans multiple pages and to choose the number of items you want to appear on an individual page.



Designer Grids

In Designer, the pages you will use to add, edit, and delete basic study components are displayed as grids. An example of the Codelists grid is shown below.

The screenshot shows the 'DataLabs Designer' interface for the 'Aspirin41' study. The 'Codelists' section is active, displaying a table with the following data:

	Codelist Name	Codelist Description	SAS Format Name	Last Updated	Valid	Edit	Delete
<input type="checkbox"/>	AbNormal	AbNormal		07-Apr-2010 06:00:01 PM UTC	✓		
<input type="checkbox"/>	AEAction	AEAction		05-Apr-2010 03:43:07 PM UTC	✓		
<input type="checkbox"/>	AECause	AECause		05-Apr-2010 03:43:07 PM UTC	✓		
<input type="checkbox"/>	AEIntensity	AEIntensity		05-Apr-2010 03:43:07 PM UTC	✓		
<input type="checkbox"/>	AEType	AEType		05-Apr-2010 03:43:06 PM UTC	✓		
<input type="checkbox"/>	AmountUOM	AmountUOM		05-Apr-2010 03:43:06 PM UTC	✓		
<input type="checkbox"/>	BottleLabel	Bottle Label		05-Apr-2010 03:43:06 PM UTC	✓		
<input type="checkbox"/>	BPPosition	Blood Pressure Position		05-Apr-2010 03:43:06 PM UTC	✓		
<input type="checkbox"/>	Condition	Condition		05-Apr-2010 03:43:06 PM UTC	✓		
<input type="checkbox"/>	DailyDose	Daily Dose		05-Apr-2010 03:43:06 PM UTC	✓		

Annotations in the image point to the 'Toolbar' (top navigation), 'Grid Item' (checkbox in the first column), 'Delete Item' (delete icon), and 'Edit Item' (edit icon).

Toolbar Buttons

The toolbar buttons provide a way for you to quickly access the basic components of a study. Toolbar buttons are organized, from left to right, to follow the typically used to design a study.

Note: If only the Home button appears on the toolbar, a study has not been selected. The full toolbar is only available when you've selected the study you want to work with.

Notification Bell

When you add, change, or delete study components, a notification message appears to show you that your action was successful.

If you want to see the notification message for the last successful change you made on the current page, roll the cursor over the notification icon .

Grid Items

In Designer, the main page for each study component is presented as a grid of rows and columns.

The name of each grid item is a link. You can click the link to add, view, or edit details for the item.

For example, on the Codelists page, you can click the name of a Codelist to view the Codelist Items associated with it.

Last Updated Date and Time Column

The Last Update Date and Time shows the last time that the item or one of its sub-items was opened for editing.

For example, on the Codelists page, the Last Updated Date and Time shows the most recent time that a codelist or an item associated with the codelist was added or edited.

Edit Icon

You can use the Edit button to open the selected row for inline editing. For more information, see "Editing Items in a Grid."

Delete Button

You can use the Delete button to delete the grid item in the selected row. For more information, see "Deleting Items from a Grid."

Common Tasks

When you use Designer to design a study, there are several common tasks you can perform in every table:

- Sorting items in a table
- Filtering items in a table
- Reordering items in a table
- Editing items
- Deleting items

Sorting Items in a Grid

In Designer, the main page for each **study component** is presented as a grid of rows and columns. When a column heading is underlined, you can use that column to sort the items in the grid.

To change the sorting order for a column

- Click the column heading.

After you sort the column, an arrow appears in the column heading which shows the current sort order:

 means ascending, where you find successively higher values as you proceed down the grid.

 means descending, where you find successively lower values as you proceed down the grid.

Filtering Items

In Designer, the main page for each **study component** is presented as a grid of rows and columns. You can use filters to search for a particular item or limit the number of items that are displayed in a grid.

To show/hide filters:

- If filters are not displayed on the grid, click the **Show/Hide Filter** link to display filters.
- If filters are displayed on the grid, click the **Show/Hide Filter** link to hide the filters.

To filter a list:

1. Type the criteria you want to use as a filter in the appropriate filter text box.

Note You cannot use special characters as filter criteria.

2. Click .


A list of filter options appear.

3. Select the filter option you want to use.

The list is updated to show only items that match the selected filter criteria.

Note: After filtering a list, you can further refine the list by choosing additional filter options. For example, you could search for all studies associated with a specific client sponsor; then, you could search the client sponsor list for all studies related to a specific therapeutic area.

To clear a filter:

1. Click  for the filter you want to clear.

A list of filter options appear.

2. Select NoFilter.

The list is updated.

Contains	Shows all items which match all or any part of a value. For example, to show all items that contain "AL," enter "AL" in the filter text box. Examples of items that contain "AL" are "AL_01," "MEDICAL," and "VITALS"
Starts with	Shows all items that start with a specific character or group of characters. For example, to show a list of all items starting with "AL," enter "AL" in the filter text box. Examples of items that start with "AL" are "AL_01," "AL_02," and "AL_03."
Ends with	Shows all items that end with a specific character or group of characters. For example, to show a list of all items that end with "ALS," enter "ALS" the filter text box. An example of an item that ends with "ALS" is "VITALS;" however, items such as "VITALS_01" or "VITALS_02" would not be included.
Equal to	Shows all items that exactly match a specific value. For example, to show all items that exactly match the value "AL_01" enter "AL_01" in the filter text box. Only items that exactly match "AL_01" would appear. Items such as "AL_02" or "ALS_03" would not appear.
Not Equal to	Shows all items that do not exactly match a specific value. For example, to show all items except those that exactly "AE_01" enter "AE_01" in the filter text box. Only items that do not exactly match "AE_01" would appear.

Does not contain	Shows all items that do not contain all or any part of a value. For example, to show all items except those that contain "01," enter "01" in the filter text box.
-------------------------	--

Reordering Items in a Grid

In Designer, lists are presented as a grid of rows and columns. When working with lists, such as events, questions, domain items, or codelist items, you may want to rearrange the order of items in the list.

Note: You cannot reorder items on paginated lists.

To change the order of items in a list:


1. On the list, click the row of the item you want to move.


Note: Do not click the item name, the edit icon or the delete icons.

The item becomes undocked from the list.


2. Drag and drop the item to a new location on the list. The blue dashed line shows the location where the item will be inserted.

Editing Items in a Grid

In Designer, the main page for each study component is presented as a grid of rows and columns. You can use the  icon to open an individual row within the grid for editing.


1. In the grid, click  for the item you want to edit.

The fields for the selected item open for editing.

2. Enter the changes you want to make.
3. Click  to save your changes.

A confirmation notification appears to indicate that the item was successfully updated.

Deleting Items from a Grid


In Designer, the main page for each study component is presented as a grid of rows and columns. You can use the  icon to delete an individual row from the grid.

Deleting a study component can invalidate the study components associated with it:

- Deleting a domain invalidates the forms associated with domain.

- Deleting a form removes the references to the form in any event or event window. Any derivations or questions that reference the form will be marked invalid.
- Deleting a codelist invalidates the domains associated with the codelist.
- Deleting a function invalidates the queries and derivations that use the function.

To delete an item from a grid using the icon:

1. In the grid, click  for the item you want to delete.
A confirmation message appears.
2. Do one of the following:
 - Click **Yes** to delete the item. A confirmation notification appears to indicate that the item was successfully deleted.
 - Click **No** to cancel the deletion.

To delete an item from a grid using the Delete key:

1. In the grid, highlight the item you want to delete.
2. Press the Delete key on your keyboard.
A confirmation message appears.
3. Do one of the following:
 - Click **Yes** to delete the item. A confirmation notification appears to indicate that the item was successfully deleted.
 - Click **No** to cancel the deletion.

Refreshing the Page

Do not use the Refresh button on your browser's window to refresh your screen in Designer. Using the browser's Refresh button does not properly refresh the cache and temporary files for your session.

A Refresh link is available on all grids within Designer. To refresh the information on a grid, click the **Refresh** link.

Keyboard Hot Keys

Following is a list of hot keys you can use in Designer.

Page and Grid Navigation	
CTRL + G	Sets focus to the first item on a grid
Down Arrow	Moves down one row on the grid
Up Arrow	Moves up one row on the grid
Tab	Moves forward one field
Shift+Tab	Moves back one field
CTRL+SHIFT+F	Moves forward one page
CTRL+SHIFT+B	Moves back one page
Accessing the Study Component Pages	
CTRL+SHIFT+H	Opens the Home page
CTRL+SHIFT+U	Opens the Study page
CTRL+SHIFT+E	Opens the Events page
CTRL+SHIFT+O	Opens the Forms page
CTRL+SHIFT+M	Opens the Domains page
CTRL+SHIFT+C	Opens the Codelists page
CTRL+SHIFT+T	Opens the Dictionaries page
CTRL+SHIFT+L	Opens the Scripting page
Data Entry	
CTRL+R	Refreshes fields within a grid
CTRL+I	Inserts a new row in a grid
CTRL+E	Opens the selected row for editing
CTRL+S	Saves the selected row
CTRL+J	Saves the selected row and inserts a new row in the grid
CTRL+SHIFT+S	Saves the selected row and opens the details page
Esc	Cancel changes and exits the grid
CTRL+SHIFT+D	Deletes the selected row
Parameter Reference Builder Navigation	
CTRL+P	Sets the focus on the Reference tab
Right Arrow	Expands the tree
Left Arrow	Collapses the tree
Up Arrow	Ascends the tree
Down Arrow	Descends the tree

Online Help	
CTRL+K	Opens Keyboard shortcut Help
CTRL+H	Opens Designer online Help


Logging out of Designer

When you are finished using Designer, log out. Logging out helps keep the system secure so that no one can use the system other than authorized users.

To log out from Designer

- Click the **Log out** link at the top of the page.

Designer logs you out of the system. The Login page appears and shows the message, "You have successfully logged out of the Designer system."

Note: If you use the  button on the browser window to log out of Designer, the cache and temporary files for your session may not be properly cleaned up.

Inactivity Timeout

If you're logged in to Designer but have not taken any recent actions, Designer will automatically log you out of Designer.

Best Practices for Study Design

Study Design Workflow

Designer allows you a great amount of flexibility in designing a study.

When you create a new study or select an existing study, Designer enables the study component buttons on the menu bar. You can choose to add study components in any order; however, following is the recommended method:

Define the identifying study information

Develop the user interface

Design the user interface that will be used in DataLabs by study personnel to collect patient information:

1. Define a master list of events that occur in the study.
2. Define a master list of forms (CRFs) that will be used to collect patient data, including
 - Questions
 - Tables
 - Informational Prompts
3. Assign forms to the appropriate events.

Define the data structure for the study

Define the structure for the data that will be used to populate information in the user interface:

1. Define all codes to be used as options in dropdown lists and radio buttons on forms.
2. Define the dictionaries that will be used for encoding.
3. Define all data domains to be used in questions on forms.
4. Assign codelists and dictionaries to the appropriate domain items.

Define the logic for automatically populating fields and verifying data entry

1. Define and test the queries that will be used to verify data entry; then activate the appropriate range and edit checks.
2. Define and test the derivations that will be used to automatically calculate and populate field values; then, assign the derivations to the appropriate domain items.

Verify and publish the study.

1. Verify the study to ensure all study components are valid, and the relationships between components are complete and valid.
2. Publish the study to create a .zip file that contains an XML file of the study data.

After the XML file has been generated, it can be loaded into DataLabs for testing.

Collaboration

Designer allows multiple users to add and edit study components simultaneously. If two users are working with the same component at the same time, only the changes saved by the last user will be saved in Designer.

For example, if two users, A and B, are simultaneously editing the Demographics form and user A saves his changes first, when user B saves his changes, they will overwrite any changes made by user A.

Creating a Study

Creating a New Study

When you create a new study, you define the basic information used to identify the study in Designer.

To create a new study:

1. On the Designer Home page, click Create Study.

The Create Study page appears.

The screenshot shows the 'Study' creation page in the DataLabs Designer application. The page has a blue header with the application name and user information. Below the header is a navigation bar with icons for Home, Study, Events, Forms, Domains, Codelists, Dictionaries, and Scripting. The main content area is titled 'Study' and contains a form with the following fields:

- Study Name: (Required)
- Study Label: (Required)
- Protocol: (Required)
- Protocol Label: (Required)
- Protocol Title: (Optional)
- External Study ID: (Optional)
- Study Phase: (Optional)
- Study Drug Name: (Optional)
- Study Indication: (Required)
- Therapeutic Area: (Dropdown)
- Client/Sponsor: (Required)
- Date/Time Format: (Dropdown, currently set to 'United States (mm/dd/yyyy hh:mm:ss AP T)')

At the bottom of the form are 'Save' and 'Cancel' buttons.

2. Enter the study properties. Required fields are highlighted in blue with the field name shown in bold text.
3. Click **Save**.

Note: If you enter invalid characters, the text box is highlighted in red and an error message appears. You cannot save the study until all invalid entries have been corrected and all required fields have been entered.

When the study is saved, Designer creates placeholders for the basic study components. After the study and its placeholders have been successfully created:

- A confirmation notification appears to indicate that the study was successfully added.
- The study component buttons are enabled in the toolbar.
- The study is set as the active study as shown in the Study Name field.

- The study is added to the Designer Home page and the Last Active date and time is updated.

Note: If the study was not successfully created, an error message appears. Review the error details, resolve any issues and re-submit the study.

Copying an Existing Study

When you copy an existing study, the basic study components of the existing study are used to create a new study in Designer.

Best Practice: You can create one or more studies as templates and then use the Create Study From Existing feature to build new studies quickly and easily.

To copy an existing study:

1. On the Designer Home page, click Create Study from Existing.

The Create Study from Existing window appears.



2. Select the study you want to copy.

The Study page appears.

Study

Study Name: Aspirin41

Study Label: Aspirin

Protocol: ASCT-5150

Protocol Label: ASCT-5150-4

Protocol Title: Topical application of aspirin to cylindromatosis tumors.

External Study ID:

Study Phase: Phase IV

Study Drug Name: Aspirin

Study Indication: cylindromatosis tumors

Therapeutic Area: Pain Management

Client/Sponsor: Aspirin

Date/Time Format: United States (mm/dd/yyyy hh:mm:ss AP T)

Save Cancel

3. Modify the study properties with the information for the new study. At a minimum you must change the study name.

Required fields are highlighted in blue and the field name is shown in bold text.

4. Click Save.

Note: If you enter invalid characters, the text box is highlighted in red and an error message appears. You cannot save the study until all invalid entries have been corrected and all required fields have been entered.

5. The Study Management page shows the progress of the study creation process.
6. After study creation process is complete, click the status message for the study creation job.
 - If study was created but contained errors, the Study Creation Messages window lists all errors.
 - If the study was created without errors:

The study component buttons are enabled on the toolbar.

The study is set as the active study as shown in the Study Name field.

The study is added to the Designer Home page and the Last Active date and time is updated.

All existing Designer users are granted access to the study.

Importing a Study

You can import an existing XML file created in Designer 4.x or 5.x. to:

- Create a new study from a reusable base study.
- Re-deploy an older study that was previously archived from Designer.
- Migrate a study from Designer v4.x to v5.x.

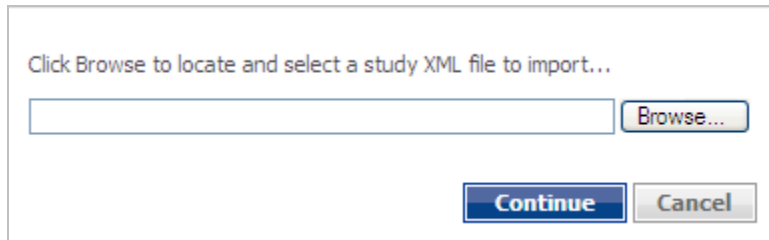
During the import process, you will have the opportunity to save or modify study properties before completing the import process.

Note: For imported studies, study level edit checks do not populate the descriptions and actions for domain level and form level edit checks.

To import a study:

1. On the Designer Home page, click Import Study.

The Import Study box appears.



2. Click Browse.
3. Navigate to and select the study XML file you want to import.
4. Click Continue.

The Study page appears.

Study

Study Name: Aspirin41

Study Label: Aspirin

Protocol: ASCT-5150

Protocol Label: ASCT-5150-4

Protocol Title: Topical application of aspirin to cylindromatosis tumors

External Study ID:

Study Phase: Phase IV

Study Drug Name: Aspirin

Study Indication: cylindromatosis tumors

Therapeutic Area: Pain Management

Client/Sponsor: Aspirin

Date/Time Format: United States (mm/dd/yyyy hh:mm:ss AP T)

Save Cancel

5. Modify any of the study properties, if necessary. Required fields are highlighted in blue and the field name is shown in bold text.

Note: To import an XML file created in Designer v4.x, you must specify a supply a Client/Sponsor and Therapeutic Area in order to complete the import process.

6. Click Save.

Note: If you enter invalid characters, the text box is highlighted in red and an error message appears. You cannot save the study until all invalid entries have been corrected and all required fields have been entered.

The Study Management page shows the progress of the import process.

7. After study import process is complete, click the status message for the import job.
- If study was imported but contained errors, the Study Import Messages window lists all errors.
 - If the study was imported without errors:
 - The study component buttons are enabled on the toolbar.
 - The study is set as the active study as shown in the Study Name field.
 - The study is added to the Designer Home page and the Last Active date and time is updated.
 - All existing Designer users are granted access to the study.

Script Authoring Status for Imported Studies

The Authoring Statuses available in Designer v5.x are different than those utilized in Designer v4.x. When importing a study generated by Designer v4.x, script authoring statuses are converted as follows:

Designer v4.x Script Authoring Status	Designer v5.x Script Authoring Status
Draft	Draft
Final	Validation
Verified	Production

Study Properties

Study Name (Required)

Appears on the DataLabs Study Version Properties screen and the Study Archive Export Report heading.

The Study Name can contain up to 16 characters. Valid characters: letters (a-z, A-Z), digits (0-9), and underscore ("_") only. No spaces or special characters are allowed.

The Study name must be unique within the Client/Sponsor.

If you are updating a study that was previously published, the Study Name must match the name of the previously-published study.

Study Label (Required)

Appears on the Header of the DataLabs workspace.

The Study Label can contain up to 50 characters. Valid characters: letters (a-z, A-Z), digits (0-9), underscore, blank, dash, dot, and opening and closing parenthesis. No special characters are allowed.

Protocol (Required)

The official unique protocol number used by the by the FDA.

Appears on the DataLabs Study Version Properties screen and the Study Archive Export Report heading

The Protocol can contain up to 100 characters.

If you are updating a study that was previously published, the Protocol must match the Protocol name of the previously-published study.

Protocol Label (Required)

Differentiates between versions of the same protocol.

Appears in the DataLabs Header Study Details

The Protocol Label can contain up to 100 characters.

Protocol Title

The official title by which the protocol is known to the FDA.

The Protocol Title can contain up to 255 characters.

External Study ID

Reference to an external system.

The External Study ID can contain up to 50 characters.

Study Phase

The clinical trial phase.

The Study Phase can contain up to 50 characters.

Study Drug Name

The name of the drug being studied.

The Study Drug Name can contain up to 50 characters.

Study Indication (Required)

The clinical efficacy claim being investigated.

The Study Indication can contain up to 50 characters.

Therapeutic Area (Required)

The general clinical trial category grouping.

The Therapeutic Area can contain up to 50 characters.

Client / Sponsor (Required)

The study stakeholder.

The Client/Sponsor can contain up to 50 alphanumeric characters. Valid characters include:

!@#%&*()_+|}{":?./;'[]\=-

Can contain spaces

Date/Time Format (Required)

Defines the date and time format that will be used to display dates for the study within DataLabs.

Note: The Date/Time Format does not determine the format used to display dates within Designer.

Note: If you are updating a study that was previously published, the Date/Time format you select must match the Date/Time format of the previously-published study.

Events

Overview

A study is comprised of a series of events for which patient data is collected. In Designer, there are three types of events:

- **Scheduled Events:** Throughout the duration of the study, patients in a study are expected to adhere to a data collection schedule as defined by the study protocol. A scheduled event represents a pre-planned patient visit.
- **Unscheduled Events:** Unforeseen circumstances, such as an adverse reaction to the study medication, may cause a patient to make a visit outside of the schedule of pre-planned patient visits. An unscheduled event represents an event that is not part of the pre-planned schedule as defined by the study protocol.

An Unscheduled Event is automatically added to the Events page when you create a new study.

- **Common Event:** The Common Event is associated with forms that can be collected at any time during the study and that are not associated with a particular event. An example is a form used to collect patient information about concomitant medications.

The Common Event is automatically added to the Events page when you create a new study.

The following sections describe how to:

- Define the scheduled events for which patient data is to be collected, you can:
- Assign forms to an event.
- Define a schedule for the event.
- Define event cycles for manually publishing events and forms in DataLabs.
- Disable event date collection for events.
- Assign individual or multiple forms to an event.

Adding a Scheduled Event

Scheduled events represent a chronological series of patient visits based on the study protocol. You can use the Events page to add scheduled events for the study.

Before you begin adding events, determine the number of events you'll create, the name of each event, and the order in which you want the events to appear in the patient's casebook in DataLabs. This will allow you to set up the study's event structure more quickly and easily.

To add a scheduled event:

1. On the menu bar, click Events.

The Events page appears.

The screenshot shows the 'Events' page with a table of existing events. The table has columns for Event Name, Event Label, Event Type, Publish Event On, Event Date, Event Category, Last Updated, Edit, and Delete. The 'Add Event' button is highlighted with a red box.

	Event Name	Event Label	Event Type	Publish Event On	Event Date	Event Category	Last Updated	Edit	Delete
▶	Common	Common	Common	Screened	Disabled		16-Apr-2010 02:30:42 PM UTC		
▶	Unscheduled	Unscheduled	Unscheduled	Screened	Enabled		21-Apr-2010 11:22:24 PM UTC		
▶	<input type="checkbox"/> Screening	Screening	Scheduled	Screened	Enabled		21-Apr-2010 11:22:24 PM UTC		
▶	<input type="checkbox"/> Dosing	Dosing	Scheduled	Enrolled	Enabled		19-Apr-2010 09:55:33 PM UTC		
▶	<input type="checkbox"/> Review	Review	Scheduled	Enrolled	Enabled		21-Apr-2010 06:01:28 PM UTC		
▶	<input type="checkbox"/> Pain	Pain	Scheduled	Screened	Enabled		21-Apr-2010 11:22:24 PM UTC		
▶	<input type="checkbox"/> Dosing2	Dosing 2	Scheduled	Enrolled	Enabled		16-Apr-2010 02:31:00 PM UTC		
▶	<input type="checkbox"/> Review2	Review 2	Scheduled	Enrolled	Enabled		16-Apr-2010 02:30:59 PM UTC		
▶	<input type="checkbox"/> Complete	Complete	Scheduled	Screened	Enabled		20-Apr-2010 10:00:42 PM UTC		

2. Click Add Event.

A new row is added to the Events grid.

The screenshot shows the 'Events' page with a new row added to the table. The 'Add Event' button is highlighted with a red box. The new row has empty input fields for Event Name, Event Label, Event Date, and Event Category, and a green checkmark in the Edit column and a red X in the Delete column.

	Event Name	Event Label	Event Type	Publish Event On	Event Date	Event Category	Last Updated	Edit	Delete
▶	<input type="text"/>	<input type="text"/>		--	Enabled	<input type="text"/>			

3. Enter the event properties. Required fields are highlighted in blue.

Note: If you enter invalid characters, the text box that contains invalid characters is highlighted in red and an error message appears. You cannot save the event until all invalid entries have been corrected and all required fields have been entered.

4. Click to save your changes.

- A confirmation notification appears to indicate that the event was successfully added.

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- The event is added to the Events grid and its Last Updated date and time is updated.

Note: The order in which events appear on the Event page is the order in which the events will appear in patient casebooks in DataLabs. You can re-order events by clicking and dragging an event to a new position.

Event Properties

Event Name (Required)

Defines the short, unique name for the event. The Event Name is used internally by Designer and DataLabs to identify the event.

The Event Name can contain up to 50 characters. Valid characters include A-Z, a-z, 0-9 and spaces. Underscores are not allowed. An event name of "Required" is not allowed.

Event Label (Required)

Defines a unique display name of the event. The event label is the display name for the event in DataLabs.

The Event Label can contain up to 50 characters. Valid characters include A-Z, a-z, 0-9 and spaces. The following special characters are also allowed: ()-_. An event label of "Required" is not allowed.

Event Type (Read Only)

Displays the event type as Scheduled, Unscheduled or Common.

Publish Event on (Required)

Selects which patient workflow action publishes the event in DataLabs. When an event is published in DataLabs, the event and its associated forms will appear in a patient's casebook.

Options include:

- [blank] (default)
- Screened
- Failed
- Enrolled
- Discontinued
- Completed
- Cycle...

Note An event cycle represents a set of events and forms that can be manually published in DataLabs. Event cycles are automatically published in order starting with cycle 1; therefore, event cycles should be logically ordered within the study design.

Event Date

Determines if DataLabs users will be able to enter an event date for the event.

- Enabled - In DataLabs, users will be able to enter an event date for the event.

- Disabled - In DataLabs, users will be able to enter an event date for the event.

Note Event date collection is always enabled for the Unscheduled Event and cannot be changed. Event date collection is always disabled for the Common Event and cannot be changed.

Event Category (Optional)

Defines the CDISC category the event falls into. Valid characters include: A-Z, a-z, 0-9, !@#%&*_+ | } { " : ? > < , . / ; ' [] \ = - and spaces.

Defining the Number of Event Cycles

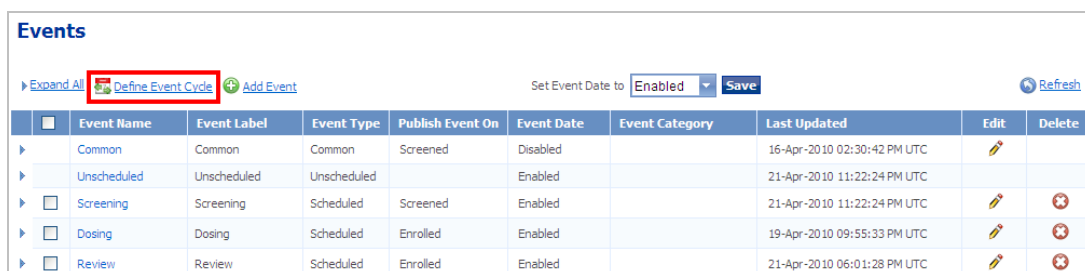
Although the study protocol determines the number of visits for the study, there may be times when you want to publish one or more additional sets of events and their associated forms. This would allow you to extend a patient's participation beyond the length of the originally proposed study and to collect additional patient data.

An event cycle represents a set of events and forms that can be manually published in DataLabs by authorized DataLabs users. You can configure a study to have none, one or multiple event cycles.

To define the number of event cycles for a study:

1. On the menu bar, click Events.

The Events page appears.

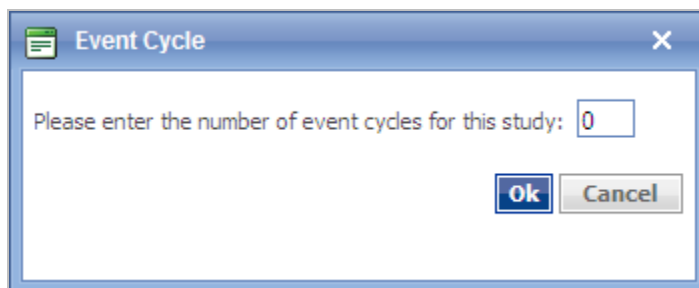


The screenshot shows the 'Events' page with a table of event configurations. The 'Define Event Cycle' button is highlighted with a red box. The table has the following data:

	Event Name	Event Label	Event Type	Publish Event On	Event Date	Event Category	Last Updated	Edit	Delete
▶	Common	Common	Common	Screened	Disabled		16-Apr-2010 02:30:42 PM UTC		
▶	Unscheduled	Unscheduled	Unscheduled		Enabled		21-Apr-2010 11:22:24 PM UTC		
▶	Screening	Screening	Scheduled	Screened	Enabled		21-Apr-2010 11:22:24 PM UTC		
▶	Dosing	Dosing	Scheduled	Enrolled	Enabled		19-Apr-2010 09:55:33 PM UTC		
▶	Review	Review	Scheduled	Enrolled	Enabled		21-Apr-2010 06:01:28 PM UTC		

2. Click Define Event Cycle.

The Event Cycle window appears.



The 'Event Cycle' dialog box contains the following text and controls:

Please enter the number of event cycles for this study:

Buttons:

3. Enter the number of cycles you want to define for the study.
4. Click OK.

When you add a new event or edit an existing event, you can select the event cycle that will be used to publish the event.

Reducing the Number of Event Cycles

The number of cycles that a study contains can only be reduced if no events have been associated to any of the cycles that you want to reduce. For example, if the study contains three cycles and all three cycles are associated with events, you cannot reduce the number of event cycles for the study to 2.

Note Event cycles are associated with events in the Publish Event on field on the Event page.

Setting an Event Schedule Window

You can schedule a window of time during which an event should occur in relation to a preceding event. For example, you can set a schedule to indicate that a patient's second visit should happen within five to ten days after the patient's first visit.

The minimum, maximum, and ideal values defined for the event schedule window can be used to trigger a query if the event does not occur within the specified schedule. These values can also be used to derive the value of a field on a CRF.

Note: You cannot define an event schedule window for the first event, the Common Event, and the Unscheduled Event.

To set the event schedule window:

1. On the menu bar, click Events.

The Events page appears.

2. Click the name of the event you want to schedule.

The Event Details page appears.

The screenshot shows the 'Review' page with the 'Window' tab selected. Below the tabs is a table with five columns: 'Window Reference Event', 'Unit of Time', 'Minimum', 'Ideal', and 'Maximum'. Each column contains a dropdown menu or a text input field. The 'Window Reference Event' dropdown is set to '--', 'Unit of Time' is '--', and the 'Minimum', 'Ideal', and 'Maximum' input fields all contain the value '0'. A 'Save' button is located at the bottom left of the form.

3. Click the Window tab.

This screenshot is identical to the previous one, showing the 'Review' page with the 'Window' tab selected. The table fields are: 'Window Reference Event' (dropdown set to '--'), 'Unit of Time' (dropdown set to '--'), 'Minimum' (input field with '0'), 'Ideal' (input field with '0'), and 'Maximum' (input field with '0'). A 'Save' button is at the bottom left.

3. Enter the event schedule window properties.
4. Click **Save**.

A confirmation notification appears to indicate that the event schedule window was successfully added.

Note: If you enter invalid characters, the text box that contains the invalid characters is highlighted in red and an error message appears. You cannot save the event window schedule until all invalid entries have been corrected and all required fields have been entered.

Event Schedule Window Properties

Window Reference Event

Select from a list of previous events, the event to use as a reference for the time window.

Note: You cannot select the Common Event or Unscheduled Event as reference events.

Unit of Time

Select the unit of time used for the minimum/ideal/maximum for the event schedule window.

Minimum

Enter the *minimum* time the selected event will occur after the reference event.

Ideal

Enter the *ideal* time the selected event will occur after the reference event. This value must be greater than the minimum.

Maximum

Enter the *maximum* time the selected event will occur after the reference event. This value must be greater than the ideal.

Disabling Event Date Collection

In DataLabs, users can manually enter a date for each event to indicate the date the event occurred. In Designer, you can enable or disable event date collection for each event within a study. If you disable event date collection for an event, users will not be able to enter a date for that event in DataLabs.

Note Event date collection is always enabled for the **Unscheduled Event** and cannot be changed. Event date collection is always disabled for the **Common Event** and cannot be changed.

To disable event date collection:

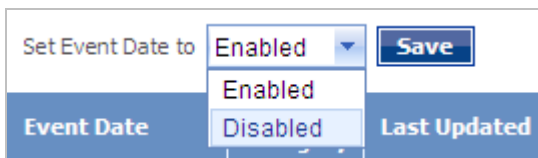
1. On the menu bar, click Events.

The Events page appears.

2. Select the events for which you want to disable event collection.

	Event Name	Event Label	Event Type	Publish Event On	Event Date	Event Category	Last Updated	Edit	Delete
<input type="checkbox"/>	Common	Common	Common	Screened	Disabled		05-Apr-2010 03:42:50 PM UTC		
<input type="checkbox"/>	Unscheduled	Unscheduled	Unscheduled		Enabled		05-Apr-2010 09:17:38 PM UTC		
<input type="checkbox"/>	Screening	Screening	Scheduled	Screened	Enabled		05-Apr-2010 03:43:11 PM UTC		
<input type="checkbox"/>	Dosing	Dosing	Scheduled	Enrolled	Enabled		05-Apr-2010 03:43:12 PM UTC		
<input type="checkbox"/>	Pain	Pain	Scheduled	Screened	Enabled		07-Apr-2010 05:57:49 PM UTC		
<input type="checkbox"/>	Review	Review	Scheduled	Enrolled	Enabled		05-Apr-2010 03:43:11 PM UTC		
<input checked="" type="checkbox"/>	Dosing2	Dosing 2	Scheduled	Enrolled	Enabled		05-Apr-2010 03:43:12 PM UTC		

3. Select Disabled in Set Event Date to.



4. Click Save.

The Event Date status changes to Disabled for the selected events.

Adding Forms to an Event

Assigning a Form to an Event

Each event has one or more forms associated with it. In DataLabs, during an event, patient data is collected on the forms associated with the event. You can use the Event Details page to assign forms to an event.

Assigning Forms to the Unscheduled Event

An unscheduled event represents an event that is not part of the pre-planned schedule as defined by the study protocol.

In DataLabs, when a user adds an unscheduled event for a patient, the user is presented with a list of all of the forms associated with the Unscheduled Event. The user selects, from the list, the form(s) to use to collect information for that specific event.

In Designer, you use the Event Details page to create a list of the forms a DataLabs user can select from when adding an unscheduled event to a patient's casebook.

Note: You cannot add patient status forms to the Unscheduled Event.

Assigning Forms to the Common Event

The Common Event is associated with forms that can be collected at any time during the study and that are not associated with a particular event. When a study is created the Common Event is automatically created and the patient status forms are automatically associated with it.

You cannot remove the patient status forms from the Common Event; however, if your study protocol calls for it, you can add other non-visit related forms to the Common Event.

To assign a form to an event:

1. On the menu bar, click Events.

The Events page appears.

Event Name	Event Label	Event Type	Publish Event On	Event Date	Event Category	Last Updated	Edit	Delete
Common	Common	Common	Screened	Disabled		16-Apr-2010 02:30:42 PM UTC		
Unscheduled	Unscheduled	Unscheduled		Enabled		21-Apr-2010 11:22:24 PM UTC		
Screening	Screening	Scheduled	Screened	Enabled		21-Apr-2010 11:22:24 PM UTC		
Form Name		Form Label		Planned/Optional		Restricted		
Demo		Demographics		Planned		Unrestricted		
PRM		Patient Recruitment Method		Planned		Unrestricted		
MedHist		Medical History		Planned		Unrestricted		
Incl		Inclusion		Planned		Unrestricted		
Excl		Exclusion		Planned		Unrestricted		
<input type="checkbox"/>	Dosing	Dosing	Scheduled	Enrolled	Enabled	19-Apr-2010 09:55:33 PM UTC		
<input type="checkbox"/>	Review	Review	Scheduled	Enrolled	Enabled	21-Apr-2010 06:01:28 PM UTC		
<input type="checkbox"/>	Pain	Pain	Scheduled	Screened	Enabled	21-Apr-2010 11:22:24 PM UTC		

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- Click the name of the event you want to assign a form to.

The Event details page appears.

Form Name	Form Label	Planned/Optional	Restricted	Edit	Remove
Demo	Demographics	Planned	Unrestricted		
PRM	Patient Recruitment Method	Planned	Unrestricted		
MedHist	Medical History	Planned	Unrestricted		
Ind	Inclusion	Planned	Unrestricted		
Exd	Exclusion	Planned	Unrestricted		

- On the Forms tab, click **Add Form**.

A row is added to the Forms grid.

- Select the form you want to assign to the event.

Form Name	Form Label	Planned/Optional	Restricted	Edit	Remove
AE		Planned	<input type="checkbox"/>		
AE	Demographics	Planned	Unrestricted		
ConMed	Patient Recruitment Method	Planned	Unrestricted		
CRA	Medical History	Planned	Unrestricted		
Demo2					
Ind	Inclusion	Planned	Unrestricted		

- Enter the form properties. Required fields are highlighted in blue.

- Click to save your changes.

- A confirmation notification appears to indicate that the form was successfully added to the event.
- The form is added to the Forms grid.
- The Last Updated date and time is updated for the event associated with the form.

Form Properties

Form Name (Required)

Select the form you want to add to the event.

Planned/Optional (Optional)

Selects whether the form is planned (required) or optional for collection for the event.

Note This selection affects the expected count in DataLabs.

Restricted (Optional)

Selects whether users lacking the proper permissions in DataLabs will be restricted from accessing the form.

Assigning Multiple Forms to an Event

Each event has one or more forms associated with it. In DataLabs, during an event, patient data is collected on the forms associated with the event.

To assign multiple forms to an event:

1. On the menu bar, click Events.

The Events page appears.

Events

Click the right arrow or Expand All to see the forms assigned to an event.

Expand All Define Event Cycle Add Event Set Event Date to Enabled Save Refresh

Event Name	Event Label	Event Type	Publish Event On	Event Date	Event Category	Last Updated	Edit	Delete
Common	Common	Common	Screened	Disabled		16-Apr-2010 02:30:42 PM UTC		
Unscheduled	Unscheduled	Unscheduled	Screened	Enabled		21-Apr-2010 11:22:24 PM UTC		
Screening	Screening	Scheduled	Screened	Enabled		21-Apr-2010 11:22:24 PM UTC		
Form Name		Form Label		Planned/Optional		Restricted		
Demo		Demographics		Planned		Unrestricted		
PRM		Patient Recruitment Method		Planned		Unrestricted		
MedHist		Medical History		Planned		Unrestricted		
Incl		Inclusion		Planned		Unrestricted		
Excl		Exclusion		Planned		Unrestricted		
Dosing	Dosing	Scheduled	Enrolled	Enabled		19-Apr-2010 09:55:33 PM UTC		
Review	Review	Scheduled	Enrolled	Enabled		21-Apr-2010 06:01:28 PM UTC		
Pain	Pain	Scheduled	Screened	Enabled		21-Apr-2010 11:22:24 PM UTC		

2. Click the name of the event you want to assign forms to.

The Event details page appears.

Screening

Forms Window

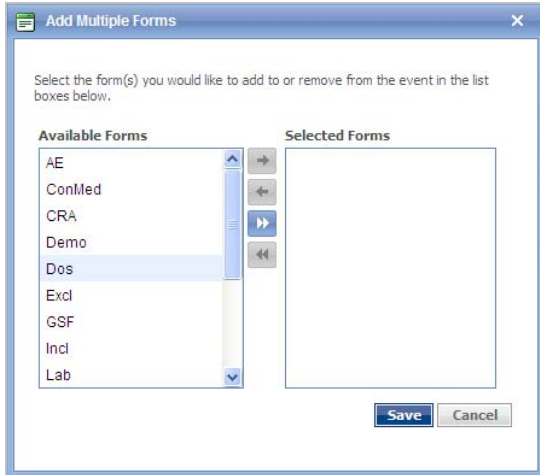
Add Form Add Multiple Forms Refresh




Form Name	Form Label	Planned/Optional	Restricted	Edit	Remove
Demo	Demographics	Planned	Unrestricted		
PRM	Patient Recruitment Method	Planned	Unrestricted		
MedHist	Medical History	Planned	Unrestricted		
Incl	Inclusion	Planned	Unrestricted		
Excl	Exclusion	Planned	Unrestricted		

3. On the Forms tab, click **Add Multiple Forms**.

The Add Multiple Forms window appears.

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5. Do one of the following:
 - To add individual forms to the event, in the Available Forms box, select the form you want to add and click .
 - To add multiple forms to the event, in the Available Forms box, press the CTRL key and select the forms you want to add, then click .
 - To add all forms to the event, click .
6. Click Save to save your changes.
 - The forms are added to the Events Details page and the Last Updated date and time is updated for the event.
 - The Last Updated date and time is updated for the event associated with the form.

Forms

Overview

A study is comprised of a series of events for which patient data is collected. For each event, DataLabs personnel use case report forms (CRFs) to record patient information. For example, a form could be used to collect patient demographics or medical history.

A form can contain three types of information:

- **Questions:** A question consists of a prompt and a data entry field where a user can enter or select an answer to the question.
- **Tables:** A table is used to group related questions on a form. A table consists of one or more columns and two or more rows.
- **Informational Text:** Informational text provides notes and instructions to the personnel entering data into the form in DataLabs.

As you add these items to a form, the order in which they appear on the form in Designer will be the order in which they will appear on the form in DataLabs.

The following sections describe how to:

- Add forms to a study.
- Create a form by copying a form from the current study or from another study.
- Add questions to forms.
- Add tables to forms.
- Add questions to tables.
- Add informational text to forms.

Creating Forms

Adding a Form to the Study

In DataLabs, study personnel use forms to record patient information. For example, a form could be used to collect patient demographics or medical history. You can use the Forms page to define each form you are going to use in the study.

To add a form:

1. On the menu bar, click Forms.


The Forms page appears.

Form Name	Form Label	Last Updated	Valid	Edit	Delete
AE	Adverse Event	16-Apr-2010 02:31:00 PM UTC	Valid: The form (a) has at least one questions and (b) none of the questions are invalid.		
Comp	Completed	16-Apr-2010 02:30:42 PM UTC			
ConMed	Concomitant Medications	21-Apr-2010 02:49:18 PM UTC			
CRA	Cardio Risk	21-Apr-2010 02:50:48 PM UTC	Invalid: The form (a) has no valid questions or (b) has at least one invalid question.		
Demo	Demographics	16-Apr-2010 02:31:00 PM UTC			
Demo2	Demographics2	16-Apr-2010 02:31:02 PM UTC			
Disc	Discontinued	16-Apr-2010 02:30:42 PM UTC			
Dos	Dosing	16-Apr-2010 02:31:01 PM UTC			
Enroll	Enrolled	16-Apr-2010 02:30:42 PM UTC			
Excl	Exclusion	16-Apr-2010 02:31:02 PM UTC			

2. Click Add Form.

A new row is added to the Forms grid.

Form Name	Form Label	Last Updated	Valid	Edit	Delete
AE	Adverse Event	16-Apr-2010 02:31:00 PM UTC			

3. Enter the form name and form label.
4. Click  to save the changes.
 - A confirmation notification appears to indicate that the form was successfully added.
 - The form is added to the Forms grid and its Last Updated date and time and Validity status is updated.

Once you define a form, you can define the create the structure of the CRF, including questions, tables, and informational text. For more information, see "Adding Question to a Form," "Adding Tables to a Form," and "Adding Information Text to a Form."

You can also assign the form to the events for which the form will be used to collect patient information. For more information, see "Assigning a Form to an Event."

Form Name and Form Label

Form Name (Required)

Defines the short, unique name for the form. The form name is used internally by both Designer and DataLabs to identify the form.

The form name can contain up to 50 characters. Valid characters: letters (a-z, A-Z), digits (0-9), and underscore ("_") only. Spaces are not allowed.

Form Label (Required)

Defines the unique display name of the form. The form label appears as the form name throughout the study and on the header of the DataLabs workspace.

The form label can contain up to 50 characters. Valid characters include letters (a-z, A-Z), digits (0-9), underscore ("_"), spaces, and the special characters ()_./\ - only.

Copying a Form

There are studies where a number of forms are similar to one another. You can use the Forms page to create a new form by copying an existing form.

Best Practice: You can create one or more studies as templates and then use the Create Study From Existing feature to build new studies.

When a form is copied, the following information is copied into the new form:

- Form properties
 - Form name
 - Form label
- Form components and their details
 - Questions
 - Tables
 - Info prompts
 - Conditional properties
 - Edit checks
 - Range checks

In addition, the study component associations are maintained in the new form, including: domains, domain items, codelists, dictionaries, and derivations. Any queries associated with the form are not copied and must be copied separately. For information on copying a query, see "Copying a Query."

Note You cannot copy Patient Status forms.

To copy a form:

1. On the menu bar, click Forms.

The Forms page appears.

2. Select the form(s) you want to copy.

<input type="checkbox"/>	Form Name	Form Label	Last Updated	Valid	Edit	Delete
<input type="checkbox"/>	AE	Adverse Event	05-Apr-2010 03:43:12 PM UTC	✓		
<input type="checkbox"/>	Comp	Completed	05-Apr-2010 03:42:50 PM UTC	✓		
<input type="checkbox"/>	ConMed	Concomitant Medications	05-Apr-2010 03:43:13 PM UTC	✓		
<input type="checkbox"/>	CRA	Cardio Risk	05-Apr-2010 03:43:13 PM UTC	✓		
<input checked="" type="checkbox"/>	Demo	Demographics	05-Apr-2010 09:00:33 PM UTC	✓		

2. Click Copy Form.

A new row is added to the Forms grid for each new copy. The name of each newly-copied form is appended with a suffix, "COPY_01" and is inserted according to alphabetical order within the Forms grid.

<input type="checkbox"/>	Form Name	Form Label	Last Updated	Valid	Edit	Delete
<input type="checkbox"/>	AE	Adverse Event	05-Apr-2010 03:43:12 PM UTC	✓		
<input type="checkbox"/>	Comp	Completed	05-Apr-2010 03:42:50 PM UTC	✓		
<input type="checkbox"/>	ConMed	Concomitant Medications	05-Apr-2010 03:43:13 PM UTC	✓		
<input type="checkbox"/>	CRA	Cardio Risk	05-Apr-2010 03:43:13 PM UTC	✓		
<input checked="" type="checkbox"/>	Demo	Demographics	05-Apr-2010 09:00:33 PM UTC	✓		
<input type="checkbox"/>	Demo_Copy1	Demographics_Copy1	05-Apr-2010 09:04:13 PM UTC	✓		

If you are copying multiple forms and an error is encountered during the copy process, the system skips that form and proceeds to the next one.

When all of the selected forms have been copied, a message appears to indicate the number of forms that were successfully copied.

Copying a Form from Another Study

In DataLabs, study personnel use forms to record patient information. You can use the Forms page to copy a form from another study. The following information is copied from the existing form into the new form:

- Parameters
- Script Text
- Form References

To copy a form from another study:

1. On the menu bar, click Forms.

The Forms page appears.

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Forms

[Add Form](#) [Copy Form](#) [Create Form from Existing](#) [Show/Hide Filter](#) [Refresh](#)

<input type="checkbox"/>	Form Name	Form Label	Last Updated	Valid	Edit	Delete
<input type="checkbox"/>	AE	Adverse Event	16-Apr-2010 02:31:00 PM UTC			
<input type="checkbox"/>	Comp	Completed	16-Apr-2010 02:30:42 PM UTC			
<input type="checkbox"/>	ConMed	Concomitant Medications	21-Apr-2010 02:49:18 PM UTC			
<input type="checkbox"/>	CRA	Cardio Risk	21-Apr-2010 02:50:48 PM UTC			
<input type="checkbox"/>	Demo	Demographics	16-Apr-2010 02:31:00 PM UTC			
<input type="checkbox"/>	Demo2	Demographics2	16-Apr-2010 02:31:02 PM UTC			
<input type="checkbox"/>	Disc	Discontinued	16-Apr-2010 02:30:42 PM UTC			
<input type="checkbox"/>	Dos	Dosing	16-Apr-2010 02:31:01 PM UTC			
<input type="checkbox"/>	Enroll	Enrolled	16-Apr-2010 02:30:42 PM UTC			
<input type="checkbox"/>	Exd	Exclusion	16-Apr-2010 02:31:02 PM UTC			

Page size: 10 24 items in 3 pages

2. Click Create Form from Existing.

The Please select a Study page appears.

Please select a Study

Client/Sponsor	Study Name	Study Label	Protocol	Therapeutic Area	Drug Name
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Sponsor 1	Aspirin	Aspirin41	069752	Pain Management	Drug Name
Sponsor 2	Aspirin41	Aspirin	211573	Pain Management	Drug Name
Sponsor 3	Kidney	Kidney Diseases 11	024579	Nephrology	Drug Name
Sponsor 4	TCell	T Cell Immunodeficiency	069752	Infectious Disease	Drug Name
Sponsor 5	Diabetes	Diabetes Study	099571	Endocrinology	Drug Name
Sponsor 6	Back_Pain	Back Pain Study	076407	Pain Management	Drug Name
Sponsor 7	Rheuma	Rheumatology Study	024589	Rheumatology	Drug Name
Sponsor 8	Eating	Eating Disorders	053283	Psychiatry	Drug Name

Page size: 10 8 items in 1 pages

3. Select the study that contains the form you want to copy.

The Please select a form page appears.

Form Name	Form Label	Last Updated	Valid
AE	Adverse Event	05-Apr-2010 03:43:12 PM UTC	✓
ConMed	Concomitant Medications	05-Apr-2010 03:43:13 PM UTC	✓
CRA	Cardio Risk	05-Apr-2010 03:43:13 PM UTC	✓
Demo	Demographics	05-Apr-2010 09:00:33 PM UTC	✓
DIQ	DIQ	05-Apr-2010 09:04:13 PM UTC	✓
Dos	Dosing	05-Apr-2010 03:43:13 PM UTC	✓
Excl	Exclusion	05-Apr-2010 03:43:14 PM UTC	✓
GSP	Genetic Sample	05-Apr-2010 03:43:14 PM UTC	✓
Incl	Inclusion	05-Apr-2010 03:43:13 PM UTC	✓
Lab	Laboratory	05-Apr-2010 03:43:13 PM UTC	✓

4. Do one of the following:
 - Select **Copy Associated Domains** to copy the form properties, table headings, domains and their associated components from the existing form to the new form.
 - Clear **Copy Associated Domains** to copy only the form properties and table headings from the existing form to the new form.
5. Select the form you want to copy.

The Please set Form and Domain properties page appears.

	Includ	Existing	New		Includ	Existing	New	
Form Name:		AE	AE	Enter a new Form Name and Form Label.				
Form Label:		Adverse Event	Adverse Event					
Table Name:		Events	Events					
Domain:		XXAE	XXAE	Select if you want to copy an item's associated codelist, dictionary, or derivation.				
Item:	✓	AESerious	AESerious		Codelist	✓	YesNoNA	YesNoNA
Item:	✓	AETerm	AETerm		Dictionary	✓	Conditions	Conditions

6. Do the following:
 - Enter the form name and form label for the new form.
 - Enter table names, if any, for the tables on the new form.
 - Select the domain items you want to copy and enter a new name for each domain item.
 - For each domain item you want to copy, indicate if you want to copy its associated codelist, dictionary, or derivation. Enter a new name for the codelist, dictionary, or derivation.

Printed Documentation

7. Click **Save**.

- A confirmation notification appears to indicate that the form was successfully added.
- The form is added to the Forms grid and its Last Updated date and time and Validity status is updated.

Form Questions

Adding a Question to a Form

In DataLabs, study personnel use forms to record patient information. A question appears as a prompt on the form and represents a specific piece of patient information to be collected, such as the patient's blood pressure or ethnicity.

Note The order in which questions appear on the form in Designer will be the order in which they will appear on the form in DataLabs. You can reorder questions by clicking and dragging a question to a new location on the Questions grid.

You can use the Form details page to add a question prompt to a form.

To add a question to a form:

1. On the menu bar, click Forms.

The Forms page appears.

2. Click the name of the form you want to add questions to.

The Form Details page appears.

#	Question Prompt	Data Type	Valid	Edit	Delete
1.	Did any adverse event occur?	Valid: A domain and domain item have been assigned to the question.	✓	✎	✖
2.	Was a physical exam performed?	Invalid: A domain and domain item have not been assigned to the question.	✗	✎	✖

3. Click Add Question.

A new row is added to the Questions grid.

#	Question Prompt	Data Type	Valid	Edit	Delete
	<input type="text"/>	<Undefined>	✗	✎ ✗	✖

4. Enter the question prompt.

5. Click ✓ to save the changes.

- A confirmation notification appears to indicate that the question was successfully added.
- The question is added to the Questions grid and the question's validity is updated.

After a question prompt has been added to Designer, you can define question properties which define how the question will appear and behave in DataLabs. For more information, see "Adding Question Properties."

Adding Question Properties

In DataLabs, study personnel use forms to record patient information. A question appears as a prompt on the form and represents a specific piece of patient information to be collected, such as the patient's blood pressure or ethnicity.

Question properties define how a question will appear and behave in DataLabs. You can:

- Hide a question so that it is only displayed to DataLabs users with the appropriate permissions.
- Display or hide the question based on answers to other questions on the form. These are called conditional questions.
- Select the method in which answers to the question are displayed (drop down list, radio buttons, etc.).
- Specify that the answer to the question must be in a particular format or within a certain range of values. These are called edit checks and range checks, respectively.

To add a properties to a question:

1. On the Form Details page, click the question prompt you want to add properties to.
The Question Properties page appears.

2. Enter the question properties.
 - To hide the question so that it is only displayed to DataLabs users with the appropriate permissions, select **Question Hidden**.
 - To display the question based on answers to other questions on the form, add conditional properties. For more information, see [Adding Conditional Questions](#).
 - To specify that the answer to the question must be in a particular format or within a certain range of values, add edit checks. For more information, see [Adding Edit Checks](#).

3. Click Save to save the changes.
 - A confirmation notification appears to indicate that the question was successfully added.
 - The question is added to the Questions grid and its validity status is updated.

Question Properties

Domain Name (Required)

Select the domain that contains the domain item you want to assign to the question.

Note The Domain Name list includes domains that have not been assigned domain items.

Item Name (Required)

Select the domain item you want to assign to the question. The list of items displayed is based on the domain you selected.

Note Only questions you haven't already added to a form appear in the list (since you can't place the same question on the form twice).

Display Options

Allows you to choose the method presented on the form to DataLabs users for selecting or entering a response to the question. The Display Options you can choose depend on the data type associated with the domain item.

- For date fields, you can indicate if a calendar (datepicker) will be available.
- For text fields, you can select "Text" or "TextArea"
- For codelists, you can select whether the codelist items will be shown as a "Drop-Down" list or as "Radio" buttons.

Question Prompt (Required)

Defines the text that will appear on the form in DataLabs, describing the question to the user.

The Question Prompt is automatically populated based on the Question Prompt entered on the Form Details page; however, if you edit the Question Prompt on the Question Properties page, it will be updated on the Questions grid.

Question Hidden

If selected, only authorized users will be able to view the question on the form in DataLabs. This option is usually used with derived fields where it is necessary to collect a value for the study data, but does not need to be seen by the DataLabs users who is filling out the form.

On the Form Details page, hidden questions are numbered with a decimal suffix (for example, 3.1).

Note If Question Hidden is selected, the question cannot be conditional, PDE Verify or Column Display.

PDE Verify Only

If selected, the question will only go through paper data entry (PDE) verification on the second pass.

If cleared, the question will go through second pass paper data entry.

Note A question can be either Question Hidden or PDE Verify Only, but not both.

Adding a Conditional Question

In DataLabs, a conditional question will become active based on the answer of another question on the same form.

Example If there is a question on an adverse event form that asks "Is the adverse event continuing?" If a user enters "No," a second question can appear on the form prompting the user to enter the date the adverse event stopped. Therefore, you would set the "Stop Date" question to be conditional upon "No" being selected for the "Is the adverse event continuing" question.

On the Form Details grid, conditional questions are marked with a "C" for "Conditional."

Restrictions:

- A question can be conditional on a question on the same form. No cross-form conditional questions are permitted.
- A table question can be conditional on a question in the same table; however a table question cannot be conditional on a non-table question.
- If a question is Hidden or Derived, it cannot be marked as conditional.

A conditional question is active only if another question on the form matches certain criteria.

To add a conditional question:

1. On the Form Details page, click the question prompt you want to define as a conditional question.

The Question Properties page appears.

Properties

Question Edit Checks

Save Save & Close Cancel

Question

Domain Name: Item Name:

Display Options: Short Prompt:

Question Prompt:

Question Hidden PDE Verify Only None

Conditional

Item Name: In this example, the prompt "Stop Date" will appear on the form only if a DataLabs user selects "No" as the answer to "Is the Adverse Event continuing?"

Comparator:

Values:

2. Enter the question properties.
3. Enter the conditional properties.
3. Click Save to save the changes.
 - A confirmation notification appears to indicate that the question was successfully added.
 - The question is added to the Questions grid and its validity status is updated.

Conditional Question Properties

Item Name

Defines the question sets the condition. If the question is in a table, only those questions in the same table are listed.

Comparator

Selects the method to compare the values.

Values

Defines the value(s) to use with the conditional question.

- If you select "In List" or "Not In List as your comparator), you can enter multiple values, delimited with a pipe (|).
- If you have select "Equal To" or "Not Equal To" as the comparator, it treats all special characters—such as comma (,), pipe (|), etc.—literally, and not as separators.

Valid characters: (a-z, A-Z), digits (0-9), spaces and `~!@#%&*()_+|}{":?><./;[]\=-``

Table Questions

Adding a Table to a Form

A table provides for groups of related information which can be entered multiple times within the same form.

Examples

- Concomitant medications
- Adverse events
- Medical history

There are two types of tables:

- **Default tables:** Contain user-defined data in each column and requires that, in DataLabs, users must manually add rows to the form. Default tables are typically used for information that may not be expected, such as adverse events, but must be collected.
- **Autobuild tables:** Contain specific columns filled with pre-defined values and is automatically built based on one or more codelists when a user checks out the form in DataLabs. Autobuild tables are typically used when information is expected an required to be collected, such as "body systems" on a Physical Exam form. For more information, see Adding an AutoBuild Table.

Note The order in which tables appear on the form in Designer will be the order in which they will appear on the form in DataLabs.

You can use the Form Details page to add a table to a form.

To add a table to a form:

1. On the menu bar, click Forms.

The Forms page appears.

2. Click the name of the form you want to add a table to.

The Form Details page appears.

#	Question Prompt	Data Type	Valid	Edit	Delete
1.	Did any adverse event occur?		✓	✎	✖
2.	Was a physical exam performed?		✗	✎	✖
3.	Adverse Events		✗	✎	✖

3. Click Add Table.

A new row is added to the Questions grid.

#	Question Prompt	Data Type	Valid	Edit	Delete
		<Undefined>			

4. Enter the table prompt.
5. Click to save the changes.
 - A confirmation notification appears to indicate that the table was successfully added.
 - The table is added to the Questions grid and the table's validity status is updated.

After a table has been added to Designer, you can define table properties which give you options for how the table will appear and behave in DataLabs. For more information, see "Adding Table Properties."

Adding Table Properties

You can use the Table Properties page to set various properties for the table which will help users in collecting patient data in DataLabs.

To add a properties to a table:

1. On the Form Details page, click the table you want to add properties to.

The Table Properties page appears.

Home » Forms » AE » Adverse Events

Properties

No table questions are defined

Form Name: AE

Domain Name:

Table Name:

Table Prompt: Adverse Events

AutoBuild

Structure Fixed

Max Table Rows:

2. Enter the table properties.
3. Click Save to save the changes.
 - A confirmation notification appears to indicate that the table properties were successfully added.

Table Properties

Form Name (Read only)

Displays the short, unique name for the form on which the table appears.

Domain Name (Required)

Selects the domain from which to select the question items appearing in the table. All question items in a table must be from the same Domain, though it can be a different domain than the non-table questions on the form.

Table Name (Required)

Defines a short, unique name to refer to the table. The table name can contain up to 10,000 characters. Valid characters include: letters (a-z, A-Z), digits (0-9), and underscore ("_") only. No spaces are allowed.

Table Prompt (Required)

Defines the text that will appear on the form in DataLabs, describing the table to the user.

AutoBuild

Selects whether the table will be automatically built using one or more codelists.

Note An AutoBuild table can be created using a maximum of three codelists.

Structure Fixed (AutoBuild tables only)

If you opt to AutoBuild a table, this selects if the table structure is fixed. In DataLabs, users will not be able to add or delete rows, or select different codelist options.

Example A Physical Exam form may include a table of the parts of the body that need to be examined and the types of results that need to be recorded.

Max Table Rows

Determines the maximum number of rows that can be added to a table in DataLabs. You can enter 0-3 numeric characters.

Note This option is not available for fixed AutoBuild tables.

Adding AutoBuild Tables

An AutoBuild table is one which fills in selected column(s) with pre-defined values from a code list (whereas a default table contains user-defined data in each column, adding rows to a form table). For each column used as a key sequence, DataLabs creates a row in the table.

Example You have the following code lists (and values) tagged to be used as key sequences (to record pain severity in lower extremities, in various positions during the day):

Time Period (1)	Position (2)	Joint (3)
Morning (6am – noon)	Standing	Ankle
Afternoon (noon-6pm)	Sitting	Knee
Evening (6pm-midnight)		Hip

The final, non-key sequence column, Severity (0), can be any question type. DataLabs would create a table with the following rows:

Time Period	Position	Joint	Severity
Morning (6am – noon)	Standing	Ankle	
Morning (6am – noon)	Standing	Knee	
Morning (6am – noon)	Standing	Hip	
Morning (6am – noon)	Sitting	Ankle	
Morning (6am – noon)	Sitting	Knee	
Morning (6am – noon)	Sitting	Hip	
Afternoon (noon-6pm)	Standing	Ankle	
Afternoon (noon-6pm)	Standing	Knee	
Afternoon (noon-6pm)	Standing	Hip	
Afternoon (noon-6pm)	Sitting	Ankle	
Afternoon (noon-6pm)	Sitting	Knee	
Afternoon (noon-6pm)	Sitting	Hip	
Evening (6pm-midnight)	Standing	Ankle	
Evening (6pm-midnight)	Standing	Knee	
Evening (6pm-midnight)	Standing	Hip	
Evening (6pm-midnight)	Sitting	Ankle	
Evening (6pm-midnight)	Sitting	Knee	
Evening (6pm-midnight)	Sitting	Ankle	

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To create an autobuild table:

1. Define the code lists that will be used by the table as key sequences.
 2. Add a table to the form.
 3. Add table properties. Be sure to select AutoBuild.
 4. Add a question to the table.
 5. Add table question properties.
- If you want the question used as a key sequence in a column, enter the **Key Sequence** number (1-N); then, enter the column's **Header** name.
 - If you want the question to be used to record data, enter) in the Key Sequence; then, enter the column's Header name.

Adding a Question to a Table

A table provides for groups of related information, which can be entered in multiple times within the same form. You can choose whether to display the information as a row or column and assign headings to columns.

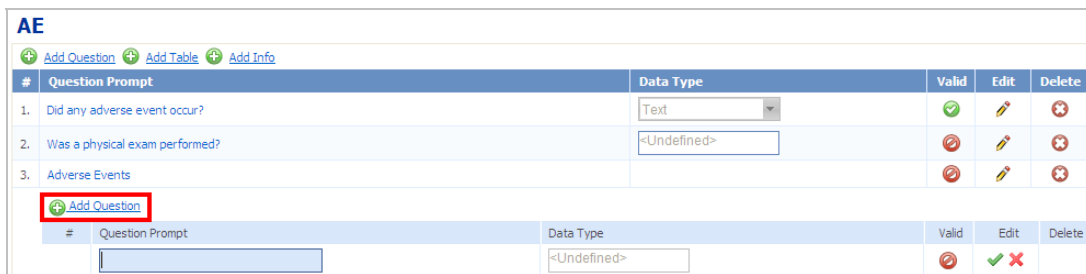
Note At least one question within the table must be displayed as a column and have a header name.

You can use the Form Details page to add questions to a table.

To add a question to the table:

1. On the Form Details page, click Add Question for the table you want to add questions to.

A new row is added to the Questions grid.



#	Question Prompt	Data Type	Valid	Edit	Delete
1.	Did any adverse event occur?	Text	✓	✎	✖
2.	Was a physical exam performed?	<Undefined>	✗	✎	✖
3.	Adverse Events		✗	✎	✖

2. Enter the question prompt.
5. Click ✓ to save the changes.
 - A confirmation notification appears to indicate that the question was successfully added.
 - The question is added to the Questions grid and the question's validity is updated.

Adding Table Question Properties

When you add a question to a table, the Table options on the Question Properties page are enabled.

Table question properties give you a broad range of options for how a table and its questions will appear and behave in DataLabs.

To add a properties to a table question:

1. On the Form Details page, click the table question prompt you want to add properties to.
The Question Properties page appears.

The screenshot shows the 'Properties' page for a question. It is divided into several sections:

- Question Section:**
 - Domain Name: AE
 - Item Name: AESerious
 - Display Options: Drop-Down
 - Short Prompt: (empty)
 - Question Prompt: Was the AE serious?
 - Options: Question Hidden, PDE Verify Only, None
- Data Section:**
 - Data Type: Text
 - Dictionary: (empty)
 - Codelist Name: YesNoNA
 - Max Length: 2
 - Codelist Items: (0) [Blank] *, (Y) Yes, (N) No, (NA) Not applicable
 - Min Length: 1
 - Max Precision: (empty)
 - Min Precision: (empty)
- Conditional Section:**
 - Item Name: --
 - Comparator: --
 - Values: (empty)
- Table Section:**
 - Table Name: Events_1
 - Header Name: Serious?
 - Key Sequence: (empty)

2. Enter the table question properties.
 - To hide the question so that it is not displayed to DataLabs users, select **Question Hidden**.
 - To display the question based on answers to other questions, enter the Conditional properties. For more information, see [Conditional Question Properties](#).
3. Click Save.

Table Question Properties

Domain Name (Required)

Select the domain that contains the domain item you want to assign to the question.

Note The Domain Name list includes domains that have not been assigned domain items.

Item Name (Required)

Select the domain item you want to assign to the question. The list of items displayed is based on the domain you selected.

Note Only questions you haven't already added to a form appear in the list (since you can't place the same question on the form twice).

Display Options

Allows you to choose the method presented to users for selecting or entering a response to the question. The Display Options you can choose depend on the data type associated with the domain item.

- For date fields, you can indicate if a calendar (datepicker) will be available.
- For text fields, you can select "Text" or "TextArea"
- For codelists, you can select whether the codelist items will be shown as a "Drop-Down" list or as "Radio" buttons.

Question Prompt (Required)

Defines the text that will appear on the form in DataLabs, describing the question to the user.

The Question Prompt is automatically populated based on the Question Prompt entered on the Form Details page; however, if you edit the Question Prompt on the Question Properties page, it will be updated on the Questions grid.

Question Hidden

If selected, only authorized users will be able to view the question on the form in DataLabs. This option is usually used with derived fields where it is necessary to collect a value for the study data, but does not need to be seen by the DataLabs users who is filling out the form.

On the Form Details page, hidden questions are numbered with a decimal suffix (for example, 3.1).

Note If Question Hidden is selected, the question cannot be conditional, PDE Verify or Column Display.

PDE Verify Only

If selected, the question will only go through paper data entry (PDE) verification on the second pass.

If cleared, the question will go through second pass paper data entry.

Note A question can be either Question Hidden or PDE Verify Only, but not both.

Table Name (Read Only)

Displays the name of the table to which the question belongs.

Header Name

If you want the question to be displayed as a table column, type the column's Header Name.

Note *At least one table* question must be displayed in a column and have a header name.

Key Sequence (AutoBuild Tables only)

Determines the numeric order of the codelists used in AutoBuild tables (1-N). This field is required and must be unique.

Moving Table Questions

Moving a Question into a Table Associated with a Different Domain

If you move a question into a table and the question and table are associated with different domains, a confirmation message appears. If you click **Yes** on the confirmation message:

- The question will be moved into the table
- The question's domain will be changed to the table's domain
- The item name associated with the question will be cleared

Moving a Conditional Question

If you move a conditional question into a table, a confirmation message appears. If you click **Yes** on the confirmation message the question is moved into the table and the conditional criteria for the question will be cleared.

Informational Prompts

Adding Informational Prompts to a Form

You can add informational text to a form to provide notes and instructions to the personnel entering data into the form in DataLabs. You can format the text using the built-in HTML editor or standard HTML tags.

Note You cannot add an informational prompts to a table.

Note The order in which informational prompts appear on the form in Designer will be the order in which they will appear on the form in DataLabs.

To add an informational section to a form:

1. On the menu bar, click Forms.
The Forms page appears.
2. Click the form you want to add informational text to.
The Form Details page appears.

The screenshot shows the 'AE' Form Details page with a table of questions. The table has columns for '#', 'Question Prompt', 'Data Type', 'Valid', 'Edit', and 'Delete'. There are three main rows of questions, with the third one having two sub-rows.

#	Question Prompt	Data Type	Valid	Edit	Delete
1.	Did any adverse event occur?	Text	✓	✎	✖
2.	Was a physical exam performed?	<Undefined>	✗	✎	✖
3.	Adverse Events		✗	✎	✖
3.x.1.	Adverse Event Type	Text	✓	✎	✖
3.x.2.	Was the AE serious?	Text	✓	✎	✖

3. Click Add Info.

A new row opens on the Form Details page.

The screenshot shows the 'AE' Form Details page with the 'Add Info' button highlighted in a red box. The table below it is empty, and the status at the bottom says 'No Questions Found'.

#	Question Prompt	Data Type	Valid	Edit	Delete
		<Undefined>	✗	✎ ✖	


No Questions Found

4. Enter the text you want to appear as informational text on the CRF in DataLabs.

The screenshot shows the 'AE' Form Details page with the text 'ly if the patient has an adverse event' entered in the 'Question Prompt' field of the table.

#	Question Prompt	Data Type	Valid	Edit	Delete
	ly if the patient has an adverse event	<Undefined>	✗	✎ ✖	

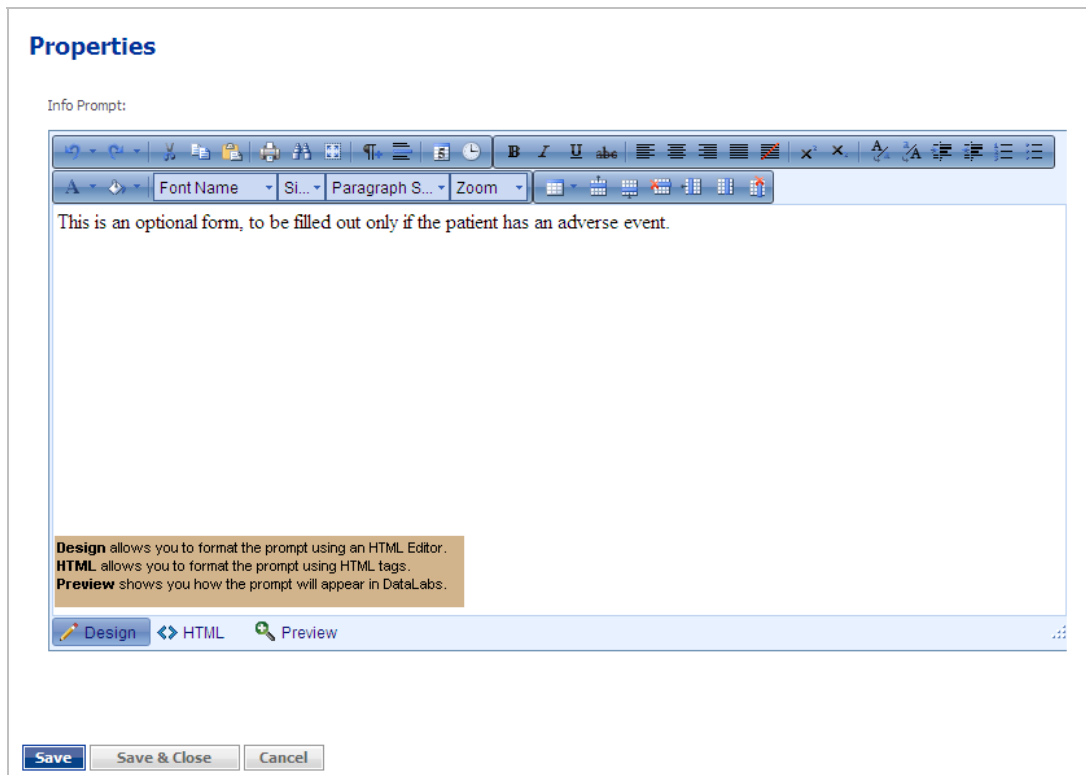
Note You cannot add or edit HTML tags for the informational text on the Form Details page. You must use the HTML Editor on the Info Prompt Properties page to add or edit HTML tags.

5. Click  to save the changes.
 - A confirmation notification appears to indicate that the informational prompt was successfully added.
 - The prompt is added to the Questions grid and its validity status is updated.

Formatting the Informational Prompt

To format the informational prompt:

1. On the Form Details page, click the informational prompt you want to format.
The Info Prompt Properties page appears.



2. Do one of the following:
 - Use the Design tab to enter and format the informational prompt using the built-in HTML Editor options.

Note On the Design tab, do not use HTML tags to format text. If you enter HTML tags on the Design tab, they will be rendered as text in DataLabs.

- Use the HTML tab to enter and format the informational prompt using text and HTML tags.

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












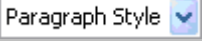







- Use the Preview tab to preview how the text will appear in DataLabs.













Note If the Preview pane contains a link, clicking the link will result in an error.

3. Click Save to save the changes.

- A confirmation notification appears to indicate that the info prompt was successfully updated.
- The prompt is added to the Questions grid and its validity is updated.

HTML Editor Toolbar

Icon	Tool Name	Description
	Convert to Uppercase	Converts the text of the current selection to uppercase, preserving the non-text elements such as images and tables.
	Convert to Lowercase	Converts the text of the current selection to lowercase, preserving the non-text elements such as images and tables.
	Zoom	Changes the level of text magnification.
	Find and Replace	Finds (and replaces) text in the editor's content area.
	Print	Prints the contents of the Design tab.
	Cut	Cuts the selected content and copies it to the clipboard.
	Copy	Copies the selected content to the clipboard.
	Paste	Pastes the copied content from the clipboard into the editor.
	Select All	Selects the contents of the Design tab.
	New Paragraph	Inserts a new paragraph at the cursor position.
	Undo	Undoes the last action.
	Redo	Repeats the last action which has been undone.
	Insert Date	Inserts the current date.
	Insert Time	Inserts the current time.
	Format Block	Applies standard text styles to the selected text.
	Justify Left	Aligns the selected paragraph to the left margin.
	Justify Center	Aligns the selected paragraph to the center.
	Justify Right	Aligns the selected paragraph to the right margin.
	Justify Full	Justifies the selected paragraph.
	Justify None	Removes the alignment of the selected paragraph.
	Insert Unordered List	Creates a bulleted list from the selection.
	Insert Ordered List	Creates a numbered list from the selection.

	Insert Horizontal Rule	Inserts a horizontal line at the cursor position.
B	Bold	Applies bold formatting to the selected text.
<i>I</i>	Italic	Applies italic formatting to the selected text.
<u>U</u>	Underline	Underlines the selected text.
abc	Strikethrough	Applies strikethrough formatting to the selected text.
x^2	Superscript	Applies superscript formatting to the selected text.
x_2	Subscript	Applies subscript formatting to the selected text.
Fonts 	Font Name	Sets the font typeface.
Size 	Font Size	Sets the font size.
	Foreground Color	Changes the foreground color of the selected text.
	Background Color	Changes the background color of the selected text.
	Increase Indent	Increases the indentation of the selected paragraph.
	Decrease Indent	Decreases the indentation of the selected paragraph.
	Insert Table	Inserts a table at the cursor position.
	Insert Row Above	Inserts a row above the selected row in a table.
	Insert Row Below	Inserts a row below the selected row in a table.
	Delete Row	Deletes the selected row.
	Insert Column Left	Inserts a column to the left of the selected column.
	Insert Column Right	Inserts a column to the right of the selected column.
	Delete Column	Deletes the selected column.

HTML Tag Recommendations

The following table is a sample list of which tags are allowed, and those which are *not recommended* (since they could cause display problems within DataLabs):

Allowed

<i> <p> <div> <table> <html> <style> <form> <iframe> <a>

 <tr> <meta> <script> <input>
 <hr/> <td> <head> <menu>
 <body>

Editing a Question Prompt on a Patient Status Form

In DataLabs, patient status forms are used to change a patient's status. For example, when a DataLabs user submits the "Enroll" patient status form for a patient, the patient's status automatically changes from Screened to Enrolled.



When a study is created, patient status forms are automatically added to the Common Event. In addition, each patient status form is automatically populated with the following question prompts:

Form	Questions
Screened	Screen ID
	Patient Initials
	Screen Date
Enrolled	Enroll ID
	Enrolled Date
Failed	Failed Date
Discontinued	Discontinued Date
Completed	Completed Date

You cannot add or delete questions on a patient status form; however, you can edit the prompts for existing questions.

Although you can change the text displayed for a question prompt, you cannot change the data type allowed for user responses to the question.

To edit a question prompt on a patient status form:

1. On the menu bar, click Events.
The Events page appears.
2. Click the Common event on the Events grid.
The Event Details page appears.
2. Click the name of the patient status form you want to edit.
The Form Details page appears.
3. Click  for the question prompt you want to edit.
4. Enter the changes you want to make.
5. Click  to save your changes.
 - A confirmation notification appears to indicate that the question prompt was successfully updated.
 - The Last Updated date and time is updated for the Common Event.

Domains

Adding a Domain

You can use the Domains page to define the structure of the data items that can be used in a study. A domain is a group of related data that can be used in forms. Each question on a form is related to an item defined in a domain.

Examples

- Demographics domain that contains domain items for race, gender, age, etc.
- Vital Signs domain that contains domain items for blood pressure, heart rate, pulse, etc.
- Medical history domain that contains domain items for past and present medical conditions, family history, current treatment, etc.

To add a domain:

1. On the menu bar, click **Domains**.

The Domains page appears.

Domain Name	Domain Description	SAS DataSet Name	Items	Last Updated	Valid	Edit	Delete
AE	Adverse Events		1	19-Apr-2010 04:39:55 PM UTC	✓	✎	✖
CardioRisk	Cardio Risk		7	16-Apr-2010 02:30:58 PM UTC	✓	✎	✖
ConMed	Concomitant Medications		8	16-Apr-2010 02:30:57 PM UTC	✓	✎	✖
CylindromatosisDiag	Cylindromatosis Diagnosis		2	16-Apr-2010 02:30:56 PM UTC	✓	✎	✖
Demo	Demographics	Demo	5	16-Apr-2010 02:30:58 PM UTC	✓	✎	✖
Dosing	Dosing		6	16-Apr-2010 02:30:59 PM UTC	✓	✎	✖
Excl	Exclusion		2	16-Apr-2010 02:30:58 PM UTC	✓	✎	✖
GSF	Genetic Sample		1	16-Apr-2010 02:30:59 PM UTC	✓	✎	✖


2. Click Add Domain.

A new row is added to the Domains grid.

Domain Name	Domain Description	SAS DataSet Name	Items	Last Updated	Valid	Edit	Delete
<input type="text"/>	<input type="text"/>	<input type="text"/>			✗	✓ ✖	

3. Enter the domain properties. Required fields are highlighted in blue.

Note: If you enter invalid characters, the text box is highlighted in red and an error message appears. You cannot save the domain until all invalid entries have been corrected and all required fields have been entered.

4. Click  to save your changes.
 - A confirmation notification appears to indicate that the domain was successfully added.
 - The domain is added to the Domains grid and its Last Updated date and time and Validity is updated.

Domain Properties

Domain Name (Required)

Defines the short name for the domain. The Domain Name can contain up to 35 alphanumeric characters and underscores. It may not contain spaces or special characters.

The Domain Name must be unique within a study.

Domain Description (Optional)

Defines the longer display name of the domain. The Domain Description can contain up to 180 alphanumeric characters. Valid special characters include: () _ - .

SAS Dataset Name (Optional)

Defines the name of the **SAS** format. The SAS Dataset name can contain up to 8 alphanumeric character and underscores. It may not contain spaces or begin with a digit. It may contain one \$. If \$ is used it must be the first character in the field

Note HTML tags are not permitted as they may impact the way text appears in DataLabs.

Adding Items to a Domain

You can use the Domain Items page to define a group of related data items that can appear on forms.

Examples

Domain	Domain Items
Demographics	Race, Gender, Age, etc.
Vital Signs	Blood Pressure, Heart Rate, Respiration, etc.
Medical History	Medical Conditions (past and present, family history, current treatment, etc.

To add an item to a domain:

1. On the Domains page, click the name of the domain you want to add items to.

The Domain Items page appears.

Item Name	Source	Data Type	Codelist	Dictionary	Derivation	Max Len	Min Len	Max Pre	Min Pre	SAS Field	SDTM Var	Notes	Edit	Delete
AESerious	EDC	Text	YesNoNA			2	1							
AETerm	Encoding	Text		Conditions		20	0							
AECancer	EDC	Text	YesNo			1	1							
AEType	EDC	Text	AEType			1	1							
AEAction	EDC	Text	AEAction			12	1							
AEPrima...	EDC	Text	AECause			13	1							
AEWorse...	EDC	Text	YesNoNA			2	1							

2. Click Add Item.


A new row is added to the Domain Items grid.

Item Name	Source	Data Type	Codelist	Dictionary	Derivation	Max Len	Min Len	Max Pre	Min Pre	SAS Field	SDTM Var
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
AESerious	EDC	Text	YesNoNA			2	1				

3. Enter the domain item properties. Required fields are highlighted in blue.

Note: If you enter invalid characters, the text box is highlighted in red and an error message appears. You cannot save the domain item until all invalid entries have been corrected and all required fields have been entered.

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4. Click  to save the domain item.
 - A confirmation notification appears to indicate that the domain item was successfully added.
 - The domain item is added to the Domain Items grid.

Domain Item Properties

Item Name (Required)

Defines the short name for the item. The Item Name may contain up to 35 alphanumeric characters, and underscores. The Item Name cannot start with a digit or contain special characters.

Must be unique within a study.

Cannot be one of the 11 DataLabs reserved words: sitekey, siteid, patientkey, patientidentity, eventkey, eventshortname, formkey, formlabel, invalid, datarow, or datarowactive.

Source (Required)

Selects the source used to populate the item. Depending on the source you select, only specific properties are available.

- **EDC:** The item will be populated by user input in DataLabs.
- **Encoded:** The item will be populated by an external encoding system based on user input in DataLabs.
- **Derived:** The item will be calculated based on the results of a derivation script.
- **External:** The item is populated from an external system.


Data Type (Required)

Selects the type of data that can be used to populate the item in DataLabs. Depending on the data type you select, only specific properties are available.

Note: In DataLabs, a question on a CRF accepts *any* input from the user. The data type defines the item's data type and does not get applied until the data is exported, or reporting views are applied.

- **Date:** The item will only accept date values.
- **Float:** The item will only accept a floating decimal number.
- **Integer:** The item will only accept integer values.
- **Text:** The item either accepts free-form text or uses a codelist.

CodeList

Selects the codelist used to populate the item. The codelist you select determines the options that appear on a drop-down list or option buttons for the item. To see a list of codelists or to add a new codelist, click .

You can only select a codelist if the Data Type is "Text" and the Source is not "Encoded" or "Derived."

Dictionary

Selects the dictionary to use to encode the item.

You can only select a dictionary if the Data Source is "Encoded" and the Data Type is "Text."

Note: DataLabs does not support the ability to place a question that has been encoded on more than one form.

Derivation

Designates the derivation script that will be used to calculate the value for the item.

In DataLabs, when derivations are "run", the derived fields within a form is populated based on the current data in the study. Derivations can be run when 1) a form is checked out, 2) a form is checked in, 3) any parameters associated with the derivation are changed, or 4) the Derivation Wizard is run in Study Administration.

If you have not defined the derivation script you want to assign to this item, select <Unassigned>. The domain item will be marked as invalid until you assign a script to it.

Derivations can be assigned to all items except those that use a codelist or that are encoded.

MinPre & MaxPre

Defines the number of digits required to the right of the decimal point.

You can only define the minimum and maximum precision if the Data Type is "Float".

Example 123.456 has a precision of 3, while 12.34567 has a precision of 5.

MinLen & MaxLen (Required)

Defines the maximum (character) length of an item. This field is required. Date fields have a default MaxLen of 10 for US and ISO format, 11 for European.

Example A text field containing "a boy and his dog" has a length of 17 (the spaces are counted), while a float field containing 123.45 has a length of 5 (the decimal point is not counted).

SAS Field Name

Defines the field name that will be used by **SAS**. When creating a new domain item, this field is automatically populated with the first eight characters of the domain item name.

The SAS Field Name can contain up to 8 alphanumeric characters and underscores. It cannot start with a digit, contain spaces, or contain special characters.

The SAS Field Name must be unique within the study.

SDTM Var Name

Defines the field name that will be used by SDTM (Submission Data Tabulation Model). When creating a new domain item, this field is automatically populated with the first eight characters of the domain item name.

The SDTM Var Name can contain up to 8 alphanumeric characters and underscores. It cannot start with a digit, contain spaces, or contain special characters.

Notes

Defines a short comment about the item and can contain up to 360 characters.

Codelists

Adding a Codelist

A codelist is a list of items that can be used as options in dropdown lists and radio buttons on forms.

Examples

- Race
- Gender
- Age
- Weight Units
- Temperature Units

Codelist must be defined before they can be assigned to domain items which, in turn, are assigned to forms. You can use the Codelists page to add a codelist to the study.

Note You can also add a codelist as you're adding a domain item.

To add a codelist:

1. On the Designer toolbar, click **Codelists**.

The Codelists page appears.

<input type="checkbox"/>	Codelist Name	Codelist Description	SAS Format Name	Last Updated	Valid	Edit	Delete
<input type="checkbox"/>	AbNormal	AbNormal		16-Apr-2010 02:30:56 PM UTC	✓	✎	✖
<input type="checkbox"/>	AEAction	AEAction		16-Apr-2010 02:30:56 PM UTC	✓	✎	✖
<input type="checkbox"/>	AECause	AECause		16-Apr-2010 02:30:56 PM UTC	✓	✎	✖
<input type="checkbox"/>	AEIntensity	AEIntensity		16-Apr-2010 02:30:56 PM UTC	✓	✎	✖
<input type="checkbox"/>	AEType	AEType		16-Apr-2010 02:30:56 PM UTC	✓	✎	✖
<input type="checkbox"/>	AmountUOM	AmountUOM		16-Apr-2010 02:30:55 PM UTC	✓	✎	✖
<input type="checkbox"/>	BottleLabel	Bottle Label		16-Apr-2010 02:30:56 PM UTC	✓	✎	✖
<input type="checkbox"/>	BPPosition	Blood Pressure Position		16-Apr-2010 02:30:55 PM UTC	✓	✎	✖
<input type="checkbox"/>	Condition	Condition		16-Apr-2010 02:30:55 PM UTC	✓	✎	✖
<input type="checkbox"/>	DailyDose	Daily Dose		16-Apr-2010 02:30:56 PM UTC	✓	✎	✖


2. Click Add Codelist.

A new row is added to the Codelist grid.

<input type="checkbox"/>	Codelist Name	Codelist Description	SAS Format Name	Last Updated	Valid	Edit	Delete
<input type="checkbox"/>						✓ ✖	

3. Enter the codelist properties. Required fields are highlighted in blue.

Note: If you enter invalid characters, the text box is highlighted in red and an error message appears. You cannot save the codelist until all invalid entries have been corrected and all required fields have been entered.

4. Click  to save the codelist.
 - A confirmation notification appears to indicate that the codelist was successfully added.
 - The codelist is added to the Codelists grid and its Last Updated date and time and Validity status is updated.

After a codelist has been added, you can:

- Assign items to the codelist. For more information, see "Adding Items to a Codelist."
- Assign the codelist to domain items. For more information, see "Adding a Domain Item."

Codelist Properties

Codelist Name (Required)

Defines a unique, short name for the codelist

The codelist name can include up to 50 alphanumeric characters. It cannot contain spaces.

Codelist Description (Optional)

Defines the longer display name of the Code List

The codelist description can contain up to 255 alphanumeric characters. Valid characters include:
~!@#\$\$%^&*()_+ -= {} | [] \ ; < > ? , . /

SAS Format Name (Optional)

Defines the name of the SAS format

The SAS format name can contain up to 8 alphanumeric characters, including underscore (_) and dot (.) The SAS format name cannot contain spaces.

The SAS format name may contain one \$. If \$ is used it must be the first character in the field

Note HTML tags are not permitted as they may impact the way text appears in DataLabs.

Adding Items to a Codelist

You can use the Codelist Items page to define the items that can be used as options in dropdown lists and radio buttons on forms (CRFs). All **codelists** must include at least one item.

Examples

Codelist

Codelist Items

Gender	Male, Female
Weight Units	Pounds, Kilograms
Height Units	Inches, Centimeters

Note The order in which items appear on the codelist in Designer will be the order in which they will appear on dropdown lists in DataLabs. You can reorder items by clicking and dragging a question to a new location on the Codelist Items grid.

To add an item to a codelist:

1. On the Codelists page, click the codelist you want to add an item to.

The Codelist Items page appears.

Note: The first row shows [BLANK] which is a default item automatically added to the codelist. The Code Value for the [BLANK] item must be left empty to accommodate Level 0-2 Edit Checks.

AEAction

[Add Item](#) [Refresh](#)

Code Prefix	Code Description	Code Value	Valid	Edit	Delete
	[Blank]	X	✓	✎	✖
	None	None	✓	✎	✖
	Interrupted	Interrupted	✓	✎	✖
	Discontinued	Discontinued	✓	✎	✖
	Reduced	Reduced	✓	✎	✖
	Increased	Increased	✓	✎	✖

2. Click Add Item.

A new row is added to the Codelist Items grid.

AEAction


[Add Item](#) [Refresh](#)

Code Prefix	Code Description	Code Value	Valid	Edit	Delete
<input type="text"/>	<input type="text"/>	<input type="text"/>		✓ ✖	

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3. Enter the codelist item properties. Required fields are highlighted in blue.

Note: If you enter invalid characters, the text box is highlighted in red and an error message appears. You cannot save the codelist item until all invalid entries have been corrected and all required fields have been entered.

4. Click  to save the codelist item.
 - A confirmation notification appears to indicate that the codelist item was successfully added.
 - The codelist item is added to the Codelist Items grid and its Validity is updated.

Codelist Item Properties

Code Prefix

Defines the prefix displayed in drop-down combo boxes or on option buttons in DataLabs, so that list items can be numbered.

0-3 alphanumeric characters

Cannot contain special character or spaces

Must be unique within this codelist

This field is optional; however, if one code in the code list has a prefix, all other codes within the study must have a prefix.

Code Description (Required)

Defines the value displayed in drop-down combo boxes or on option buttons in DataLabs.

1 - 255 alphanumeric characters

Valid characters include: ~!@#\$\$%^&*()_+={}|[]\;:<>?,./.

Must be unique within this codelist

Code Value (Required)

Defines the actual value corresponding to the Code Description that is stored in the database. This is the value that Edit Checks (Query Scripts) reference.

1 - 255 alphanumeric characters

Valid characters include: ~!@#\$\$%^&*()_+={}|[]\;:<>?,./.

Must be unique within the code list

Note HTML tags are not permitted as they may impact the way text appears in DataLabs.

Copying a Codelist

A codelist is a list of items that can be used as options in dropdown lists and radio buttons on forms. You can use the Codelists tab to create a copy of an existing codelist. The following information is copied from the existing codelist into the new codelist:

- Codelist properties
- Codelist items

To copy a codelist:

1. On the menu bar, click Codelists.
The Codelists page appears.

2. Select the codelist(s) you want to copy.

Codelists								
Add Codelist			Copy Codelist	Create Codelist from Existing			Show/Hide Filter	Refresh
<input type="checkbox"/>	Codelist Name	Codelist Description	SAS Format Name	Last Updated	Valid	Edit	Delete	
<input type="checkbox"/>	AbNormal	AbNormal		23-Mar-2010 03:33:24 PM UTC	✓			
<input checked="" type="checkbox"/>	AEAction	AEAction		23-Mar-2010 03:33:24 PM UTC	✓			

2. Click Copy **Codelist**.

A new row is added to the Codelists grid for each new copy. The name of each newly-copied codelist is appended with a suffix, "COPY_01" and is inserted according to alphabetical order within the Codelists grid.

Codelists								
Add Codelist			Copy Codelist	Create Codelist from Existing			Show/Hide Filter	Refresh
<input type="checkbox"/>	Codelist Name	Codelist Description	SAS Format Name	Last Updated	Valid	Edit	Delete	
<input checked="" type="checkbox"/>	AEAction			23-Mar-2010 03:33:24 PM UTC	✓			
<input type="checkbox"/>	AEAction_Copy1			30-Mar-2010 04:07:51 PM UTC	✓			

If you are copying multiple codelists and an error occurs during the copy process, the system skips that codelist and proceeds to the next one.

When all of the selected codelists have been copied, a message appears to indicate the number of codelists that were successfully copied.

Copying a Codelist from Another Study

A codelist is a list of items that can be used as options in dropdown lists and radio buttons on forms.

You can use the Codelists tab to create a new codelist from a codelist in an existing study. The following information is copied from the existing codelist into the new codelist:

- Codelist properties
- Codelist items

To create a new codelist from an existing codelist:

1. On the menu bar, click Codelists.
The Codelists page appears.
2. Click Create Codelist from Existing.
The Please select a study page appears.

Note You can use filters to search for the study you want.

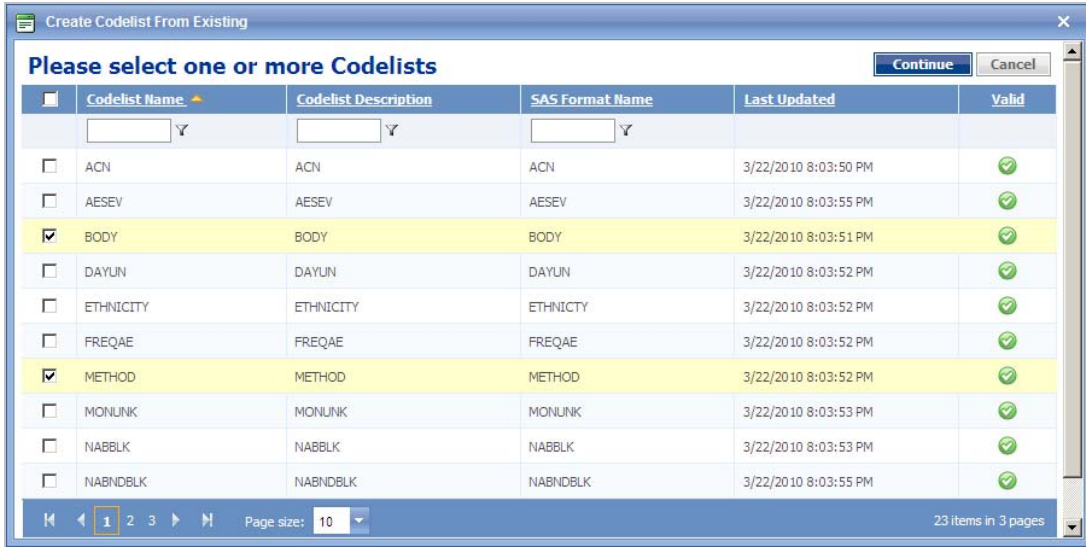
Client/Sponsor	Study Name	Study Label	Protocol	Therapeutic Area	Drug Name
Sponsor 1	Aspirin	Aspirin41	069752	Pain Management	Drug Name
Sponsor 2	Aspirin41	Aspirin	211573	Pain Management	Drug Name
Sponsor 3	Kidney	Kidney Diseases 11	024579	Nephrology	Drug Name
Sponsor 4	TCell	T Cell Immunodeficiency	069752	Infectious Disease	Drug Name
Sponsor 5	Diabetes	Diabetes Study	099571	Endocrinology	Drug Name
Sponsor 6	Back_Pain	Back Pain Study	076407	Pain Management	Drug Name
Sponsor 7	Rheuma	Rheumatology Study	024589	Rheumatology	Drug Name
Sponsor 8	Eating	Eating Disorders	053283	Psychiatry	Drug Name

Page size: 10 | 8 items in 1 pages

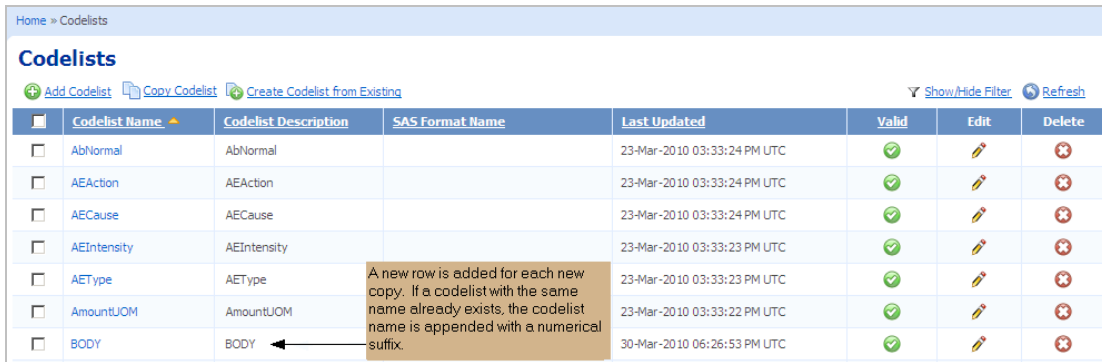
Cancel

3. Click the name of the study that contains the codelist you want to use to copy.

The Please select one or more Codelists page appears.



3. Select the codelist(s) you want to copy.
4. Click Continue.
 - A new row is added to the Codelists grid for each new copy. If a Codelist with the same name exists in the current active study, a numeric suffix is added to the Codelist name.



- If an error is encountered during the copy process, the system skips that codelist and proceeds to the next one.
- When all of the selected codelists have been copied, a message appears to indicate the number of codelists that were successfully copied.

Dictionary

Overview

A dictionary is an external third-party application that contains a standardized list of medical terms. For example, MedDRA is a dictionary that contains standardized terms to describe adverse events and medical history.

In Designer, you can designate the dictionaries that will be used to encode terms in the study and the fields (data items) that need to be encoded. Then, if DataLabs is connected to the encoding dictionary, when text is entered on a form, it can be translated into standard terms for easier reporting and analysis.

Adding a Dictionary

A dictionary is an external third-party application that contains a standardized list of medical terms. For example, MedDRA is a dictionary that contains standardized terms to describe adverse events and medical history.

In Designer, you can designate the dictionaries that will be used to encode terms in the study and the fields (data items) that need to be encoded. Then, if DataLabs is connected to the encoding dictionary, when text is entered on a form, it can be translated into standard terms for easier reporting and analysis.

You can use the Dictionaries page to designate the dictionaries to be used for encoding data.

After you've added a dictionary, you can assign it to the domain items that need to be encoded.

To add a dictionary:

1. On the menu bar, click Dictionaries.

The Dictionaries page appears.

Dictionary Name	Dictionary Description	Dictionary Version	Edit	Remove
Conditions	Conditions	3.0		
Drugs	Drugs	1.0		

2. Click Add Dictionary.

A new row opens in the Dictionaries grid.

Dictionary Name	Dictionary Description	Dictionary Version	Edit	Remove
Conditions	Conditions	3.0		
Drugs	Drugs	1.0		

3. Enter the dictionary properties. Required fields are highlighted in blue.

Note: If you enter invalid characters, the text box is highlighted in red and an error message appears. You cannot save the dictionary until all invalid entries have been corrected and all required fields have been entered.

4. Click to save the dictionary.
 - A confirmation notification appears to indicate that the dictionary was successfully added.
 - The dictionary is added to the Dictionaries grid.

Dictionary Properties

Dictionary Name (Required)

Defines a unique name for the dictionary. The dictionary name is passed to the encoding engine during the encoding process.

The dictionary name can contain up to 50 alphanumeric characters. It may contain underscores. It may not contain spaces or other special characters.

Dictionary Description (Optional)

Defines the longer, descriptive display name of the dictionary.

The dictionary description can contain up to 255 alphanumeric characters. Valid characters include: spaces, () - _ .

Dictionary Version (Optional)

Defines the current version of the dictionary used for encoding.

The dictionary version may contain up to 50 alphanumeric characters. Valid character include spaces, ~!@#%&*()_+ -= { } | \ ; < > ? , . /

Working with Edit Checks

Defining Default Edit Check Descriptions

Edit checks and range checks are built-in queries performed on a field to ensure the data entered in a form is in a specified format or within a specified range, respectively.

In DataLabs, if a user enters data in the field that is not in the correct format or within the specified range, an alert appears. If the user submits the form without addressing the alert, DataLabs automatically creates a **Data Clarification Form (DCF)**.

You can use the Study Level Edit Checks page to define the default description and action request that appears on DCFs.

Note You can override these default descriptions by defining edit checks at the domain level or form level.

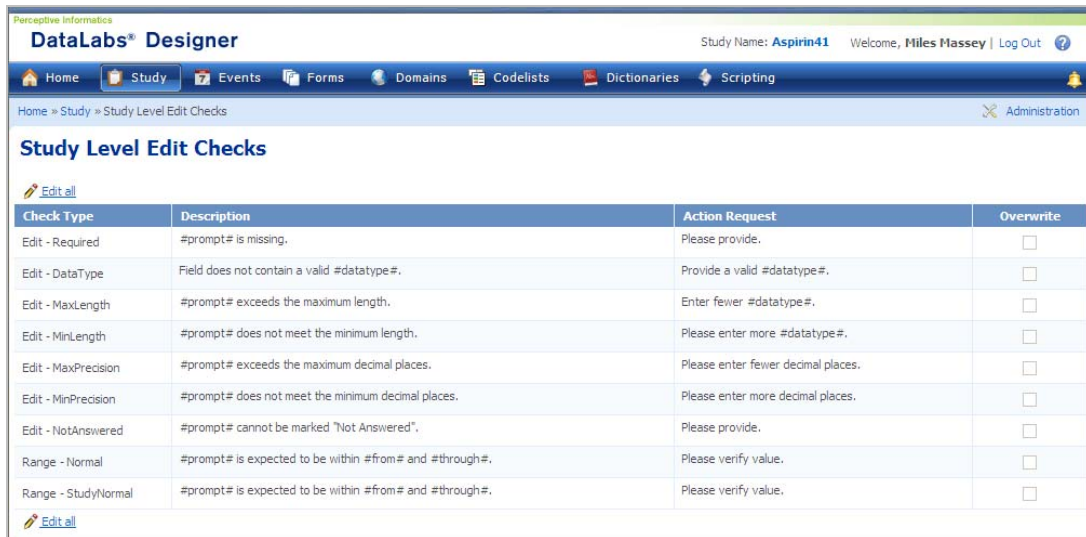
To define the default message for edit checks and range checks:

1. On the Home page, select the study for which you want to define study level edit checks.

The Create Study page appears.

2. Click Study Level Edit Checks.

The Study Level Edit Checks page appears.



Check Type	Description	Action Request	Overwrite
Edit - Required	#prompt# is missing.	Please provide.	<input type="checkbox"/>
Edit - DataType	Field does not contain a valid #datatype#.	Provide a valid #datatype#.	<input type="checkbox"/>
Edit - MaxLength	#prompt# exceeds the maximum length.	Enter fewer #datatype#.	<input type="checkbox"/>
Edit - MinLength	#prompt# does not meet the minimum length.	Please enter more #datatype#.	<input type="checkbox"/>
Edit - MaxPrecision	#prompt# exceeds the maximum decimal places.	Please enter fewer decimal places.	<input type="checkbox"/>
Edit - MinPrecision	#prompt# does not meet the minimum decimal places.	Please enter more decimal places.	<input type="checkbox"/>
Edit - NotAnswered	#prompt# cannot be marked "Not Answered".	Please provide.	<input type="checkbox"/>
Range - Normal	#prompt# is expected to be within #from# and #through#.	Please verify value.	<input type="checkbox"/>
Range - StudyNormal	#prompt# is expected to be within #from# and #through#.	Please verify value.	<input type="checkbox"/>

3. Click Edit All.

The Description, Action, and Overwrite fields open for editing.

4. Do the following:

- In Description, enter text that describes why the query generated a DCF.
- In Action Request enter text that describes what action is required by the user.

5. Select Overwrite if you want to overwrite the description and action request defined for the edit check at the domain level and/or form level.
6. Click Save to save your changes.

A notification message appears to indicate that Designer has started to update descriptions and action requests.

Note The process of updating the default messages runs in the background. Depending on the number of studies, users, and jobs running on your system, this process can take some time to complete.

Adding Domain Level Edit Checks

Edit checks and range checks are built-in queries performed on a field to ensure the data entered in a form is in a specified format or within a specified range, respectively.

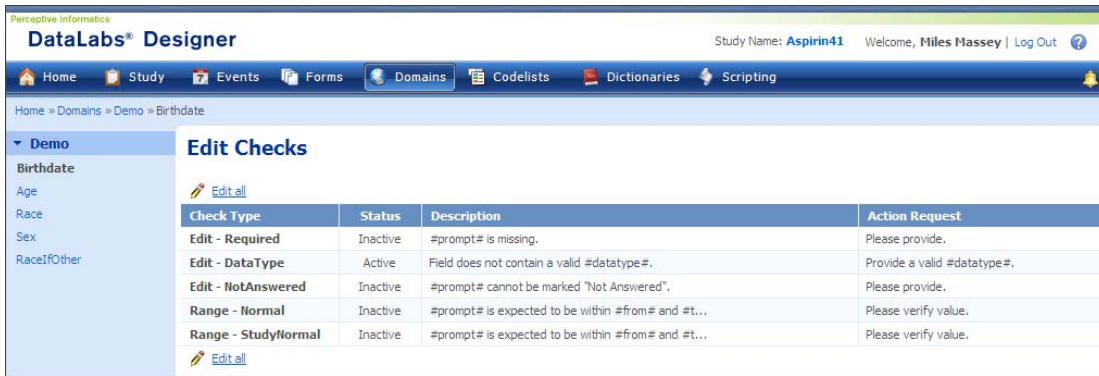
To add edit checks to a domain item:

1. From the Domains page, click the domain that contains the domain item to which you want to add edit checks.

The Domain Items page appears.

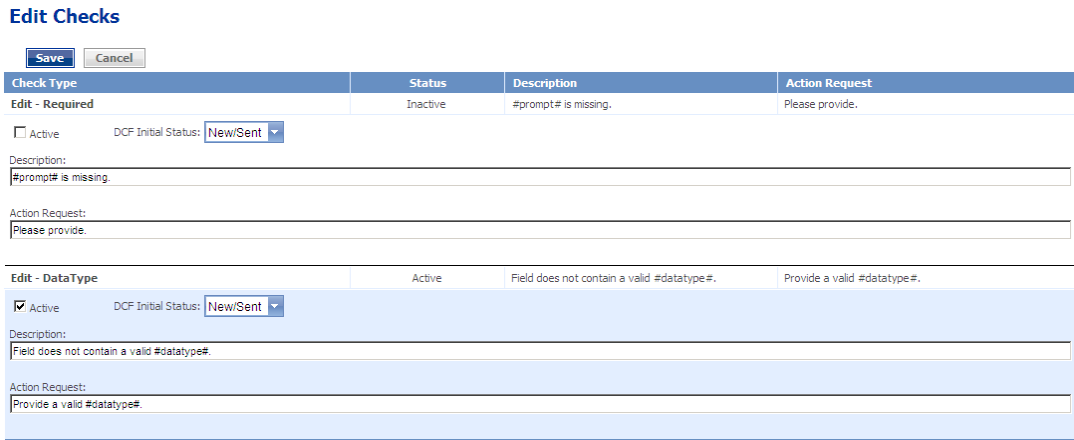
2. Click the Edit Checks tab.
3. Click the domain item for which you want to add edit checks.

The Edit Check page shows the edit checks available for the domain item based upon the item's source and data type.



3. Click Edit all.

The edit check properties open for editing.



4. Enter the edit check properties for each edit check.

5. Click Save to save your changes.

A confirmation notification appears to indicate that the edit check descriptions and actions were successfully added.

Activating Edit Checks for Domain Items

Edit checks and range checks are built-in queries performed on a field to ensure the data entered in a form is in a specified format or within a specified range, respectively.

For each domain item, you can select the edit checks you want to use. When the study is published, only active edit checks will be included in the XML file.

To activate or deactivate edit checks for a domain item:

1. From the Domains page, click the domain for which you want to activate or deactivate edit checks.

The Domain Items page appears.

2. Click the Edit Checks tab.

The Edit Check tab shows the edit checks available for each domain item based upon the item's source and data type.

Item Name	Source	Data Type	Required	Data Type	MaxLen	MinLen	MaxPre	MinPre	Not Answered	Normal	Study Normal
Birthdate	EDC	Date	<input type="checkbox"/>	<input checked="" type="checkbox"/>					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Age	Derived	Integer	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Race	EDC	Text	<input type="checkbox"/>						<input type="checkbox"/>		
Sex	EDC	Text	<input type="checkbox"/>						<input type="checkbox"/>		
RaceIfOther	EDC	Text	<input type="checkbox"/>		<input checked="" type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>		

3. Do one of the following:

- Select the checkbox in the grid heading to open all edit checks for editing.
- Select the edit check(s) you want to edit, and then click **Edit Selected**.

The edit check rows open for editing.

Item Name	Source	Data Type	Required	Data Type	MaxLen	MinLen	MaxPre	MinPre	Not Answered	Normal	Study Normal
Birthdate	EDC	Date	<input type="checkbox"/>	<input checked="" type="checkbox"/>					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Age	Derived	Integer	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. For each domain item, select the edit checks you want to activate. Only active edit checks will be included when a study is published.
5. Click Save to save your changes.

A confirmation notification appears to indicate that your changes were saved.

Adding Form Level Edit Checks

Edit checks and range checks are built-in queries (Level 0-3) you can use to make sure the data entered into a form meets some basic requirements.

For each data type there is a standard set of edit and range checks available, which you can activate and modify. Some of these edit and range checks are, by default, already active when you create the question, based on the question item's data type.

Tip You should always review the edit checks and range checks to make sure that the default settings are acceptable.

To use edit checks and range checks on a question:

1. From the Question Properties page, click the **Edit Checks** tab.
2. Click Edit All.

The rows open on the Edit Checks grid.

3. For each edit check, enter the edit check properties you want to use.
4. Click Save to save your changes.

A confirmation notification appears to indicate that the edit check was successfully updated.

Note In DataLabs, when a user leaves (or "tabs out" of) the question, the selected edit and range checks will run. If a check is violated, an exclamation point will appear to the right of the question (when the user moves their mouse over the exclamation point, they will be shown the check Description). Upon submission of the form, a warning box may appear, notifying the user that a DCF will be created for each check that was violated if the data is not corrected.

Scripting

Overview for Scripting

Within Designer you can create scripts that can be used to:

- Derive the value of a field.
- Query the value of a field and generate a Data Clarification Form (DCF) if the field value does not match specific a specific format or fall within a range of values.
- Create reusable functions that can be referenced by queries and derivations.

To add or work with a script:

1. Click Scripting.

The Scripting page appears.

Scripting

There are 6 scripting errors

Queries Derivations Functions

Add Query Existing Copy Query Create Query from Existing Set Active Flag to Active Save Set Authoring Status to Draft Save Show/Hide Filter Refresh

<input type="checkbox"/>	Query	Active	Authoring Status	Description	Valid	Edit	Delete
<input type="checkbox"/>	AgeRange	Active	Production	If the patient is between 18 and 45.	✗	✎	✖
<input type="checkbox"/>	CheckBMI	Active	Production		✓	✎	✖
<input type="checkbox"/>	CheckBP	Active	Production		✓	✎	✖
<input type="checkbox"/>	IsPatientEnrolled	Active	Production	Tests if the patient's status is "enrolled".	✓	✎	✖
<input type="checkbox"/>	RaceNativeAmerican	Active	Production		✓	✎	✖
<input type="checkbox"/>	ScreenIDFormat	Active	Production		✓	✎	✖
<input type="checkbox"/>	StartBeforeEndDate	Active	Production		✓	✎	✖

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2. Select the type of script you want to add or edit:

- **Functions tab** - Allows you to work with script functions that can be incorporated into derivations and queries.
- **Derivations tab** - Allows you to work with derivation scripts that can be used to calculate values for a field based on user-entered data.
- **Queries tab** - Allows you to work with query scripts that can be used to automatically generate DCFs.

Viewing Scripting Errors

You can use the Scripting Errors window to view two types of scripting errors:

- **Script errors:** the script has either syntax errors, runtime errors or logic errors. The error message box will display the kind of error and its location in the script (the non-scrolling line, `Function FunctionName(parameters)`, is counted as line 1).
- **Invalid result:** the script has no errors but is not returning the value that you expect. If a test case returns invalid then the function shape will be invalid.

On the Scripting Error window, errors are grouped by script type: queries, derivations, and functions.

To view scripting errors:

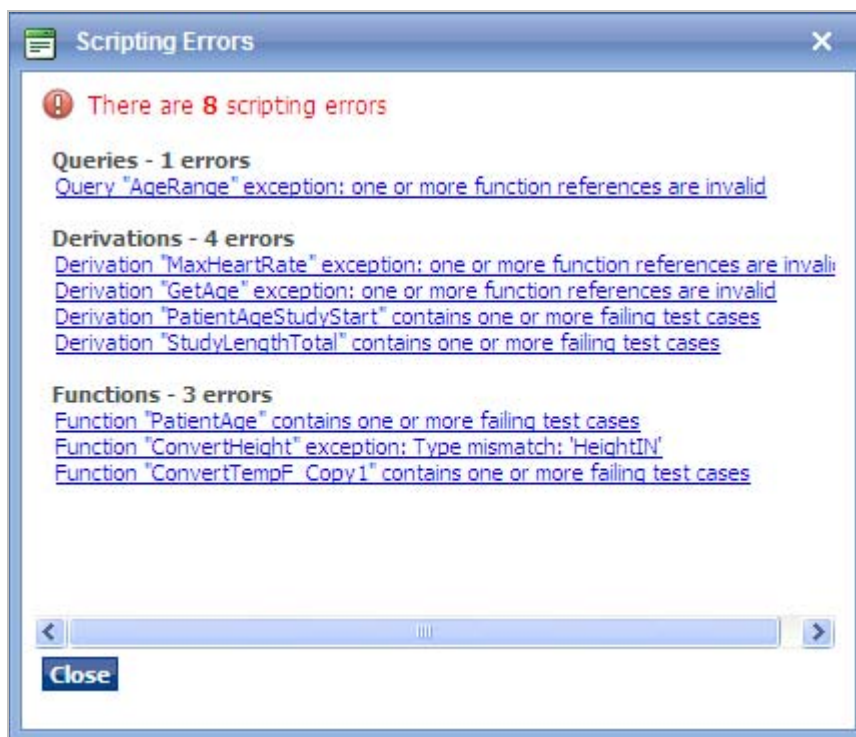
1. On the menu bar, click Scripting.

The Scripting page appears. If one or more scripts contain errors, an error message is displayed:

! There are *n* scripting errors where *n* is the number of errors.

2. Click the number in the error message.

The Scripting Errors window appears.



3. Click an error message to go to the page and script that error. For example, if a script has an invalid test case, the Test Case tab that contains the error appears.

Avoiding Script Errors Caused by Recursion

In Designer, run-time errors can occur:

- if you create a script that references a function having the same name as the script.
- if you create a script that references a parameter having the same name as the script.

This occurs because when a script runs, the script interpreter only looks locally, within the script, and does not look externally, outside of the script, for other functions or parameters.

The following examples illustrate some of the issues that can occur.

Identical Script and Function Names

In the following example, a script and a function share the same name:

```
Function Left(strWord)
    Left = Left(strWord, 1)
End Function
```

In this case "Left" is used as both the name of the derivation and also as the VBScript string function. In VBScript, the Left function returns the leftmost characters of the string.

Because the derivation and function share the same name, the interpreter assumes that this is a recursive call instead of a call to an external function. When the script runs, the following exception occurs: "Wrong number of arguments or invalid property assignment."

Identical Script and Function Names - No Parameter

In the following example, a derivation and a function share the same name, but no parameter is specified for the function:

```
Function Left(strWord)
    Left = Left(strWord)
End Function
```

In this case "Left" is used as both the name of the derivation and also as the VBScript string function. In VBScript, the Left function returns the leftmost characters of the string.

Because the derivation and function share the same name, the interpreter assumes that this is a recursive call instead of a call to an external function. When the script runs, the following exception occurs: "Out of stack space."

Identical Parameter and Function Names

In the following example, a parameter and a function share the same name:

```
Function Test(Month)
    Test = Month(Month)
End Function
```

In this case "Month" is used as both the name of the parameter and also as the VBScript date function. In VBScript, the Month function returns the month for a given date.

Because the parameter and function share the same name, the interpreter assumes that the script refers to a local parameter rather than looking for an external parameter.. When the script runs, the following exception occurs: "Type Mismatch."

Changing the Authoring Status for Scripts

As you create the scripts for a study, you can set a script's authoring status to indicate the script's readiness for publication. In addition, when a study is published, you can select, by authoring status, the queries that will be included in the published study.

1. On the Scripting page, select the type of script for which you want to set the authoring status.
2. Select the scripts for which you want to change the authoring status.

The screenshot shows the 'Scripting' interface with a notification that there are 8 scripting errors. The 'Derivations' tab is active. A dropdown menu for 'Set Authoring Status to' is open, showing options: Draft, Validation, Production, and Retired. The table below shows three derivations: BMI, CombinedID, and GetAge, all currently set to 'Production'.

Derivation	Authoring Status	Description	Valid	Edit	Delete
BMI	Production	Calculates the patient's Body Mass index	✓	✎	✖
CombinedID	Production		✓	✎	✖
GetAge	Production		✗	✎	✖

3. From the Authoring Status dropdown, select one of the following:
 - **Draft** specifies that the script is in progress, which is the default status.
 - **Validation** specifies that the script is being verified.
 - **Production** specifies that the script is verified and ready for production use.
 - **Retired** specified that the script is not currently used.
3. Click Save.

The authoring status for the selected scripts is updated in the grid.

The screenshot shows the 'Scripting' interface after the status change. The 'Authoring Status' column in the table is highlighted with a red box, and all three derivations (BMI, CombinedID, and GetAge) now have 'Draft' as their status.

Derivation	Authoring Status	Description	Valid	Edit	Delete
BMI	Draft	Calculates the patient's Body Mass index (BMI).	✓	✎	✖
CombinedID	Draft		✓	✎	✖
GetAge	Draft		✗	✎	✖

Note The scripts remain selected until you de-select them.

Functions

Quick Start for Creating Functions

A function is a reusable script that performs an operation, and returns a value. Functions can be called from a query or a derivation script.

Examples

Some examples of possible functions include:

- Calculate the patient's age using their birth date and the current date.
- Calculate the patient's body fat percent using their total weight and their lean body mass.
- Concatenate the Enroll ID and the Patient ID.
- Convert the patient's height from inches to centimeters.
- Convert the patient's weight from pounds to kilograms.

The following sections describe how to:

- Add a function.
- Define the parameters for the function.
- Write the script for the function.
- Create test cases to ensure the function returns the expected results.

Adding a Function

You can use the Functions page to define a function that can be used by queries and derivations.

To add a function:

1. On the menu bar, click Scripting.

The Scripting page appears.

2. Click the Functions tab.

The Functions page appears.

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Function	Authoring Status	Description	Valid	Edit	Delete
ConvertHeight	Production	Converts height in inches to centimeters.	✓	✎	✖
ConvertTempF	Production		✓	✎	✖
ConvertWeekday	Production		✓	✎	✖
ConvertWeight	Production	Converts weight in pounds (LB)	✓	✎	✖
PatientAge	Production	Calculates the patient's age.	✗	✎	✖
PatientBMI	Production	Body Mass Index	✓	✎	✖
PercentBodyFat	Production		✓	✎	✖
TotalStudyLength	Production		✓	✎	✖

3. Click Add Function.

A new row is added to the Functions grid.

Function	Authoring Status	Description	Valid	Edit	Delete
	Draft		✗	✓	✖

4. Enter the details for the function. Required fields are highlighted in blue.

Note: If you enter invalid data in a field, the field is highlighted in **red** and an error message appears.

5. Click ✓ to save the function.
 - A confirmation notification appears to indicate that the function was successfully added.
 - The function is added to the Functions grid and its validity status is updated.

Defining Function Parameters

You can use the Parameters tab on the Function Details page to define the function parameters and assign variable names to the data that will be passed by a query or derivation to the function.

For example if $\text{SQRT}(x)$ is a function that returns the square root of a value, then $\text{SQRT}(25)$ would return the value of 5. So, "x" is the name of the parameter and "25" is the value of the parameter.

To define a function parameter from the Functions tab:

1. Click the name of the function you want to add parameters to.

The details page for the function appears.

PatientBMI
Body Mass Index

There are 8 scripting errors

Parameters Scripting Test Cases

+ Add Parameter Refresh

Parameter Name	Valid	Edit	Delete
PatientHtUOM	✓	✎	✖
PatientHt	✓	✎	✖
PatientWtUOM	✓	✎	✖
PatientWt	✓	✎	✖

- Click the Parameter tab.
- Click Add Parameter.

A new row is added to the parameters grid.

Parameters Scripting Test Cases

+ Add Parameter Refresh

Parameter Name	Valid	Edit	Delete
<input type="text"/>	✗	✓ ✗	

- Enter the Parameter Name.

Note: If you enter invalid data in the Parameter Name field, the field is highlighted in red and an error message appears.

- Click ✓ to save your changes.
 - A confirmation notification appears to indicate that the parameter was successfully added.
 - The parameter is added to the Parameters grid.

Writing the Script for a Function

You can use the Scripting tab on the Function Details page to write the script for the function using the parameters you defined.

Rules and Restrictions

- You must define function parameters before you can write the script for a function.
- A function cannot call another function.
- A function must either return a value back to the derivation or query that calls the function or test a condition (or combination of conditions) and returns a "True" or "False" result.

Example The following function calculates a patient's body mass index (BMI) by (1) calculating the patient's height; (2) calculating the patient's weight; (3) using the patient's weight, height and factor to calculate the patient's BMI and finally returning a numerical value for PatientBMI.

Function PatientBMI(PatientHtUOM, PatientHt, PatientWtUOM, PatientWt)

```
If Not BMIHeightUOM = "0" AND Not BMIWeightUOM = "0" AND IsNumeric(BMIWeight)
Then
```

```
Dim HeightEnglish, WeightEnglish, TotalBMI
If PatientHtUOM = "IN" Then      'Converts metric height to english
    HeightEnglish = PatientHt
Else
    HeightEnglish = PatientHt * 0.393701
End If
```

```
If PatientWtUOM = "LB" Then      'Converts metric weight to english
    WeightEnglish = PatientWt
Else
    WeightEnglish = PatientWt * 2.20462
End If
```

```
'Calculate the patient's BMI
PatientBMI = (WeightEnglish / (HeightEnglish * HeightEnglish) ) * 703
PatientBMI = Round(PatientBMI,1)
```

PatientBMI
Body Mass Index

There are 8 scripting errors

Parameters Scripting Test Cases

Save Cancel

Script Text:

```
Function PatientBMI(PatientHtUOM, PatientHt, PatientWtUOM, PatientWt)
If Not BMIHeightUOM = "0" AND Not BMIWeightUOM = "0" AND IsNumeric(BMIWeight) Then
    Dim HeightEnglish, WeightEnglish, TotalBMI
    If PatientHtUOM = "IN" Then      'Converts metric height to english
        HeightEnglish = PatientHt
    Else
        HeightEnglish = PatientHt * 0.393701
    End If
    If PatientWtUOM = "LB" Then      'Converts metric weight to english
        WeightEnglish = PatientWt
    Else
        WeightEnglish = PatientWt * 2.20462
    End If
    'Calculate the patient's BMI
    PatientBMI = (WeightEnglish / (HeightEnglish * HeightEnglish) ) * 703
End Function
```

Parameters Referred By

- PatientHtUOM
- PatientHt
- PatientWtUOM
- PatientWt

2. Type the body of the script in the **Script Text** box, between **Function** *FunctionName* (*parameter1*, *parameter2*, etc.) and **End Function**.

- Click Save to save your changes

To see a list of parameters defined for the function:

- Click the **Parameters** tab.

To see a list of queries and derivations that reference this function:

- Click the **Referenced by** tab.

Creating Test Cases for Functions

You can use the Test Cases tab to test that the function has no errors and returns the expected value.

When you create a test case, you provide test values for each parameter you defined for the function and specify the value the function should return.

To create a test case from the Functions tab:

- Click the name of the function you want to create a test case for.
The details page for the function appears.
- Click the Test Cases tab.
- Click **Add Test**.

PatientBMI
Body Mass Index
There are 8 scripting errors

Parameters Scripting **Test Cases**

Add Test Case Refresh

Name	Description	Expected Results	Actual Results	Valid	Edit	Delete
Name: <input type="text"/>	Description: <input type="text"/>	Expected Results: <input type="text"/>	Actual Results: <input type="text"/>			

Test Case Parameters:

Parameter Name	Test Value
PatientHtUOM	<input type="text"/>
PatientHt	<input type="text"/>
PatientWtUOM	<input type="text"/>
PatientWt	<input type="text"/>

Run Test

Male		49.8	49.8	<input checked="" type="checkbox"/>	<input type="text"/>	
Female		19.2	19.2	<input checked="" type="checkbox"/>	<input type="text"/>	

- Enter the details for the test case.
- Click **Run Test**.

The script is tested to determine if the script has errors and if the script returns the expected value.

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- If the actual result matches the expected result and the script does not contain script errors, the test case is added to the Test Cases grid and marked Valid (✔).
 - If the actual result does not match the expected result and/or the script contains script errors, the test case is added to the Test Cases grid and is marked as Invalid (✘).
0. Do one of the following:
- Click ✔ to save the test case.
 - Click **Add Test Case** to add another test case.

Creating a Function from an Existing Function

You can use the Functions tab to create a new function from a function in an existing study.

The following information is copied from the existing function into the new function:

- Parameters
- Script Text
- Function References

To create a new function from an existing function:

1. On the menu bar, click Scripting.
The Scripting page appears.
2. Click the Functions tab.
The Functions page appears.
3. Click Create Derivation from Existing.
The Please Select a Study page appears.

Please select a Study

Client/Sponsor	Study Name	Study Label	Protocol	Therapeutic Area	Drug Name
Sponsor 1	Aspirin	Aspirin41	069752	Pain Management	Drug Name
Sponsor 2	Aspirin41	Aspirin	211573	Pain Management	Drug Name
Sponsor 3	Kidney	Kidney Diseases 11	024579	Nephrology	Drug Name
Sponsor 4	T Cell	T Cell Immunodeficiency	069752	Infectious Disease	Drug Name
Sponsor 5	Diabetes	Diabetes Study	099571	Endocrinology	Drug Name
Sponsor 6	Back_Pain	Back Pain Study	076407	Pain Management	Drug Name
Sponsor 7	Rheuma	Rheumatology Study	024589	Rheumatology	Drug Name
Sponsor 8	Eating	Eating Disorders	053283	Psychiatry	Drug Name

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Cancel

- Click the name of the study that contains the function you want to use to copy.

The Please select one or more scripts page appears.

Create Script From Existing

Please select one or more scripts

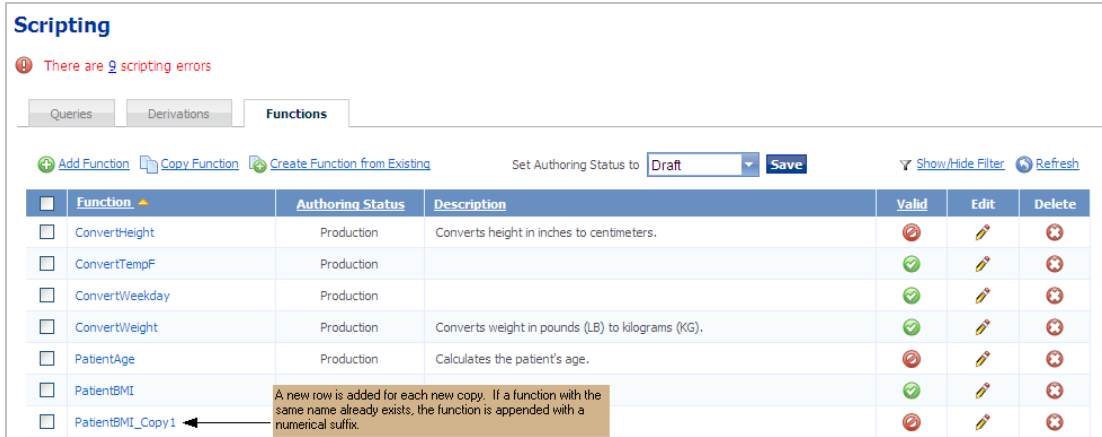
Function	Authoring Status	Description	Valid
ConvertHeight	Production	Converts height in inches to centimeters.	❌
ConvertTempF	Production		✅
ConvertWeekday	Production		✅
ConvertWeight	Production	Converts weight in pounds (LB) to kilograms (KG).	✅
PatientAge	Production	Calculates the patient's age.	❌
<input checked="" type="checkbox"/> PatientBMI	Production	Body Mass Index	✅
<input checked="" type="checkbox"/> PercentBodyFat	Production		✅
TotalStudyLength	Production		✅

Page size: 10 8 items in 1 pages

Continue Cancel

- Click Continue.

A new row is added to the Functions grid for each new copy. If a Function with the same name exists in the current active study, a numeric suffix is added to the Function name.



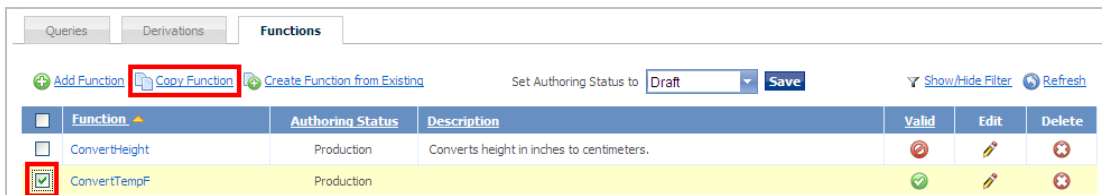
Copying a Function

You can use the Functions tab to create a copy of an existing function script. The following information is copied from the existing function into the new function:

- Parameters
- Script Text
- Function References

To copy a function:

1. On the menu bar, click Scripting.
The Scripting page appears.
2. Click the Functions tab.
The Functions page appears.
3. Select the functions you want to copy.



3. Click Copy **Function**.

A new row is added to the Functions grid for each new copy. The name of each newly-copied function is appended with a suffix, "COPY_01" and is inserted according to alphabetical order within the Functions grid.

Scripting

There are 8 scripting errors

Queries Derivations **Functions**

[Add Function](#)
[Copy Function](#)
[Create Function from Existing](#)
 Set Authoring Status to Draft [Save](#)
Show/Hide Filter [Refresh](#)

<input type="checkbox"/>	Function	Authoring Status	Description	Valid	Edit	Delete
<input type="checkbox"/>	ConvertHeight	Production	Converts height in inches to centimeters.			
<input type="checkbox"/>	ConvertTempF	Production				
<input type="checkbox"/>	ConvertTempF_Copy1					

The new function is added to the grid. Its name is appended with a numerical suffix.

If you are copying multiple functions and an error occurs during the copy process, the system skips that function and proceeds to the next one.

When all of the selected functions have been copied, a message appears to indicate the number of functions that were successfully copied.

Derivations

Quick Start for Creating Derivations

A derivation script collects parameters from study variables, calculate a value, and store the value in a field on a form.

Examples

Some examples of possible derivations include:

- Calculate the patient's age using their birth date and the current date.
- Calculate the patient's body fat percent using their total weight and their lean body mass.
- Concatenate the Enroll ID and the Patient ID.
- Convert the patient's height from inches to centimeters.
- Convert the patient's weight from pounds to kilograms.

Basic Steps

There are four basic steps you'll perform to create a derivation:

- Define a name and label for the derivation.
- Define the parameters (arguments) that will be passed to the derivation.
- Create a script for the derivation.
- Create test cases to ensure the derivation is valid.

Adding a Derivation

You can use the Derivations page to define a script that will collect parameters from study variables, calculate a value, and store the value in a field on a form.

To add a derivation:

1. On the menu bar, click Scripting.
The Scripting page appears.
2. Click the Derivations tab.
The Derivations page appears.

Derivation	Authoring Status	Description	Valid	Edit	Delete
<input type="checkbox"/> BMI	Production	Calculates the patient's Body Mass index (BMI).	✓	✎	✖
<input type="checkbox"/> CombinedID	Production		✓	✎	✖
<input type="checkbox"/> GetAge	Production		✖	✎	✖
<input type="checkbox"/> GetSex	Production		✓	✎	✖
<input type="checkbox"/> MaxHeartRate	Production	Calculate's the patient's maximum heart rate.	✖	✎	✖
<input type="checkbox"/> PatientAgeStudyStart	Production		✖	✎	✖
<input type="checkbox"/> StudyLengthTotal	Production	Calculates the number of days the patient is in...	✖	✎	✖

3. Click Add Derivation.

A new row is added to the Derivations table.

Derivation	Authoring Status	Description	Valid	Edit	Delete
<input type="checkbox"/>	Draft		✖	✓ ✖	

4. Enter the derivation properties. Required fields are highlighted in blue.

Note If you enter invalid data in a field, the field is highlighted in red and an error message appears.

5. Click ✓ to save the derivation.

- A confirmation notification appears to indicate that the derivation was successfully added.
- The derivation is added to the Derivations grid.

Note: When a new derivation is added, the derivation is shown as invalid.

Defining Parameters for a Derivation

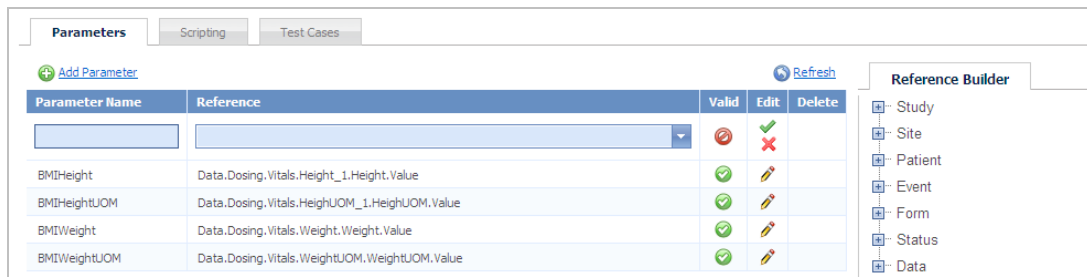
You can use the Parameters tab on the Derivation Details page to assign variable names to the study data that will be passed to the script.

To do

Parameter Name	Reference	Valid	Edit	Delete
BMIHeight	Data.Dosing.Vitals.Height_1.Height.Value	✓	✎	✖
BMIHeightUOM	Data.Dosing.Vitals.HeighUOM_1.HeighUOM.Value	✓	✎	✖
BMIWeight	Data.Dosing.Vitals.Weight.Weight.Value	✓	✎	✖
BMIWeightUOM	Data.Dosing.Vitals.WeightUOM.WeightUOM.Value	✓	✎	✖

2. Click Add Parameter.

A new row is added to the parameters grid.



4. Enter the parameter name.

Note: If you enter invalid data in a field, the field is highlighted in **red** and an error message appears.

5. Do one of the following to select a reference:
 - In the **Reference** field, enter the first few characters of the parameter you want to use in the script. As you type, the dropdown list is automatically populated with matching references. When the parameter you want to use appears, click the name of the reference.
 - On the **Reference Builder** tab, navigate to the parameter you want to use in the script; then, click the parameter name. The Reference field is automatically populated with the parameter you selected.
6. Click to save your changes.
 - A confirmation notification appears to indicate that the parameter was successfully added.
 - The parameter is added to the Parameters grid.

Authoring the Script

Writing the Script Text

Remember that when you are writing a derivation, the goal is to produce a script that returns a value, whether it be numeric, date or text.

To write the body of the script from the Derivations tab:

1. Click the name of the derivation you want to write a script for.
The details page for the derivation appears.
2. Click the Scripting tab.
3. Type the body of the script in the scrolling area of the **Script Text** box, between **Function** *FunctionName(parameter1, parameter2, etc.)* and **End Function**.
4. Click Save to save your changes.

To see a list of parameters defined for the derivation:

- Click the **Parameters** tab.

To see a list of functions you can call:

- Click the **Functions** tab.

Example The following derivation passes the values of four parameters and calculates the patient's body mass index based on their height and weight, returning a value for BMI.

```
Function BMI(BMIHeight, BMIHeightUOM, BMIWeight, BMIWeightUOM)

  If Not BMIHeightUOM = "0" AND Not BMIWeightUOM = "0" AND IsNumeric(BMIWeight)
  Then

    Dim HeightEnglish, WeightEnglish, TotalBMI

    If BMIHeightUOM = "IN" Then           'Converts metric height to english
      HeightEnglish = BMIHeight
    Else
      HeightEnglish = BMIHeight * 0.393701
    End If

    If BMIWeightUOM = "LBS" Then         'Converts metric weight to english
      WeightEnglish = BMIWeight
    Else
      WeightEnglish = BMIWeight * 2.20462
    End If

    'Calculate the patient's BMI
    BMI = (WeightEnglish / (HeightEnglish * HeightEnglish) ) * 703
    BMI = Round(BMI,1)

  Else

    BMI = 0

  End If

End Function
```

Calling a Function

From within a derivation script, you can call an existing function: either a pre-defined system function or a function created on the Functions page.

To add a function to the script from the Derivations tab:

1. Click the name of the derivation you want to call a function for.
The details page for the derivation appears.
2. Click the Scripting tab.
3. Click the Functions tabs
4. Select the functions you want to call in the script.
3. Add code to the **Script Text** that calls the function.

Example For example, first you reference a parameter on the Parameters tab.

```
PatientBirthDate      Data.Visit01.Demo.Birthdate.Birthdate.Value
```

Then you would select the Function on the Functions tab by clicking its checkbox:

Function PatientAge(BirthDate)

Then you would call the function in the script itself:

```
Function MaxHeartRate(PatientBirthDate)  
MaxHeartRate = 220 - PatientAge(PatientBirthDate)  
End Function
```

So:

- MaxHeartRate is the value you want to return from this derivation script.
- PatientAge is the function called by the derivation.
- PatientBirthDate is the parameter passed to the function.

Creating Test Cases for Derivations

You can use the Test Cases tab to verify that a derivation and that it returns the value you expect.

When you create a test case, you provide test values for each parameter you've defined and the value the derivation script should return. In order for a derivation to be valid, all test cases associated with the derivation must be valid.

To create a test case from the Derivations tab:

1. Click the name of the derivation you want to create a test case for.

The details page for the derivation appears.

2. Click the Test Cases tab.
3. Click **Add Test**.

Name	Description	Expected Results	Actual Results	Valid	Edit	Delete

Name: Description: Expected Results: Actual Results:

Test Case Parameters:

Parameter Name	Test Value
BMIHeight	<input type="text"/>
BMIHeightUOM	<input type="text"/>
BMIWeight	<input type="text"/>
BMIWeightUOM	<input type="text"/>

Run Test

4. Enter the test case properties.
5. Click the **Run Test** button.

If the actual result matches the expected result, the test case is marked Valid (✔); if it does not, it's marked Invalid (✘).

Test Results

- **Script errors:** the script has either syntax errors, runtime errors or logic errors. The error message box will display the kind of error and its location in the script.
- **Invalid result:** the script has no errors but is not returning the value that you expect. If a test case returns invalid then the script will be invalid.

Copying a Derivation

You can use the Derivations tab to create a copy of an existing query script. The following information is copied from the existing query into the new derivation:

- Parameters
- Script Text
- Function References

To copy a derivation:

1. On the menu bar, click Scripting.
The Scripting page appears.
2. Click the Derivations tab.
The Derivations page appears.
3. Select the derivations you want to copy.

Derivation	Authoring Status	Description	Valid	Edit	Delete
<input checked="" type="checkbox"/> BMI	Production	Calculates the patient's Body Mass index (BMI).	✔	✎	✘
<input type="checkbox"/> CombinedID	Production		✔	✎	✘

3. Click Copy **Derivation**.

A new row is added to the Derivations grid for each new copy. The name of each newly-copied derivation is appended with a suffix, "COPY_01" and is inserted according to alphabetical order within the Derivations grid.

Derivation	Authoring Status	Description	Valid	Edit	Delete
<input checked="" type="checkbox"/> BMI	Production	Calculates the patient's Body Mass index (BMI).	✔	✎	✘
<input type="checkbox"/> BMI_Copy1		Calculates the patient's Body Mass index (BMI).	✘	✎	✘

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If you are copying multiple derivations and an error occurs during the copy process, the system skips that derivation and proceeds to the next one.

When all of the selected derivations have been copied, a message appears to indicate the number of derivations that were successfully copied.

Creating a New Derivation from an Existing Derivation

You can use the Derivations tab to create a new derivation from a derivation in an existing study.

The following information is copied from the existing derivation into the new derivation:

- Parameters
- Script Text
- Function References

To create a new derivation from an existing derivation:

1. On the menu bar, click Scripting.
The Scripting page appears.
2. Click the Derivations tab.
The Derivations page appears.
3. Click Create Derivation from Existing.

The Create Script from Existing page appears.

Client/Sponsor	Study Name	Study Label	Protocol	Therapeutic Area	Drug Name
Sponsor 1	Aspirin	Aspirin41	069752	Pain Management	Drug Name
Sponsor 2	Aspirin41	Aspirin	211573	Pain Management	Drug Name
Sponsor 3	Kidney	Kidney Diseases 11	024579	Nephrology	Drug Name
Sponsor 4	TCell	T Cell Immunodeficiency	069752	Infectious Disease	Drug Name
Sponsor 5	Diabetes	Diabetes Study	099571	Endocrinology	Drug Name
Sponsor 6	Back_Pain	Back Pain Study	076407	Pain Management	Drug Name
Sponsor 7	Rheuma	Rheumatology Study	024589	Rheumatology	Drug Name
Sponsor 8	Eating	Eating Disorders	053283	Psychiatry	Drug Name

4. Select the study that contains the derivation you want to use to create a new derivation.
5. Select the script you want to use to create a new derivation.

Create Script From Existing

Please select one or more scripts Continue Cancel

<input type="checkbox"/>	Derivation ▲	Authoring Status	Description	Valid
<input type="checkbox"/>				
<input checked="" type="checkbox"/>	BMI	Production	Calculates the patient's Body Mass index (BMI).	
<input type="checkbox"/>	CombinedID	Production		
<input type="checkbox"/>	GetAge	Production		
<input type="checkbox"/>	GetSex	Production		
<input type="checkbox"/>	MaxHeartRate	Production	Calculate's the patient's maximum heart rate.	
<input type="checkbox"/>	PatientAgeStudyStart	Production		
<input type="checkbox"/>	StudyLengthTotal	Production	Calculates the number of days the patient is involved in the study, from Screen Date to Completion Date.	

Page size: 10 7 items in 1 pages

Continue Cancel

4. Click Continue.

- A confirmation notification appears to indicate that the derivation was successfully added.
- The derivation is added to the Derivations grid.

Queries

Quick Start for Creating Queries

A query is a script that checks study data and automatically generates a DCFs. if study data doesn't meet certain criteria. Queries run when one of their parameters changes, or can be run manually in DataLabs using Query Management.

The following table is an overview of the types of queries used by DataLabs:

Query Type	Level		Description	
	0-3	Form	The query checks the contents of a field or fields on a single CRF.	
	0-2	Single field	The query checks the contents of the current field upon exiting the field.	
Edit Check	0	Required	The field cannot be left blank.	
	1	Data Type	The data needs to be the proper type: date, float, integer, text.	
	2	Range Check	The data needs to fall within a specific range: date range, numeric range, etc.	
Range Check		Min/Max Length	The total number of characters or numbers entered in the field. For numeric fields, the decimal point is not counted in the length, so the length for "123.456" is 6.	
		Min/Max Precision	The number of digits to the right of the decimal for numeric fields. For example, a max precision of 3 would allow "123.456" but not "12.3456."	
Custom Query Script	3	Multi-field	The query checks the contents of multiple fields on a single form.	
		Not Answered Custom		
	4	Event	Custom	The query checks the contents of multiple fields, on multiple CRFs, for a single event.
	5	Patient	Custom	The query checks the contents of multiple fields, on multiple CRFs, for multiple events, for a single patient.

Examples

Some examples of queries include:

- Checks if the patient's age is in the proper range.
- Checks the Screen ID format.
- Checks that the Start Date is earlier than the End Date.
- Checks if the patient is Native American.

- Checks that the patient's blood pressure is in the normal range.
- Checks that the patient's body mass index (BMI) is in the acceptable range.

There are five basic steps you'll perform to create a query

- Define a name and label for the query.
- Define the parameters (arguments) that will be passed to the query.
- Create a script for the query.
- Create test cases to ensure the query is valid.
- Define the DCF that will be generated if the query data does not meet the criteria.

Adding a Query

You can use the Queries tab to define a query script that checks study data and automatically generates a DCF (Data Clarification Form) if the data does not meet certain criteria.

To add a query:

1. On the menu bar, click Scripting.

The Scripting page appears.

2. Click the Queries tab.

The Queries page appears.

Query	Active	Authoring Status	Description	Valid	Edit	Delete
<input type="checkbox"/> AgeRange	Active	Production	If the patient is between 18 and 45.			
<input type="checkbox"/> CheckBMI	Active	Production				
<input type="checkbox"/> CheckBP	Active	Production				
<input type="checkbox"/> IsPatientEnrolled	Active	Production	Tests if the patient's status is "enrolled".			
<input type="checkbox"/> RaceNativeAmerican	Active	Production				
<input type="checkbox"/> ScreenIDFormat	Active	Production				
<input type="checkbox"/> StartBeforeEndDate	Active	Production				

3. Click Add Query.


A new row is added to the Queries grid.

Query	Active	Authoring Status	Description	Valid	Edit	Delete
<input type="checkbox"/> <input type="text"/>	<input checked="" type="checkbox"/>	Draft	<input type="text"/>			
<input type="checkbox"/> AgeRange	Active	Production	If the patient is between 18 and 45.			

4. Enter the details for the query. . Required fields are highlighted in blue.

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Note If you enter invalid data in a field, the field is highlighted in **red** and an error message appears.

- Click  to save the query.
 - A confirmation notification appears to indicate that the query was successfully added.
 - The query is added to the Queries grid.

Defining Parameters

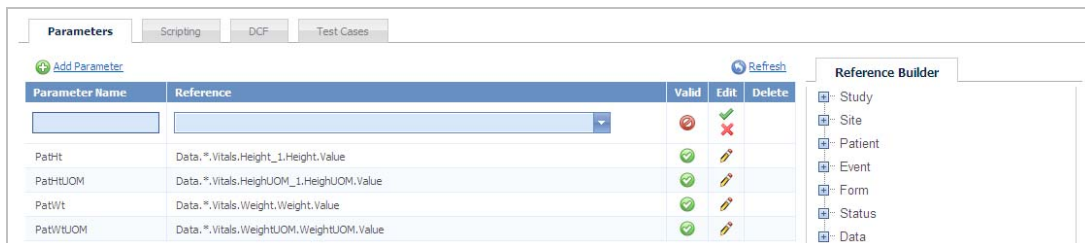
You can use the Parameters tab to assign variable names to the data that will be passed from the study data.

To define parameters for a query from the Queries tab:




2. Click Add Parameter.

A new row is added to the parameters table.



- Enter the parameter name.

Note: If you enter invalid data in a field, the field is highlighted in **red** and an error message appears.

- Do one of the following to select a reference:
 - In the **Reference** field, enter the first few characters of the parameter you want to use in the script. As you type, the dropdown list is automatically populated with matching references. When the parameter you want to use appears, click the name of the reference.
 - On the **Reference Builder** tab, navigate to the parameter you want to use in the script; then, click the parameter name. The Reference field is automatically populated with the parameter you selected.
- Click  to save your changes.

- A confirmation notification appears to indicate that the parameter was successfully added.
- The parameter is added to the Parameters grid.

Authoring the Script

Writing the Script Text

Remember that when you are writing a query, the goal is to produce a script that tests a particular condition (or combination of conditions) and produces a "True" or "False" result.

Important If the script generates a *True* result, *the query will generate a DCF*.

To write the body of the script from the Queries tab:

1. Click the name of the query you want to write a script for.
The details page for the query appears.
2. Click the Scripting tab.
3. Type the body of the script in the scrolling area of the **Script Text** box, between `Function FunctionName(parameter1, parameter2, etc.)` and `End Function`.
4. Click Save to save your changes.

To see a list of parameters defined for the query:

- Click the **Parameters** tab.

To see a list of functions you can call:

- Click the **Functions** tab.

Example The following query passes the values of one parameter to the IsPatientEnrolled query, testing to make sure that the patient's workflow Status is "Enrolled." If the patient is not enrolled, the IsPatientEnrolled variable is assigned the value of *True*; if the patient is enrolled, the variable is assigned *False*.

```
Function IsPatientEnrolled(PatientStatus)
    Dim strCurrentPatientStatus
    strCurrentPatientStatus = PatientStatus
    If strCurrentPatientStatus = "Enrolled" Then
        IsPatientEnrolled = "False"
    Else
        IsPatientEnrolled = "True"
    End If
End Function
```

Calling a Function

From within a query script, you can call an existing function: either a pre-defined system function or a function created on the Functions page.

To add a function to the script from the Queries tab:



2. Select the functions you want to call in the script.
3. Add code to the **Script Text** that calls the function.

Example The following query passes the values of one parameter to the `AcceptBMI` query, testing to make sure that the patient’s Body Mass Index (BMI) is within an acceptable range, that is, they are neither obese (a BMI of 30 or greater) or underweight (a BMI of less than 18.5) If the BMI is within an acceptable range, the `AcceptBMI` variable is assigned the value of *False* (since a *True* value generates a DCF).

First, you reference the parameter on the Parameters tab:

<u>PatWt</u>	Data.Visit1.Demo.Weight.Weight.Value
<u>PatHt</u>	Data.Visit1.Demo.Height.Height.Value

Then you would select the Function on the Script tab by clicking its checkbox (the `CalculateBMI` function takes a patient’s height and weight and calculates their Body Mass Index, a value that helps medical professionals to determine whether one is overweight, normal or underweight):

Function CalculateBMI(PatientWeight, PatientHeight)

Then you would call the function in the script itself:

```
Function AcceptBMI(PatWt,PatHt)
  PatientBMI = CalculateBMI(PatWt,PatHt)
  If PatientBMI >=30 Then      'A BMI 30 and above is obese
    AcceptBMI = "True"
  ElseIf PatientBMI < 18.5 Then 'A BMI less than 18.5 is underweight
    AcceptBMI = "True"
  Else                        'Between 18.5 - 30 is acceptable BMI
    AcceptBMI = "False"
  End If
End Function
```

So:

- `AcceptBMI` is the query which will return either a *True* or *False* value. (The query will generate a DCF if *True* returned.)

- CalculateBMI is the function called by the query.
- PatWt and PatHt are the parameters passed to the function.

Creating a Test Case for a Query

You can use the Test Cases tab to verify that the query has no errors and that it returns the expected value.

When you create a test case, you provide test values for each parameter you've defined and the value the query should return. In order for a query to be valid, all test cases associated with the query must be valid.

To create a test case from the Queries tab:

1. Click the name of the query you want to create a test case for.
The details page for the query appears.
2. Click the Test Cases tab.
3. Click **Add Test**.

Name	Description	Expected Results	Actual Results	Valid	Edit	Delete
Me		True	True	Valid		
Kam		False	False	Valid		

4. Enter the test case properties.
5. Click the **Run Test** button.

If the actual result matches the expected result, the test case is marked Valid (✔); if it does not, it's marked Invalid (✘).

Test Results

- **Script errors:** the script has either syntax errors, runtime errors or logic errors. The error message box will display the kind of error and its location in the script (the non-scrolling line, **Function** *FunctionName(parameters)*, is counted as line 1).
- **Invalid result:** the script has no errors but is not returning the value that you expect. If a test case returns invalid then the script will be invalid.

Defining a DCF

You can use the DCF tab to define the content of the DCF that can be created when the query is fired.

A DCF is created when: 1) a query script returns True, and 2) the user does not resolve the data before saving and checking in the CRF.

A DCF is not created when: 1) a query script returns False, or 2) the user resolves a query by correcting the data before saving and checking in the CRF.

To define a DCF from the Queries tab:

1. Click the name of the query you want to define a DCF for.

The details page for the query appears.

2. Click the DCF tab.

Description	Action Request	Initial Status	Warn User
BMI	Not BMI	New/Sent	<input checked="" type="checkbox"/>

3. Enter the DCF properties.

4. Click Save.

- A confirmation notification appears to indicate that the DCF was successfully added.

Copying a Query

You can use the Queries tab to create a copy of an existing query script. The following information is copied from the existing query into the new query:

- Parameters
- Script Text
- Function References
- DCF

To copy a query:

1. On the menu bar, click Scripting.

The Scripting page appears.

2. Click the Queries tab.

The Queries page appears.

- Select the queries you want to copy.

Query	Active	Authoring Status	Description	Valid	Edit	Delete
<input type="checkbox"/> AgeRange	Active	Production	If the patient is between 18 and 45.			
<input checked="" type="checkbox"/> CheckBMT	Active	Production				
<input type="checkbox"/> CheckBP	Active	Production				

- Click Copy Query.

A new row is added to the Queries grid for each new copy. The name of each newly-copied query is appended with a suffix, "COPY_01" and is inserted according to alphabetical order within the Queries grid.

Query	Active	Authoring Status	Description	Valid	Edit	Delete
<input type="checkbox"/> AgeRange	Active	Production	If the patient is between 18 and 45.			
<input checked="" type="checkbox"/> CheckBMT	Active	Production				
<input type="checkbox"/> CheckBMT_Copy1		Production				

If you are copying multiple queries and an error occurs during the copy process, the system skips that query and proceeds to the next one.

When all of the selected queries have been copied, a message appears to indicate the number of queries that were successfully copied.

Creating a New Query from an Existing Query

You can use the Queries tab to create a new query from a query in an existing study.

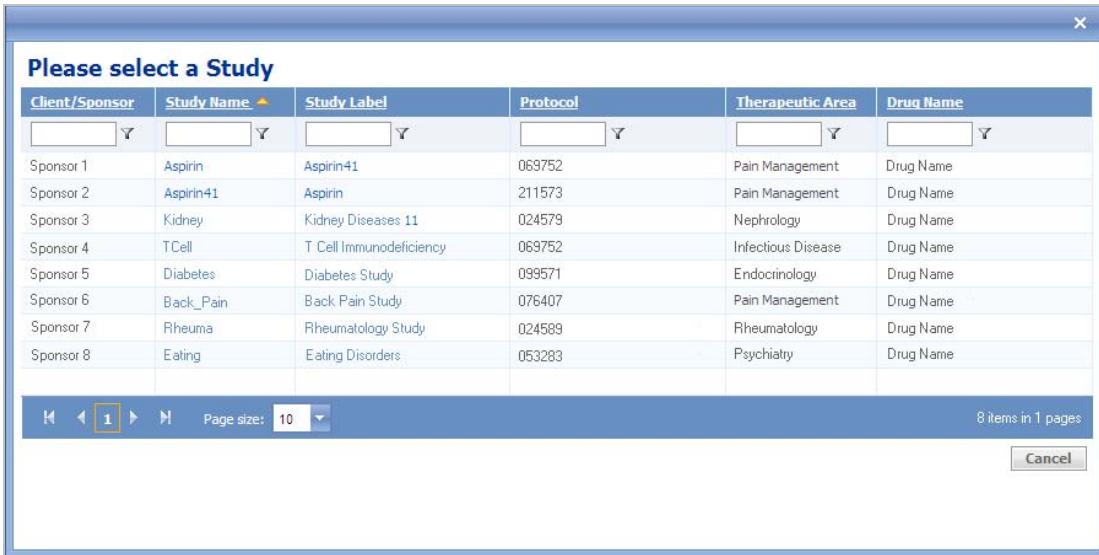
The following information is copied from the existing query into the new query:

- Parameters
- Script Text
- Function References
- DCF

To create a new query from an existing query:

- On the menu bar, click Scripting.
The Scripting page appears.
- Click the Queries tab.
The Queries page appears.
- Click Create Query from Existing.
The Create Script from Existing page appears.

Note You can use filters to search for the study you want to use as a template for creating the new study.



4. Select the study that contains the query you want to use to create a new query.
5. Select the script you want to use to create a new query.



4. Click Continue.
 - A confirmation notification appears to indicate that the query was successfully added.
 - The query is added to the Queries grid.

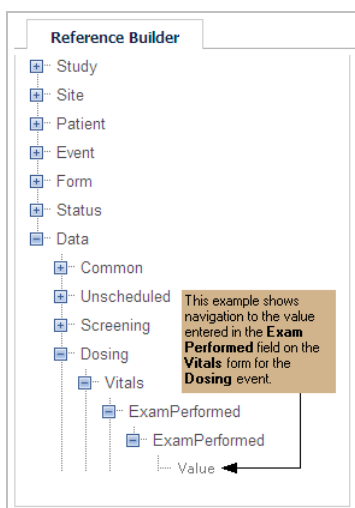
Using the Parameter Reference Builder

When defining the parameters for queries or derivations, the Parameter Reference Builder helps you to locate and reference data parameters in the study.

Reference Builder Tab

The Reference Builder tab is available on the Parameters tab of the Queries page and the Derivations page.

The tree structure allows you to navigate down to the item level (or property level if the item is in a table). As you navigate the tree, reference appears in the Reference field of the Parameters grid.



Where Clause Dialog Box

Using the Where Clause dialog box, you can call parameters from a form table by constructing the equivalent of a VBScript Where clause to aggregate table data.

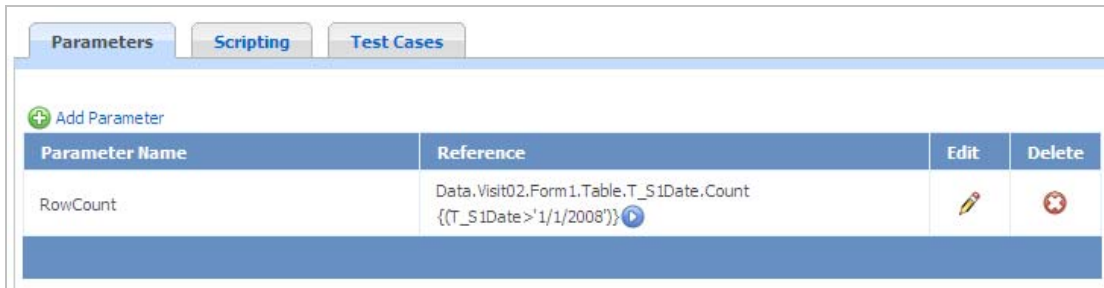
Note You can only access the Where Clause dialog box only after you select a parameter reference that contains an item in a *table* and a property that is an *aggregate* mathematical function (Count, Min, Max, Avg, Sum).

To build a where clause:

1. On the Parameters tab do one of the following:
 - In the **Reference** field, select a table item that includes an aggregate mathematical function
 - In the Parameter Reference Builder, navigate to a table item that includes an aggregate mathematical function and click the table parameter (e.g., Count {}).

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- The Where Clause button appears to the right of the Reference field on the Parameter grid.



- Click the Where Clause button.

The Where Clause dialog box opens.

Where Clause

Item:

Comparator:

Type: Date

Argument

Value:

Column:

Condition:

- Enter the Where Clause properties.
- Click Save.

The Where Clause is added to the Parameters grid.

Where Clause Properties

Item

The Where Clause Item lists all available items that exist in the same table as the referenced (selected) item. When an item is selected, the: Type, Argument Column, and Condition properties may change accordingly.

Note: If you want the aggregate of two table items, you would select a different item here.

Comparator

The Where Clause Comparator indicates how the selected Item and Argument will be compared.

Select from the following Comparator options:

- Equal To (The Default)
- Equal To
- Than
- Less Than or Equal To
- Greater Than
- Greater Than or Equal To

Type (Read Only)

The Type property displays the data type of the selected Item. The Type property can be one of the following:

- Text
- Date
- Numeric

Note Both Integer and Float items are considered “Numeric”.

Argument

The Where Clause Argument provides the value to compare with the specified Item. The Argument can be either:

- **Value:** Defines a fixed value to compare with the specified item.
- **Column:** Provide a selection of other items (of the SAME Type) in the same table to compare with the specified item.

Example If Item Type is Text, then ONLY Text items are listed in the Argument Column dropdown.

Condition

The Condition textbox displays the Where Clause syntax as it is being built.

Publishing a Study

Verifying the Study

Study verification ensures all study components are valid, and the relationships between components are complete and valid.

You can use the Verify Study action to verify study components before publishing the study to DataLabs. It is recommended that you verify a study after collaborating on the study design with multiple designers.

Note: When a study is verified, the study's components are not locked; therefore, it is possible for another user to modify study's components as the study is being verified.

To verify a study:

1. On the Home page, select the study you want to verify.

The Create Study Page appears.

The screenshot shows the 'DataLabs Designer' interface. The top navigation bar includes 'Home', 'Study', 'Events', 'Forms', 'Domains', 'Codelists', 'Dictionaries', and 'Scripting'. The 'Study' page is active, showing a form with the following fields:

- Study Name: Aspirin41
- Study Label: Aspirin
- Protocol: ASCT-5150
- Protocol Label: ASCT-5150-4
- Protocol Title: Topical application of aspirin to cylindromatosis tumors.
- External Study ID: (empty)
- Study Phase: Phase IV
- Study Drug Name: Aspirin
- Study Indication: cylindromatosis tumors
- Therapeutic Area: Pain Management
- Client/Sponsor: Aspirin
- Date/Time Format: United States (mm/dd/yyyy hh:mm:ss AP T)

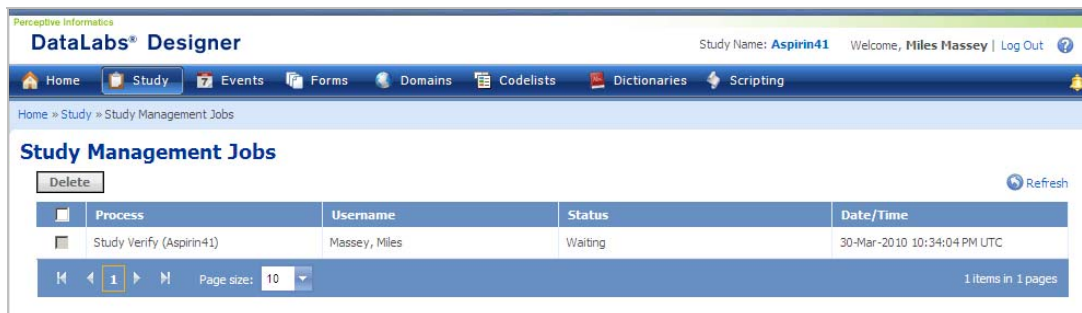
At the bottom of the form are 'Save' and 'Cancel' buttons. On the left sidebar, under 'Actions', 'Verify Study' is highlighted.

2. Click Verify Study.

A confirmation message appears.

3. Click Continue.

The Study Management Jobs Page appears and shows the progress of the study verification.



4. After study verification is complete, click the status message for information about the study verification job. Possible status messages include:
 - **Complete** - indicates that no verification errors or warning were found during study verification. Click the **Complete** link to view the total number of study components verified.
 - **Complete with Warnings** - indicates that non-critical study verification rules were encountered during study verification. Click the **Complete with Warnings** link to view a list of warnings. For more information, see "Resolving Warnings."
 - **Complete with Errors** - indicates that critical study verification rules were encountered during study verification. Click the **Complete with Errors** link to view a list of errors. For more information, see "Resolving Errors."

Publishing the Study XML File

You can use the Publish Study action to create a .zip file that contains an XML file of the study data. During the Publish Study process:

- Queries with unselected Authoring Statuses are excluded.
- Form Edit Check text variables are replaced with appropriate substitution text values.
- Queries that use the wildcard (asterisk) parameter for the Event, and reference multiple Forms, are duplicated for each Event containing all referenced Forms.

Note When a study is published, the study's components are not locked; therefore, it is possible for another user to modify study's components as the study is being published.

To publish the study XML file:

1. On the Home page, select the study you want to publish.

The Study Page appears.

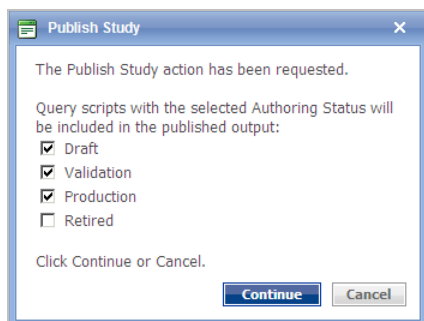
The screenshot shows the 'DataLabs Designer' interface. The top navigation bar includes 'Home', 'Study', 'Events', 'Forms', 'Domains', 'Codelists', 'Dictionaries', and 'Scripting'. The 'Study' page is active, displaying a form with the following fields:

- Study Name: Aspirin41
- Study Label: Aspirin
- Protocol: ASCT-5150
- Protocol Label: ASCT-5150-4
- Protocol Title: Topical application of aspirin to cylindromatosis tumors.
- External Study ID: (empty)
- Study Phase: Phase IV
- Study Drug Name: Aspirin
- Study Indication: cylindromatosis tumors
- Therapeutic Area: Pain Management
- Client/Sponsor: Aspirin
- Date/Time Format: United States (mm/dd/yyyy hh:mm:ss AP T)

At the bottom of the form are 'Save' and 'Cancel' buttons.

2. Click Publish Study.

The Publish Study Confirmation window appears.



3. Select the query authoring statuses you want to include in the published study output XML file.
3. Click Continue.

The Study Management page shows the progress of the study publication.

4. After study publication is complete, click the status message for the study publication job.



- If study was published but contained errors, the Study Publication Messages window lists all errors.
 - If the study was published without errors, the Publish Study File Download dialog box appears.
5. Do one of the following:
 - Click **Open** to open the zip file.
 - Click **Save** to save the .zip file.

Administration

Accessing Administration

The Administration page gives administrators access to the functions needed to configure and manage Designer.

Note: Only users who have been assigned the role of Administrator have access to the Administration page.

User Management

The User Management page shows a list of all users who are permitted to access Designer, each user's username, display name, and role.

From the User Management page an administrator can:

- Add a user to Designer
- Change a user's role
- Remove a user from Designer

To access the User Management page:

From the Administration page, click  User Management.

Adding User(s) to Designer

A user is any individual who is given access to Designer. A Designer administrator can use the Add/Remove Users page to select the users who are permitted to access Designer.



To be able to add a user to Designer:

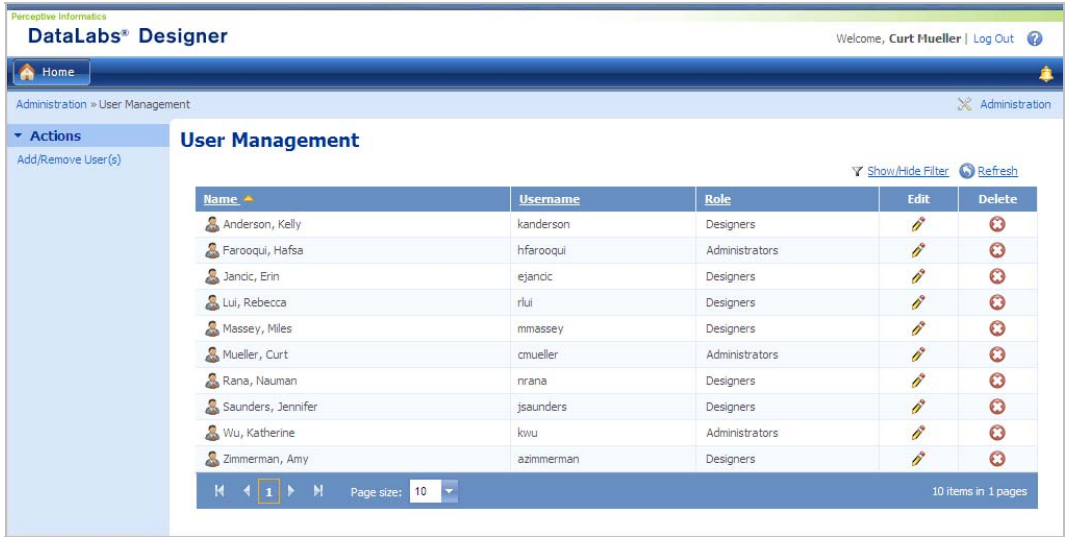
- You must have been assigned the Administrator role in Designer.
- The user you want to add must be a member of the Active Directory group selected during Designer installation.

Note: During installation, a Designer administrator is designated. This administrator initially grants users the ability to access Designer and assigns each user a role of either Designer or Administrator.



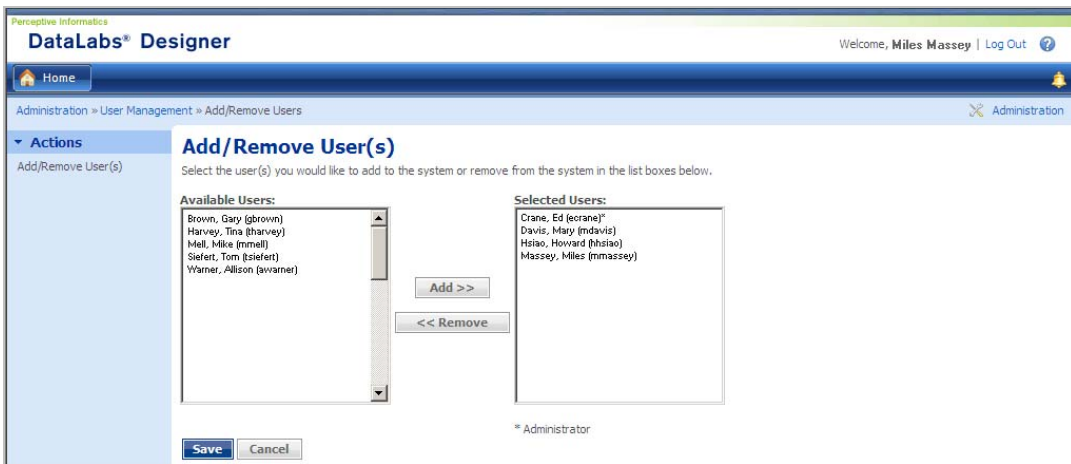
To add

1. **Administration**
2.  User Management
Adding/managing users and giving access to studies.
3. _____
4. Click  User Management.
5. The User Management page appears.



- From the User Management page, click **Add/Remove User(s)**.

The Add/Remove User(s) page appears. The Available Users box shows all users that are eligible to be added to Designer.



- In the Available users box, select the user(s) you want to add.

- Click **Add**.

The selected user name(s) are added to the Selected Users box.

- Click **Save**.

- The selected user(s) are added to Designer and, by default, are assigned the role of "Designer."

Changing a User's Role

A user is any individual who is given access to Designer. The actions a user can perform are determined by the user's role. A Designer administrator can use the User Management page to change a user's role.

Designer provides two pre-defined roles:

- **Designer** - A user with the role of "Designer" can access Designer and work with all study components for all studies. When a user is added to Designer, by default, the user is assigned the role of Designer.
- **Administrator** - A user with the role of "Administrator" can perform all of the actions the Designer role can perform. In addition, an administrator can access Administration options, add and remove users from Designer, and add or change user roles.

Note: A user cannot be assigned to multiple roles at one time.

Note: An administrator cannot change his own role.

To change a user's role:

1. On the User Management page, click  for the user whose role you want to change.

The row that contains the user's information opens for editing.



Administration » User Management


User Management

Actions: Add/Remove User(s)

Show/Hide Filter Refresh

Name	Username	Role	Edit	Delete
Crane, Ed	ecrane	Administrators		
Massey, Miles	mmassey	Designers	 	
Sullivan, Barb	bsullivan	Administrators		

Page size: 10 3 items in 1 pages

2. In the Role box, select the role you want to assign to the user.
3. Click .

The user's new role is saved.


Removing User(s) from Designer

An Administrator can use the User Management page and the Add/Remove Users(s) page to remove a user's ability to access Designer.

Note: Removing a user from Designer does not remove the user from Active Directory.

Note: An administrator cannot delete himself from Designer.

To remove an individual user from Designer:

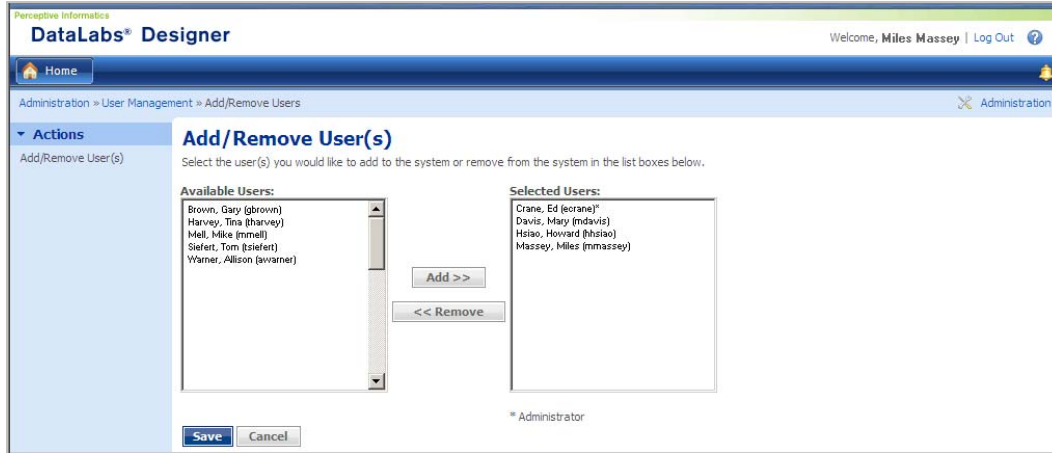
1. On the User Management page, click  for the user you want to remove.
2. A confirmation message appears.
2. Click **Yes**.

The user removed from Designer.

To remove multiple users from Designer:

1. From the User Management page, click **Add/Remove User(s)**.

The Add/Remove User(s) page appears. The Selected Users box shows all users that have access to Designer.



2. In the Selected Users box, select the user(s) you want to remove.
3. Click **Remove**.
The selected user name(s) are moved to the Available Users box.
4. Click **Save**.
5. The selected user(s) are removed from Designer.

LDAP and Designer User Accounts

A user must be added to LDAP to be allowed to access Designer.

If a username is modified in LDAP, the user's name will not be modified in Designer. (No synchronization of data)

The LDAP domain security settings for User Account Properties and Account Lockout Policy affect what happens when a user logs in to Designer.

Account Lockout Policy Settings

The Account Lockout Policy settings define how many times a user can attempt to log in to Designer before the user's account is locked and, if locked, if the user's account will unlock automatically.

- **Account lockout threshold** - Determines the number of times a user can unsuccessfully attempt to log in Designer before the user's account is locked. You can set a value between 0 and 999 failed logon attempts. If you set the value to 0, the user's account will never be locked out.

If a user exceeds the number of attempts specified as the Account lockout threshold, the user's account is locked. the user cannot log in to Designer until either the user's account is reset by an administrator or until the **Account lockout duration** has expired.

- **Account lockout duration** - Determines the number of minutes a locked-out account remains locked out before automatically becoming unlocked. You can set a value between 9 and 99,999 minutes.

If the **Account lockout duration** is greater than 0 and a user whose account is locked attempts to log in to Designer, the following message is displayed to the user, "Login Failed: You cannot login to the system because one or more of the following has occurred: an incorrect username and/or password was entered, account is locked, password has expired. Please contact your System Administrator for more information."

If the **Account lockout duration** is set to 0, the user's account will be locked out until an administrator explicitly unlocks it. If the user attempts to log in to Designer, the following message is displayed to the user, "Login Failed. You cannot login to the system because one or more of the following has occurred: an incorrect username and/or password was entered, account is locked, password has expired. Please contact your System Administrator for more information."

User Account Properties

The User Account Properties dialog box specifies if, after a user's password is reset, the user is required to change his password the next time the user logs in to Designer.

Password Expiration

- **Password never expires** - If selected, the selected user's Designer password will never expire. This setting overrides the **Maximum Password Age** defined in the Password policy.

If cleared, the selected user's Designer password will expire based on the **Maximum Password Age** setting in the Password policy.

If the user's password expires, the next time the user attempts to log in to Designer, the following message is displayed to the user, "Login Failed. You cannot login to the system because one or more of the following has occurred: an incorrect username and/or password was entered, account is locked, password has expired. Please contact your System Administrator for more information."

- **User must change password at next logon** - If selected, when a user's password has been reset by the administrator, the following message appears to the user the next time the user logs in to Designer, the following message is displayed to the user, "Log in Failed. Your cannot login to the system because one or more of the following has occurred: an incorrect username and/or password was entered, account is locked, password has expired. Please contact your System Administrator for more information."

Note: If both the **User must change password at next logon** and **Password never expires** settings are selected, the user will not be prompted to change his password when the user logs into the system.

Getting Help

About Online Help

The online Help system is intended to give you a comprehensive introduction to Designer™. It is not intended to be an exhaustive resource on everything you may need to know about Designer. Instead, it is meant to get you started in using Designer's basic functions. It assumes that you have some experience with computers, but at the same time does not expect you to be a "power user."

Related Documents

DataLabs Designer comes with the following documentation in PDF format.

- *User's Guide* - A guide to using Designer to design clinical trial studies that can be loaded into DataLabs.
- *Designer Release Notes* - A short overview of what's new, of defects that have been fixed since the last release, and of known issues in the current release of Designer.

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