



4.1 Create Dataset

To create a dataset, you first [define the dataset](#) (specify the criteria for the dataset) for the current Site or Study. Then you [generate and download the file](#) (extract data that matches the definition to a file format you select).

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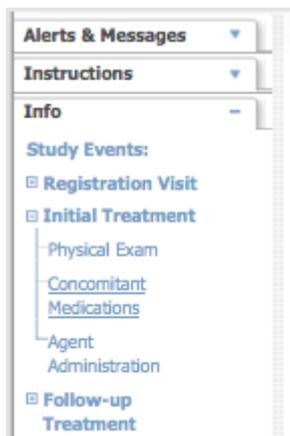
4.1.1 Define Dataset

To define a dataset for the current Study or Site, perform the following steps:

1. Select Tasks > Create Dataset.
The Create Dataset page for the current Study or Site opens.
2. Click Proceed to Create a Dataset.
The Create Dataset: Select Items page opens.

The screenshot displays the OpenClinica Enterprise interface for the 'Create Dataset: Select Items' step. The top navigation bar includes 'Home', 'Subject Matrix', 'Notes & Discrepancies', 'Study Audit Log', and 'Tasks'. The left sidebar contains 'Alerts & Messages', 'Instructions', and 'Info'. Under 'Info', 'Study Events' is expanded, showing 'Registration Visit', 'Initial Treatment' (selected), 'Follow-up Treatment', and 'Adverse Events'. Below this are 'Event Attributes', 'Subject Attributes', 'CRF Attributes', 'Group Attributes', 'View Selected Items', and 'Select All Items in Study'. The main content area has a title 'Create Dataset: Select Items' and instructions: 'Please select one CRF from the left side info panel, then select one or more items in a CRF that you would like to include to this dataset. You may select all items in the study by going to the "View Selected Items" (hyperlink) page and clicking "Select All". You may also click Event Attributes/Subject Attributes to specify which event/subject attribute will be shown in the dataset.' A callout box with an arrow points to the sidebar with the text 'Use task pane on the left side to select CRFs'. Below the instructions is a 'Workflow' diagram with seven steps: 'Extract Datasets', 'Create Dataset Instructions', 'Select Items or Event/Subject Attributes', 'Define Temporal Scope', 'Specify Dataset Properties', 'Confirm Dataset Properties', and 'Generate Dataset'.

3. In the Info sidebar panel, click an Event, and then click a CRF for the Event that you want to include in the dataset definition. For the example shown, the Initial Treatment Event was selected, and then the Concomitant Medications CRF for the Event was selected. You can add more Event CRFs in a later step.



After clicking an Event CRF, a table displays, listing all of the Event's CRF Items you can include in the dataset definition. It also lists the metadata for each item, which was defined when the CRF was created.

Create Dataset: Select Items

Please select one CRF from the left side info panel, then select one or more items in a CRF that you would like to include to this dataset. You may select all items in the study by going to the "View Selected Items" (hyperlink) page and clicking "Select All".

You may also click Event Attributes/Subject Attributes to specify which event/subject attribute will be shown in the dataset.

Use task pane on the left side to select CRFs

Event Name: Initial Treatment
 CRF Name: Concomitant Medications
 Description: Group con med form

Select All Items Save and Add More Items Save and Define Scope Cancel

Show the following items in this dataset:

	Name	Description	Version(s)	Section(s)	Group(s)	Data Type	Units	Response Type	Response Label	PHI	Required?	Double Data Entry	Default Value	Max Repeats
<input type="checkbox"/>	Con_Med_Name	Medication name	v1.0	Concomitant Meds	CONCOMITANT MEDICATIONS	st		text	text	No	No			40
<input type="checkbox"/>	Con_Med_Start	Start date	v1.0	Concomitant Meds	CONCOMITANT MEDICATIONS	date		text	text	No	No			40
<input type="checkbox"/>	Con_Med_End	End date	v1.0	Concomitant Meds	CONCOMITANT MEDICATIONS	date		text	text	No	No			40
<input type="checkbox"/>	Con_Med_Cont	Ongoing/Continuing	v1.0	Concomitant Meds	CONCOMITANT MEDICATIONS	int		radio	y,n	No	No			40
<input type="checkbox"/>	Con_Med_form	Dose	v1.0	Concomitant Meds	CONCOMITANT MEDICATIONS	st		text	text	No	No			40

Save and Add More Items Save and Define Scope Cancel

- In the table, select the checkbox for each Item to include in the dataset definition, or select the Select All Items checkbox. If you are selecting many but not all Items in the CRF, you might find it easier to use Select All Items, then for each item you want to exclude, select its checkbox to clear it.

Note: With some large studies (> 10,000 Items), the 'Select All' function may not work. If this is the case you will have to manually select each Item you want in your dataset.

- If you want to add more Event CRFs:
 - Click the Save and Add More Items button.
 - Repeat steps 3 to 5 to select the Event CRF Items to include in the dataset definition.

- To see the Items already selected, click the View Selected Items link in the Info sidebar panel.

If you want to select all Items for all CRFs for all Events, instead of selecting each Event and CRF, instead click Select All Items in Study in the Info sidebar panel.

- To select non-CRF Attributes to include in the dataset definition, click the link for it in the Info sidebar panel.

The Create Dataset: Select Attributes page opens for the option you chose.

For example, when you click Subject Attributes, the Create Dataset: Select Subject Attributes page opens.

- Select the checkbox for each Attribute to include.
- If you want to include Attributes of a different type:
 - Click Save and Add More Items.
 - Repeat steps 6 to 8 to select additional Attributes to include in the dataset definition.
 - To see the Attributes already selected, click the View Selected Items link in the Info sidebar panel.
- After selecting all Items and Attributes you want to include in the dataset, click the Save and Define Scope button.

The Create Dataset: Define Temporal Scope page opens.

- Set a date range for the dataset definition by following the onscreen instructions: the date you

specify is the Subject enrollment date. For example, if you select 2011 for the year for the Beginning Date and Ending Date, the dataset will include all Subjects who enrolled in 2011. After specifying the date range, click the Continue button. The Create Dataset: Specify Dataset Properties page opens.

Create Dataset: Specify Dataset Properties

Please enter the dataset properties in the fields. Be descriptive. **Name and Description fields are required.**

Name:

Description:

Item Status:

- Data from CRFs Marked Complete
- Data from CRFs not Marked Complete
- Data from all Available CRFs

Meanwhile, if you choose to output your data in CDISC ODM XML format, you may like to set some properties for your CDISC ODM XML data file. Currently, the available properties include MetaDataVersion ODM ID, MetaDataVersion Name, Previous Study ODM ID and Previous MetaDataVersion ODM ID which you like to include in your ODM output file. The inputs for CDISC ODM XML format are optional. If you leave them empty, default value will be used, that is, MetaDataVersion ODM ID="v1.0.0", MetaDataVersion Name="MetaDataVersion_v1.0.0", and no include in this file. If you input previous study ODM ID, you have to input previous MetaDataVersion ODM ID, otherwise no include in you ODM output file. If you only input previous MetaDataVersion ODM ID, then current study ODM ID will be include in your ODM output file.

MetaDataVersion ODM ID:

MetaDataVersion Name:

Previous Study ODM ID:

Previous MetaDataVersion ODM ID:

11. Provide a Name and Description for the dataset definition, and optionally, change the Item Status. You can also specify ODM ID values, which you might use if you export the dataset to an ODM file format. Then click Continue.

The Create Dataset: Confirm Dataset Properties page opens.

12. Verify the Name and Description, then click Confirm and Save.

The Download Data page opens. Now that the dataset definition exists, at any time you can generate and download a file containing all data that matches the criteria you specified.

4.1.2 Generate and Download Dataset

1. After [creating](#), [editing](#), or [selecting](#) a dataset definition, the Download Data page displays. On the page, click Run Now for the file format you want. OpenClinica 3.11 introduced SAS Data and Syntax file formats. For more information about the file formats, see [Formats for Dataset Files](#).

Download Data: ConcomitantMedications2011

Dataset Name:	ConcomitantMedications2011
Dataset Description:	All ConMeds for 2011
Item Status:	Data from all Available CRFs

To view or download data, select from the formats provided below. You may also select from the archived dataset files at the bottom of the page.

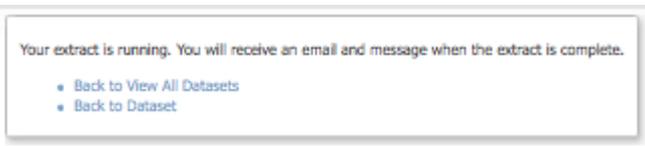
- CDISC ODM XML 1.3 Full with OpenClinica extensions [Run Now](#)
- CDISC ODM XML 1.3 Clinical Data with OpenClinica extensions [Run Now](#)
- CDISC ODM XML 1.3 Clinical Data [Run Now](#)
- CDISC ODM XML 1.2 Clinical Data with OpenClinica extensions [Run Now](#)
- CDISC ODM XML 1.2 Clinical Data [Run Now](#)
- View as HTML [Run Now](#)
- Excel Spreadsheet [Run Now](#)
- Tab-delimited Text [Run Now](#)
- SPSS data and syntax [Run Now](#)
- Datamart in a downloadable format. [Run Now](#)
- Datamart [Run Now](#)
- SAS Data and Syntax [Run Now](#)

Note: Large extracts may take some time to run. Once complete, you will receive an email notification and you can download your extract in the table below.

Archive of Exported Dataset Files:

No Pages	<input type="text"/>	Find			
File Name	Run Time (Seconds)	File Size (Bytes)	Created Date	Created By	Action
There are no rows to display.					

- OpenClinica displays a page that reports your extract is running. OpenClinica maintains a queue of dataset extracts, including scheduled jobs and dataset extracts initiated by other users. New data extract requests are added to the end of the queue. You can view the queue to see where your data extract is in the list. For more information, see [View or Cancel Data Exports](#). After a few moments (or longer, for a large dataset or when there were already other requests in the queue), the dataset file is available. To view it, click Back to Dataset.



- The Download Data page displays again, and the dataset you generated is listed in the Archive of Exported Dataset Files table. The example below shows a dataset generated with an Excel Spreadsheet format. Click the Download icon  in the Actions column for the dataset.

Archive of Exported Dataset Files:					
Page 1 of 1	<input type="text"/>	Find			
File Name	Run Time (Seconds)	File Size (Bytes)	Created Date	Created By	Action
EXCEL_ConcomittantMedications2011_2012-02-01-093307720.xls.zip	1.0	750	Feb 1, 2012	StuartDirk	 

The file downloads using your web browser's download features. For more information, see [Downloading Datasets](#).

OpenClinica also sends an email to you that contains a link to the dataset file, providing another way for you to access the file, if that option was specified in the [datainfo.properties file](#) as part of your system configuration.

- Open the file to verify that it contains the data you expected. If not, you can [edit the dataset definition](#) in OpenClinica and generate the dataset file again.

Data in the dataset file reflects the OpenClinica database at the time the dataset file is generated, not at the time you download the file. The dataset file name includes the date and time the file was generated.

The Archive of Exported Dataset Files table includes only one dataset file for each format for the dataset definition. When you generate a dataset file, if a dataset file having the same format already exists in the table, the file you generate replaces the existing file in the table. If you want both files, download the existing file, and then generate the dataset and download it using a different, or you can edit the dataset definition and save it using a different name and generate a the dataset for it.