

16.3.1 Data Manager and Study Director Home Page

A Data Manager and Study Director see the same information in the home page. It shows summary tables for the current Study or Site: Subject Enrollment By Site, Subject Enrollment For Study, Study Progress, and Subject Status Count.

In the percentage columns, the amount of highlighting represents the percentage number. For example, 0% is not highlighted at all, 50% is half highlighted, and 100% is fully highlighted.

Home Page for Data Manager and Study Director Roles, at the Study Level:

Docetaxel in Patients With ... (R01-123456) | Change Study/Site StuartDirk (Study Director) en | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks | Report Issue | Support | Study Subject ID Go

Welcome to Docetaxel in Patients With Completely Resected NSCLC

Notes & Discrepancies Assigned to Me: 0

Site	Enrolled	Expected Enrollment	Percentage
Cambridge Center for Surgical Oncology	8	20	40%
Center for Cancer Research at Cambridge	3	20	15%
Somerville Cancer Research Consortium	12	20	60%
Somerville Medical Center	3	20	15%

Study	Enrolled	Expected Enrollment	Percentage
Docetaxel in Patients With Completely Resected NSCLC	26	100	26%

Event Status	# of Events	Percentage
scheduled	59	70%
data entry started	8	10%
completed	13	15%
signed	1	1%
locked	0	0%
skipped	1	1%
stopped	2	2%

Study Subject Status	# of Study Subjects	Percentage
available	26	100%
signed	0	0%
removed	0	0%

Subject Enrollment by Site

This table is a summary of enrollment at each Site in the Study:

- **Site:** Name of Site.
- **Enrolled:** Number of Subjects who met the criteria for the protocol and have already enrolled at that Site.

- **Expected Enrollment:** Total number of Subjects expected to enroll at that Site, based on preliminary data collected for the Study protocol.
- **Percentage:** The number of Subjects enrolled divided by expected enrollment for that Site.

Subject Enrollment For Study

This table is a summary of enrollment at the Study level (This table is not shown when the Current Study or Site is set to the Site level):

- **Study:** Name of Study.
- **Enrolled:** Number of Subjects who met the criteria for the protocol and have already enrolled in the Study.
- **Expected Enrollment:** Total number of Subjects expected to enroll in the Study, based on preliminary data collected for the Study protocol.
- **Percentage:** The number of Subjects enrolled divided by expected enrollment for the Study.

Study Progress

This table is a summary of Events for the current Study or Site, reporting the progress that has been made within each Event:

- **Event Status:** Values that Event Status can be set to, for all Events in the Study or Site.
- **Number of Events:** The number of Events in the Study or Site having that status.
- **Percentage:** The number of Events having that status divided by the total number of Events in the table.

Subject Status Count

This table is a summary of the status of Subjects in the Study:

- **Study Subject Status:** Values that Subject Status can be set to.
- **Number of Study Subjects:** The number of Study Subjects currently having that status, including any Subjects removed from the Study.
- **Percentage:** The number of Subjects whose Subject Case Books have been signed (after all Events for the Subject were signed) divided by total enrollment for the Study.

Tasks Available to a Data Manager or Study Director

Modules (groups of Tasks) available for the Data Manger and Study Director are:

- Submit Data
- Monitor and Manage Data
- Extract Data
- Study Setup
- Other

Some of the Tasks a Data Manager or Study Director can perform are:

- Create and Manage CRFs
- Create and Manage Event Definitions
- Create and Manage Rules
- View and Manage Events
- Create and Manage Sites
- Manage Subjects
- Manage Study
- Extract Data

This page is not approved for publication.