


## 6.6.1 Accessing Rule Designer

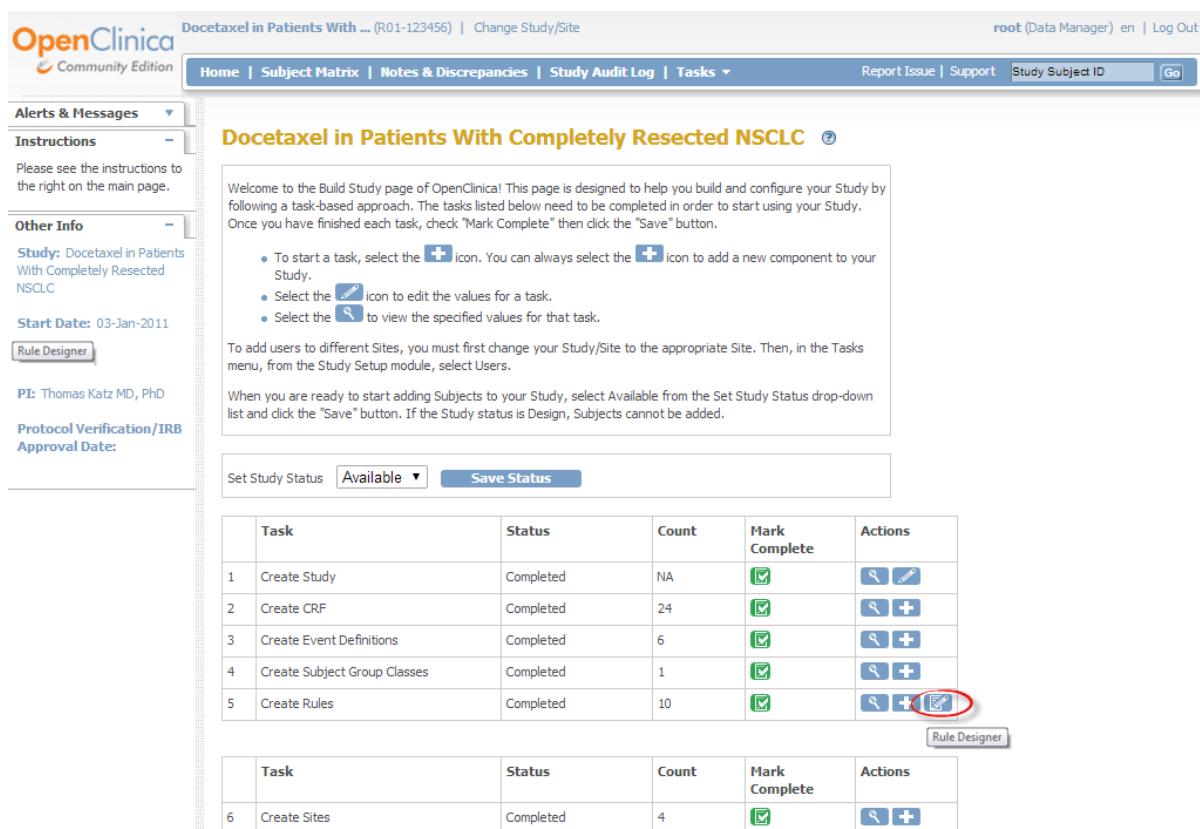
### Accessing Rule Designer

You can access Rule Designer from the Build Study page or from the Manage Rules page. Each option is outlined below:

1. To access Rule Designer from the Build Study page:

- Log into OpenClinica.
- On the **Tasks** menu, select **Build Study**.
- In the **Create Rules** row **Actions** column, click  (the Rule Designer icon - see below).

### Accessing Rule Designer from the Build Study page



OpenClinica Community Edition

Docetaxel in Patients With ... (R01-123456) | Change Study/Site

root (Data Manager) en | Log Out

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

**Alerts & Messages**

**Instructions**

Please see the instructions to the right on the main page.

**Other Info**

Study: Docetaxel in Patients With Completely Resected NSCLC

Start Date: 03-Jan-2011





Rule Designer

PI: Thomas Katz MD, PhD

Protocol Verification/IRB Approval Date:

**Docetaxel in Patients With Completely Resected NSCLC**

















Welcome to the Build Study page of OpenClinica! This page is designed to help you build and configure your Study by following a task-based approach. The tasks listed below need to be completed in order to start using your Study. Once you have finished each task, check "Mark Complete" then click the "Save" button.

- To start a task, select the  icon. You can always select the  icon to add a new component to your Study.
- Select the  icon to edit the values for a task.
- Select the  to view the specified values for that task.




To add users to different Sites, you must first change your Study/Site to the appropriate Site. Then, in the Tasks menu, from the Study Setup module, select Users.

When you are ready to start adding Subjects to your Study, select Available from the Set Study Status drop-down list and click the "Save" button. If the Study status is Design, Subjects cannot be added.



Set Study Status: Available | Save Status

Task	Status	Count	Mark Complete	Actions
1 Create Study	Completed	NA		 
2 Create CRF	Completed	24		 
3 Create Event Definitions	Completed	6		 
4 Create Subject Group Classes	Completed	1		 
5 Create Rules	Completed	10		  

Rule Designer

Task	Status	Count	Mark Complete	Actions
6 Create Sites	Completed	4		 

2. To access Rule Designer from the Manage Rules page:

- Log into OpenClinica.
- On the **Tasks** menu, select **Build Study** and in the **Create Rules** row, click  (the View icon)
- OR
- On the **Tasks** menu, in the **Monitor and Manage Data** section, select **Rules**.
- On the **Manage Rules** page, click . (See below).

## Accessing Rule Designer from the Manage Rules page

OpenClinica Community Edition

Docetaxel in Patients With ... (R01-123456) | Change Study/Site

FOOT (Data Manager) en | Log Out

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

Alerts & Messages

Instructions

This page allows you to view and manage your study rules. OpenClinica rules provide edit check, email action and other capabilities during the course of data capture and in batch mode.

You may click on the action icons to view, test, execute and manage these rules. By default the table is filtered by Rule Status (Available) and sorted by Item Name. Use the column headers and filter fields (gray boxes) to sort and filter, or filter by Event CRF by using the tree in the 'Info' panel below

Info





















Study: Docetaxel in Patients With Completely Resected NSCLC

- Study XML: Download
- Unique CRFs: 24
- Unique Items: 630
- Unique Rule Assignments: 13

Study Events (click to filter by CRF)

- Registration Visit
- Initial Treatment
- Follow-up Treatment
- Adverse Events
- Foot Event
- Stop Event

### Manage Rules for Docetaxel in Patients With Completely Resected NSCLC

CRF	Item Name	Rule Name	Rule OID	Expression	Execute On	Action Summary	Actions
1_AEYN	Insert 2nd AE	AE_EVENT_2	I_ADVER_1_AEYN eq 1	true	Type: ShowAction Message: "Another AE was experienced. Please complete the following fields." Run On: InitialDataEntry, DoubleDataEntry, AdministrativeDataEntry DestinationProperty: IG_ADVER_AE2	    	
1_AEYN	I_ADVER_1_AEYN_EVENTSCHEDULE	I_ADVER_1_AEYN_EVENTSCHEDULE	I_ADVER_1_AEYN eq 1	true	Type: EventAction Run On: Not Scheduled, Scheduled DestinationProperty: STARTDATE	    	
2_AEYN	Insert 3rd AE	AE_EVENT_3	I_ADVER_2_AEYN eq 1	true	Type: ShowAction Message: "Another AE was experienced. Please complete the following fields." Run On: InitialDataEntry, DoubleDataEntry, AdministrativeDataEntry DestinationProperty: IG_ADVER_AE3	    	
3_AEYN	Insert 4th AE	AE_EVENT_4	I_ADVER_3_AEYN eq 1	true	Type: ShowAction Message: "Another AE was experienced. Please complete the following fields." Run On: InitialDataEntry, DoubleDataEntry, AdministrativeDataEntry DestinationProperty: IG_ADVER_AE4	    	

The Rule Designer interface displays.

## The Rule Designer interface

OpenClinica | Rule Designer

New Rule | Open Rule | Exit Rule Designer

Show OIDs or names

View by CRF

- Verification of Informed Consent
- Eligibility
- Physical Exam
- KitchenSink
- DF3DM
- Concomitant Medications
- Agent Administration
- Adverse Events

Designer XML Test

Validate Save

Target:

Run on a Schedule: ☐ OFF

Rule OID:

Rule Expression:

Actions:

Validate Save

Help

Getting started

1. Expand the tree on the left and drag a selected Item into the Target.
2. Provide an OID for your Rule and write an expression. You can build your expression by dragging items from the tree on the left.
3. Select an action from the drop down. Fill the selected action.
4. Submit your rule.

Item Metadata

Entity Metadata

Functional approval by Laura Keita. Signed on 2015-07-27 11:45AM

Approved for publication by Cal Collins. Signed on 2015-07-27 2:03PM

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