OpenClinica

1.1.1 Verify Source Data

Users whose <u>Roles have appropriate permission</u> can verify source data in OpenClinica. To perform Source Data Verification, follow these steps:

1. <u>Change the Current Study or Site</u> to the one you want to perform Source Data Verification for.

Select Tasks > Source Data Verification.
The Source Data Verification page for the current Study or Site opens.

Source Data Verification for Docetaxel in Patients With Completely Resected NSCLC @								
View By Ev	ent CRF View By	v By Study Subject ID						
Select: All Shown, None 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
								Apply Filter Clear Filter
	SCRC001	R01-12345-SCRC	Registration Visit(1)	05-Jul-2011	Eligibility/ v1.0	100% Required		SDV
	SCRC001	R01-12345-SCRC	Registration Visit(1)	05-Jul-2011	Physical Exam/ English	Partial Required	C	SDV
	SCRC001	R01-12345-SCRC	Registration Visit(1)	05-Jul-2011	Verification of Informed Consent/ v2.0	100% Required		SDV
	SCRC005	R01-12345-SCRC	Registration Visit(1)	05-Jul-2011	Eligibility/ v1.0	100% Required		SDV
	SCRC005	R01-12345-SCRC	Registration Visit(1)	05-Jul-2011	Physical Exam/ English	Partial Required		SDV
	SCRC005	R01-12345-SCRC	Registration Visit(1)	05-Jul-2011	Verification of Informed Consent/ v2.0	100% Required		SDV
	SCRC002	R01-12345-SCRC	Registration Visit(1)	05-Jul-2011	Eligibility/ v1.0	100% Required		SDV
	SCRC002	R01-12345-SCRC	Registration Visit(1)	05-Jul-2011	Verification of Informed Consent/ v2.0	100% Required		SDV
	SCRC002	R01-12345-SCRC	Registration	05-Jul-2011	Physical Exam/	Partial Required		SDV

- 3. <u>Customize the view</u> so the page shows only those CRFs or Subjects whose data you want to verify. By default, the view is By CRF, which lists only CRFs that are marked complete and therefore ready for Source Data Verification. The By Subject view lists all Subjects in the current Study or Site.
- 4. View details for the CRFs whose data you want to verify. How you access the CRF depends on how you set the view in the SDV page:
 - $\circ\,$ In the Event CRF view, for the CRF you want to view, click the icon in the CRF Status column.
 - In the Study Subject ID view, click the View icon in the Actions column for the Subject. The page shows all Event CRFs ready for verification for that Subject. Click the CRF Status icon for the CRF you want to view.

The completed CRF opens in a new window.

- 5. Review the data in the CRF. You can add a Query type <u>Discrepancy Note</u> to record a question about any Item.
- 6. When you finish reviewing data in the CRF, click the Close button in the CRF window, which closes it. (Note that if you click Exit instead, the window remains open, showing Subject details.)
- 7. To mark the data as verified, in the Source Data Verification page click the SDV button for the CRF.

In the SDV status column, the checkbox is replaced by an SDV Complete icon 🧖. In the Audit

Log for the Subject, the Event CRF Source Data Verification Status is reported as true, and the date, time, and user are also recorded.

- 8. Continue viewing details and marking CRFs as verified, changing the view as needed. You can mark multiple CRFs as verified in any of these ways:
 - **All Eligible CRFs for a Subject:** In the Study Subject ID view, click the SDV button for the Subject to mark all eligible CRFs for that Subject as verified.
 - Selected CRFs or Subjects: In either the CRF or Subject view, select the checkbox in the SDV Status column for all CRFs or Subjects you want to mark as verified. You can deselect a row by clicking the checkbox again, or clear all selected rows by clicking the None link (located above the column headers). Then click the SDV All Checked button at the bottom of the page.
 - All CRFs or Subjects Shown: In either the CRF or Subject view, to select all CRFs or Subjects on the page, click the All Shown link (located above the column headers), which selects all checkboxes in the SDV Status column on that page. You can deselect a row by clicking its checkbox, or clear all selected rows by clicking the None link (located above the column headers). Then click the SDV All Checked button at the bottom of the page.

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