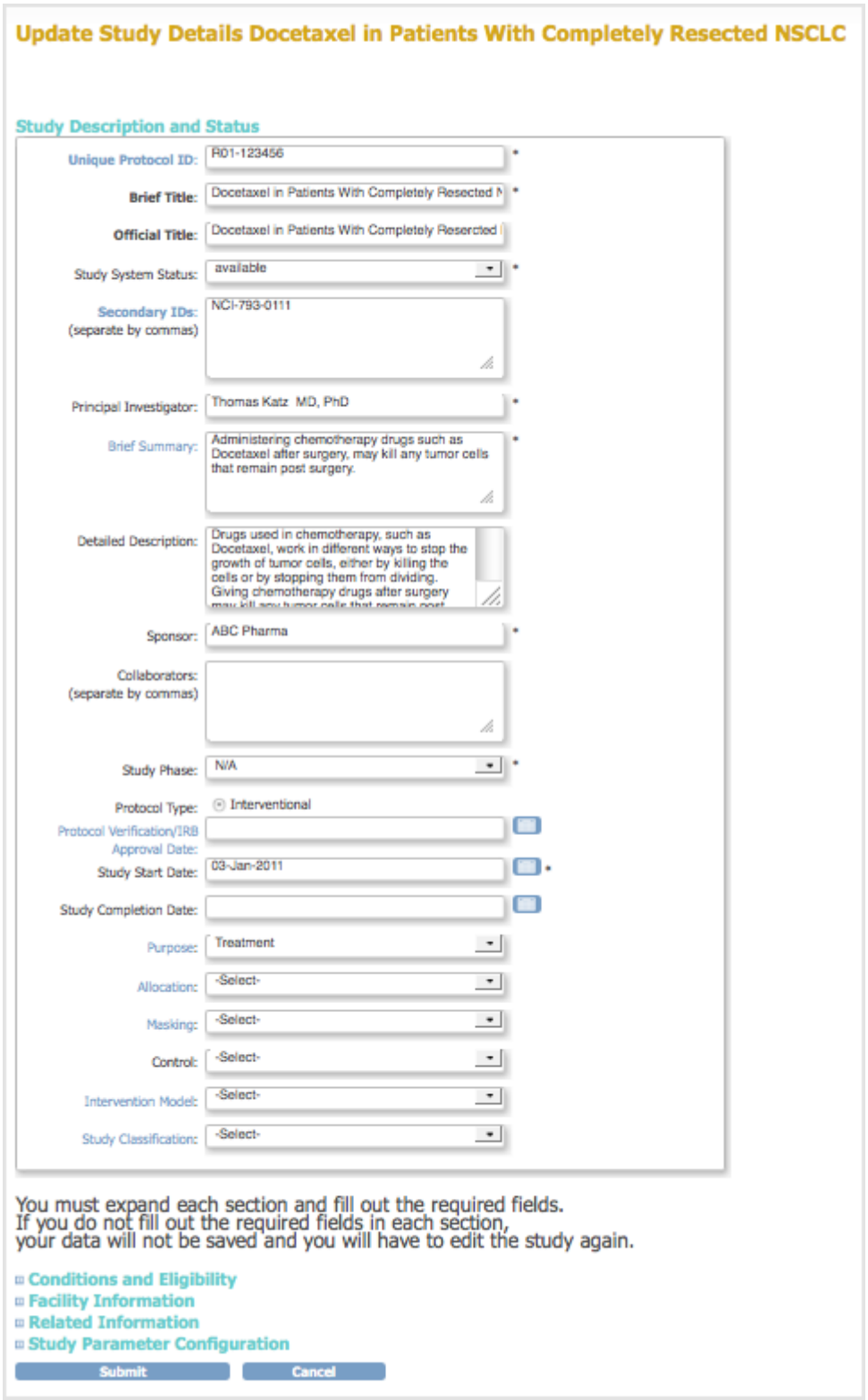
3.3 Create Study Edit Details

You can add or make changes to details for the current Study using the Study Setup module.

1. Access the Build Study page by selecting Tasks > Build Study.
2. In the Actions column of the table, for the Create Study task, click the Edit icon.
   The Update Study Details page opens. Values that were already supplied for the Study, either when it was created or in a previous editing session, are shown on the page.
3. Complete at least the required fields (marked with an asterisk *) for each section on the page; you need to expand each section to see the fields in it.

   Note: If a required field does not have a value, you cannot save any of the information you provide. If you cannot provide the value for a required field, enter a temporary value so that you can save all of the information you entered, then update the temporary value later. For more information about the fields, see About Study Details.

   Note: There are some OpenClinica configuration settings that impact every Study. See Configuring the OpenClinica Application.



4. After completing the fields, click the Submit button.
   The Build Study page displays.

Expanded Sections in the Update Study Details Page:

Conditions and Eligibility

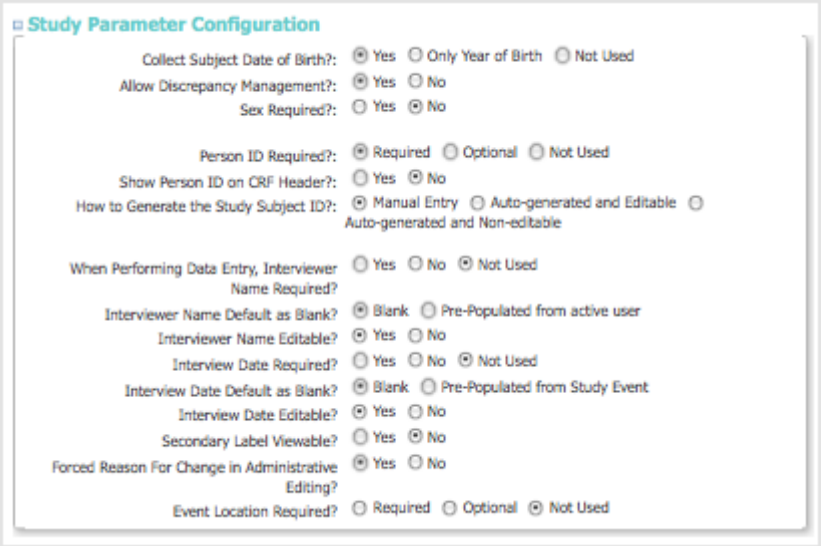
Conditions:	NSCLC
Keywords: (separate by commas)	Docetaxel, Non Small Cell Lung Cancer, NSLC
Eligibility Criteria:	
Sex:	Both
Minimum Age:	18
Maximum Age:	
Healthy Volunteers Accepted:	No
Expected total enrollment:	100 *

Facility Information

Facility Name:	OpenClinica Medical Facility
Facility City:	Waltham
Facility State/Province:	MA
Postal Code:	02451
Facility Country:	USA
Facility Contact Name:	Alicia Goodwin
Facility Contact Degree:	
Facility Contact Phone:	617-123-4567
Facility Contact Email:	agoodwin@example.com

Related Information

MEDLINE Identifier:	
Results Reference?:	No
URL Reference	
URL Description:	



Approved for publication by Ben Baumann. Signed on 2014-03-24 8:39AM

Not valid unless obtained from the OpenClinica document management system on the day of use.

3.3.1 About Study Details

The following information can help you complete or edit values in the Update Study Details page.

All Sections

- When a field name is a link (blue text), you can click it to see the definition at the clinicaltrials.gov website.
- Information you provide in all sections except Study Parameter Configuration is for reporting and does not affect data collection. For example, if you specify a minimum age, OpenClinica does not use that information to verify the age of a Subject you add to the Study. The information you provide in Study Parameter Configuration does impact data collected in OpenClinica for the Study. For example, if you specify Yes for Collect Subject Date of Birth, then the full date of birth must be entered when adding a Subject to the Study.

Study Description and Status Section

- Unique Protocol ID is the user-defined number assigned to the Study when it was first created in OpenClinica.
- You cannot modify the Study System Status on the Update Study Details page. For more information, see Status of a Study.
- Principal Investigator is the person running the Study, and is responsible for the Study being completed and performed correctly.

Conditions and Eligibility Section

- This section can be used as a guideline for conditions and eligibility for the Study.
- Expected total enrollment is used for reporting statistics. It does not limit how many Subjects can be added to the Study, nor is it treated as a required minimum.

Facility Information Section

- Facility information can be for the sponsor, or a main location for the Study. There can be multiple facilities within a Study, where each is defined as a Site after the Study has been created.

Related Information Section

- The URL Reference and URL Description can be used to indicate where you publish your Study results.

Study Parameter Configuration Section

- If 'Collect Subject Date of Birth' parameter is set to 'Only Year of Birth', then the date of birth will be stored internally as January first of the year.
- If you specify No for Allow Discrepancy Management, you cannot create Notes and Discrepancies for CRF Data for the Study.
- If you edit the Sex Required field to change it from Yes to No, the item still appears in the CRF header but completing the field is not required.
- You can specify whether or not the Person ID is required in OpenClinica release 3.1 and higher. In releases prior to 3.1, you specify the parameter using show_unique_id for global ID in the datainfo.properties configuration file.
- When you specify Interviewer Name Required, and Interview Name Pre-Populated from active user, the active user is the user who scheduled the Event.
- When you specify Yes for Forced Reason For Change in Administrative Editing, a Discrepancy Note will be required to modify any Item in a CRF after that CRF has been marked complete.
- The 'Location' field can be used when scheduling or editing a study event. If set to 'Not Used' it will not appear in the user interface for the study.