OpenClinica

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 <u>Build Study page</u> 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 <u>About Study Details</u>.

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

vescription and	R01-123456		
Inique Protocol ID:	Prestant in Onionte With Completely Depart		
Brief Title:	Docetaxel in Patients With Completely Resection		
Official Title:	Docetaxel in Patients With Completely Reserct	ed I	
Study System Status:	available	- •	
Secondary IDs: eparate by commas)	NCI-793-0111		
		li.	
rincipal Investigator:	Thomas Katz MD, PhD		
Brief Summary:	Administering chemotherapy drugs such as Docetaxel after surgery, may kill any tumor cel that remain post surgery.	s *	
		li.	
Detailed Description:	Drugs used in chemotherapy, such as Doctaxel, work in different ways to stop the growth of tumor cells, either by killing the cells or by stopping them from dividing. Giving chemotherapy drugs after surgery may kill and tumor cells that remain cent	1.	
Sponsor:	ABC Pharma	i.	
Collaborators:		-	
eparate by commas)		li.	
Study Phase:	N/A	• •	
Protocol Type:	 Interventional 		
tocol Verification/IRB			
Study Start Date:	03-Jan-2011		
dy Completion Date:			
Purpose:	Treatment	-	
Allocation:	-Select-	-	
Maskipor	-Select-	•	
Control	-Select-	•	
Totor until Medele	-Select-	-	
Church Charal Franking	-Select-	-	
Study Classification:			
ust expand ead do not fill out ata will not be	ch section and fill out the required fields in each secti saved and you will have to edit	ed fields. on, the study again.	

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			
	A			
Eligibility Criteria:				
Sex:	Both			
Minimum Age:	18			
Maximum Age:				
Healthy Volunteers Accepted:	No			
Expected total enrolment:	100			

Facility Information			
Facility Name:	OpenClinica Medical Facility		
Facility City:	(Waltham		
Facility State/Province:	МА		
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 Informa	tion
MEDLINE Identifier:	
Results Reference?:	No
URL Reference	
URL Description:	

Study Parameter Configuration	
Collect Subject Date of Birth?:	Yes Only Year of Birth Not Used
Allow Discrepancy Management?:	Yes O No
Sex Required?:	○ Yes
Person ID Required?: Show Person ID on CRF Header?:	Required Optional Not Used Yes ONo
How to Generate the Study Subject ID?:	 Manual Entry Auto-generated and Editable
	Auto-generated and Non-editable
When Performing Data Entry, Interviewer Name Required?	○ Yes ○ No ③ Not Used
Interviewer Name Default as Blank?	Blank O Pre-Populated from active user
Interviewer Name Editable?	
Interview Date Required?	○ Yes ○ No ◎ Not Used
Interview Date Default as Blank?	Blank O Pre-Populated from Study Event
Interview Date Editable?	Yes O No
Secondary Label Viewable?	O Yes ⊙ No
Forced Reason For Change in Administrative Editing?	⊕ Yes ○ No
Event Location Required?	Required Optional O Not Used

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 <u>clinicaltrials.gov</u> 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 <u>Status of a Study</u>.
- 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 <u>Notes and</u> <u>Discrepancies</u> 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.