OpenClinica

1.1.2 Customize the View in Source Data Verification

You can customize the view in the Source Data Verification page to adapt it for the workflow you use. For example, you can review all CRFs for a Subject to verify that Subject. Or if you use a sampling method, you can review a sample of CRFs for a Site, then mark all CRFs for that Site as verified. This section describes the ways you can customize the view.

This page is not approved for publication.

1.1.2.1 View by CRF or by Subject

You can view Source Data Verification information by CRF or by Subject:

- **By CRF:** Click the View By Event CRF tab, and the table shows all CRFs in the current Study or Site that have been marked complete and therefore are eligible for Source Data Verification. CRFs are listed by Event Date, with the oldest at the top of the table. The CRF view also reports whether or not Source Data Verification is required for a CRF (shown in the SDV Requirement column, and specified in the CRF Event Definition). With this CRF view, you can mark one CRF or selected CRFs as verified.
- **By Subject:** Click the View By Study Subject ID tab, and the table shows all Subjects in the Study, reporting how many CRFs are eligible for verification and how many have already been verified for each Subject (shown in the # of CRFs Completed and the # of CRFs SDV'd columns). The view lists all Subjects, even those with no CRFs eligible for Source Data Verification (SDV N/A appears in the Actions column for Subjects who have no CRFs ready for Source Data Verification). With this Subject view, you can mark all CRFs for one or more Subjects as verified. You can also show the By CRF view for any Subject by clicking the View icon for that Subject, in order to access the Subject's CRF data.

Source Data Verification Page with the By Subject ID View for the Current Site; the Pointer is Hovering Over the Row for Subject CAM105, Temporarily Highlighting the Row in Yellow:

Source Data Verification for Cambridge Center for Surgical Oncology @													
View By Event CRF View By Study Subject ID													
Select: All Shown, None													
SDV Status	Study Subject ID	Group	# of CRFs Completed	# of CRFs SDV'd	Total Event CRFs	Actions							
						Apply Filter	Clear Filter						
	CAM102	Regimen II	1	0	1	_ ا	SDV						
	CAM103	Regimen III	7	0	7	8	SDV						
	CAM104	Regimen I	0	0	0	٩.	SDV N/A						
	CAM105	Regimen I	7	1	7		SDV						
	CAM106	Regimen II	0	0	0	٩.	SDV N/A						
	CAM107	Regimen III	0	0	0	S	SDV N/A						
	CAM108	Regimen I	0	0	0	٩.]	SDV N/A						
	CAM101	Regimen III	5	5	7	8							
Results 1 -	8 of 8.												
SDV All C	hecked												

After Clicking the View Icon for Subject CAM105 in the By Subject ID View, the Page Shows CRFs Eligible for Source Data Verification for Subject CAM105. Below Column Headers, the Study Subject ID Field Indicates the Data is for CAM105:

Source	Source Data Verification for Cambridge Center for Surgical Oncology @											
View By Event CRF View By Study Subject ID												
K Show More The table is sorted by Event Date												
SDV Status	Study Subject ID	Site ID	Event Name	Event Date	CRF Name / Version	SDV Requirement	CRF Status	Actions				
	CAM105							Apply Filter Clear Filter				
	CAM105	R01-123456-CCSO	Registration Visit(1)	06-Jul-2011	Verification of Informed Consent/ v2.0	100% Required		SDV				
	CAM105	R01-123456-CCS0	Registration Visit(1)	06-Jul-2011	Physical Exam/ English	Partial Required		SDV				
	CAM105	R01-123456-CCSO	Registration Visit(1)	06-Jul-2011	Eligibility/ v1.0	100% Required		SDV				
	CAM105	R01-123456-CCSO	Initial Treatment(1)	06-Jul-2011	Agent Administration/ v1.0	Partial Required	C	SDV				
	CAM105	R01-123456-CCS0	Initial Treatment(1)	06-Jul-2011	Concomitant Medications/ v1.0	100% Required		SDV				
	CAM105	R01-123456-CCSO	Initial Treatment(1)	06-Jul-2011	Physical Exam/ English	Partial Required	C	SDV				
8	CAM105	R01-123456-CCSO	Follow-up Treatment(1)	06-Jul-2011	Physical Exam/ English	Partial Required						
Results 1 - 7 of 7.												
SDV All C	hecked											

1.1.2.2 Find and Organize SDV Data

In either the CRF or Subject view, you can:

- Navigate through the table pages and change the number of CRFs or Subjects shown per page
- Show more data for all rows, or hide it
- Filter the data in the table so it shows only the CRFs or Subjects you want to see

These features work the same way as in the Subject Matrix: for more information, see <u>Find and</u> <u>Organize Data in the Subject Matrix</u>.