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.

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 ⑦

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
☐	Con_Med_Name	Medication name	v1.0	Concomitant Meds	CONCOMITANT MEDICATIONS	st		text	text	No	No			40
☐	Con_Med_Start	Start date	v1.0	Concomitant Meds	CONCOMITANT MEDICATIONS	date		text	text	No	No			40
☐	Con_Med_End	End date	v1.0	Concomitant Meds	CONCOMITANT MEDICATIONS	date		text	text	No	No			40
☐	Con_Med_Cont	Ongoing/Continuing	v1.0	Concomitant Meds	CONCOMITANT MEDICATIONS	int		radio	y,n	No	No			40
☐	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

4. 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.

5. 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.
6. 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.

Create Dataset: Select Subject Attributes

Select Items or Event/Subject Attributes ⇨ Define Temporal Scope ⇨ Specify Dataset Properties ⇨ Save And Export

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.

☐ Date of Birth

☐ Sex

☐ Subject Status

☐ Person ID

☐ Secondary ID

[Save and Add More Items]   [Save and Define Scope]   [Cancel]

7. Select the checkbox for each Attribute to include.
8. 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.
9. 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.

Create Dataset: Define Temporal Scope ⊘

Filter your data by subject enrollment date by selecting a date range below.

Select the event start and end dates below. To specify data from the beginning of the year, you may leave the month field blank. However, if you specify a month, you must also specify the year.

If you do not wish to filter study event data by date of subject enrollment, you may leave the date fields blank and continue.

Beginning Date: [–Select– ▾] [–Select– ▾]

End Date: [–Select– ▾] [–Select– ▾]

Save and Export your dataset now or Apply a Filter to specify additional selection criteria based on values of parameters in CRFs.

[Continue]   [Cancel]

10. 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: v1.0.0

MetaDataVersion Name: MetaDataVersion_v1.0.0

Previous Study ODM ID:

Previous MetaDataVersion ODM ID:

[Continue]   [Cancel]

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.

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