6.4 Creating Rules

Simple single-field validation checks can be created within the CRF Template or by writing a Rule. More complex edit checks that compare values across fields, across forms, or across Events can only be addressed by writing a Rule. Rules are written in XML and then uploaded into OpenClinica. You can also use OpenClinica's Rule Designer, an XML code generator, to create your Rules.

Before writing a Rule, you should have an idea of what you want that Rule to do. For example, if date of drug administration is less than the date of informed consent, you'd like the Rule to create a Discrepancy Note.

We'll use this example to step through the process of writing a Rule.

To create a Rule using XML:

1. As a user with a Data Manager or Study Director role, Go to **Tasks > Build Study** and look up the OIDs for the Study Events, Forms, Item Groups, and Items that will be used in the Rule.

   In our example Study, the following OIDs apply:

Object	Informed Consent	Drug Administration
Study Event	SE_REGISTRATION	SE_VISIT1
Form	F_CONSENT	F_DRUGADMIN
Item Group	IG_INFORMEDCONSENT	IG_DRUGADMINISTRATION
Item	I_CONSENT_DT	I_ADMIN_DT

2. Go to **Tasks > Build Study**, and on the **Create Rules** row of the Tasks table, click .

   The Import Rule Data screen displays.

3. Click the **All Actions Without Comments** link and open the file in an XML editor.

   Free XML editors (such as Notepad++ for Windows or TextWrangler for Mac) are available on the internet. Be sure to open the file in an XML editor; if you edit the file in a browser, the Rule will not upload properly.

   The Rule Template, which contains all possible Rule Actions, displays:

```
<RuleImport>
    <RuleAssignment>
        <Target Context="OC_RULES_V1"></Target>
        <RunOnSchedule Time="17:00"/>
        <RuleRef OID="">
            <DiscrepancyNoteAction IfExpressionEvaluates="">
                <Run AdministrativeDataEntry="true" InitialDataEntry="true" DoubleDataEntry="true" ImportDataEntry="false" Batch="true" />
                <Message></Message>
            </DiscrepancyNoteAction>
            <EmailAction IfExpressionEvaluates="">
                <Run AdministrativeDataEntry="true" InitialDataEntry="true" DoubleDataEntry="true" ImportDataEntry="false" Batch="true" />
                <Message></Message>
                <To></To>
            </EmailAction>
            <NotificationAction IfExpressionEvaluates="">
                <Message></Message>
                <To></To>
                <Subject></Subject>
                <Message></Message>
            </NotificationAction>
            <ShowAction IfExpressionEvaluates="true">
                <Run AdministrativeDataEntry="true" InitialDataEntry="true" DoubleDataEntry="true" ImportDataEntry="false" Batch="false" />
                <Message></Message>
                <DestinationProperty OID=""/>
            </ShowAction>
            <HideAction IfExpressionEvaluates="">
                <Run AdministrativeDataEntry="true" InitialDataEntry="true" DoubleDataEntry="true" ImportDataEntry="false" Batch="false" />
                <Message></Message>
                <DestinationProperty OID=""/>
            </HideAction>
            <InsertAction IfExpressionEvaluates="">
                <Run AdministrativeDataEntry="" InitialDataEntry="" DoubleDataEntry="" ImportDataEntry="false" Batch=""/>
                <DestinationProperty OID="" Value="">
                    <ValueExpression Context="OC_RULES_V1"></ValueExpression>
                </DestinationProperty>
            </InsertAction>
            <EventAction IfExpressionEvaluates="true" OID="">
                <RunOnStatus not_scheduled="true" scheduled="true" data_entry_started="false" completed="false"  skipped="false" stopped="false"/>
                <EventDestination Property="STARTDATE">
                    <ValueExpression Context="OC_RULES_V1"></ValueExpression>
                </EventDestination>
            </EventAction>
        </RuleRef>
    </RuleAssignment>
    <RuleDef OID="" Name="">
        <Description></Description>
        <Expression></Expression>
    </RuleDef>
</RuleImport>
```

4. To save the template, click **File>Save As** and provide a file location and name for the Rule.

5. Once the Template is saved, there are 5 steps to writing the Rule:
    - Delete the actions you don't want the Rule to perform.
    - Identify the Target.
    - Determine if you want the Rule to run on a specified schedule once per day (currently recommended for Notification Action Rules only; for other Rule Actions, carefully consider the impact of scheduling multiple rules to run on a schedule - and managing that schedule. For example, if you set all your Rules to run at 17:00 hours, performance may be impacted. However, if you have a particularly large form with many Rules associated with it, it may be better to schedule those rules to run on a schedule to increase performance during data entry.)
    - Define the Rule (RuleDef)
    - Reference the Rule (RuleRef)

Delete the Actions You Don't Want the Rule to Perform
In the Rule Assignment portion of the template, delete the lines for the actions that you don't want. For information see Rule Action Types.

For our Discrepancy Note example, the resulting template would be as follows:

```
<RuleImport>
    <RuleAssignment>
        <Target Context="OC_RULES_V1"></Target>
        <RunOnSchedule Time="17:00"/>
        <RuleRef OID="">
            <DiscrepancyNoteAction IfExpressionEvaluates="">
                <Run AdministrativeDataEntry="true" InitialDataEntry="true" DoubleDataEntry="true" ImportDataEntry="false" Batch="true" />
                <Message></Message>
            </DiscrepancyNoteAction>
        </RuleRef>
    </RuleAssignment>
    <RuleDef OID="" Name="">
        <Description></Description>
        <Expression></Expression>
    </RuleDef>
</RuleImport>
```

Identify the Target

Place the cursor between the opening and closing tags of the **Target** and provide the OID for the Target of the Rule. For a Discrepancy Note action, the Target is the Item that will be flagged with a Discrepancy Note if a specified condition is met.

In our example of checking Drug Administration Date against Informed Consent Date, the Target is the Drug Administration Date because it is the second item value entered. The system would not know of an issue with these two items until that value is entered. Since these dates occur on different Events, the Target must begin with the Study Event OID and finish with the Item OID as follows:

```
<RuleImport>
    <RuleAssignment>
        <Target Context="OC_RULES_V1">SE_VISIT1.F_DRUGADMIN.IG_DRUGADMINISTRATION.I_ADMIN_DT</Target>
        <RunOnSchedule Time="17:00"/>
        <RuleRef OID="">
            <DiscrepancyNoteAction IfExpressionEvaluates="">
                <Run AdministrativeDataEntry="true" InitialDataEntry="true" DoubleDataEntry="true" ImportDataEntry="false" Batch="true" />
                <Message></Message>
            </DiscrepancyNoteAction>
        </RuleRef>
    </RuleAssignment>
    <RuleDef OID="" Name="">
        <Description></Description>
        <Expression></Expression>
    </RuleDef>
</RuleImport>
```

Determine if You Want the Rule to Run on a Specified Schedule

Rules will run automatically during data entry when the user clicks Save. If you want your Rule to run at a specified time each day, you can specify that time in the RunOnSchedule tag.

```
<RuleImport>
    <RuleAssignment>
        <Target Context="OC_RULES_V1">SE_VISIT1.F_DRUGADMIN.IG_DRUGADMINISTRATION.I_ADMIN_DT</Target>
        <RunOnSchedule Time="17:00"/>
        <RuleRef OID="">
            <DiscrepancyNoteAction IfExpressionEvaluates="">
                <Run AdministrativeDataEntry="true" InitialDataEntry="true" DoubleDataEntry="true" ImportDataEntry="false" Batch="true" />
                <Message></Message>
            </DiscrepancyNoteAction>
        </RuleRef>
    </RuleAssignment>
    <RuleDef OID="" Name="">
        <Description></Description>
        <Expression></Expression>
    </RuleDef>
</RuleImport>
```

With the setting highlighted above, the Rule will run at 17:00 hours (5:00pm) every day. The time must be entered in 24-hour format (00:00 to 23:59), though OpenClinica will only run the Rule based on the hour values provided. For example, if you specify 17:30, the Rule will run at 17:00.

If the time is left blank, the Rule will run at 20:00. If you remove the parameter completely, the Rule will run based on its run parameters only and will not run on a schedule.

RunOnSchedule is particularly useful for running a Rule based on OpenClinica Participate data since edit checks are limited for Patient Reported Outcome data during data entry. OpenClinica uses the Participant local date-time for RunOnSchedule execution when the Participant local date-time is available. Otherwise, the server date-time is used.

Define the Rule (RuleDef)

In the RuleDef portion of the Template, define the Rule Expression. This is the condition that will trigger the Rule to fire. Mathematic operators and logical operators can be used in the Rule Expression. For more information, see Expression Element.

The Rule Expression is always relative to the Target. Once the full Target is defined, you only need to provide the Item-level reference for the Target, but when referencing any Item outside of that Form and/or Event, the full path for the Item must be provided.

For our example, the Expression is:

I_ADMIN_DT lt SE_REGISTRATION.F_CONSENT.IG_INFORMEDCONSENT.I_CONSENT_DT

Once the Expression is written, the rest of the RuleDef is a matter of entering text to help identify and describe the Rule, as follows:

Description: A clear, concise explanation of what the Rule is doing. This is presented to users who view Rules using Task>Monitor and Manage Data>Rules, and is only displayed if the user clicks Show More.

Name: A very brief explanation of what the Rule is doing. This is presented to users who view Rules using Task>Monitor and Manage Data>Rules.

OID: The user-defined unique identifier for the Rule. This must be entered in all capital letters and can only contain letters, numbers, and underscore. It must be unique within the Study and can be no more than 40 characters.

For our example, the resulting Rule would be as follows:

```
<RuleImport>
    <RuleAssignment>
        <Target Context="OC_RULES_V1">SE_VISIT1.F_DRUGADMIN.IG_DRUGADMINISTRATION.I_ADMIN_DT</Target>
        <RunOnSchedule Time="17:00"/>
        <RuleRef OID="">
            <DiscrepancyNoteAction IfExpressionEvaluates="">
                <Run AdministrativeDataEntry="true" InitialDataEntry="true" DoubleDataEntry="true" ImportDataEntry="false" Batch="true" />
                <Message></Message>
            </DiscrepancyNoteAction>
        </RuleRef>
    </RuleAssignment>
    <RuleDef OID="I_ADMIN_DT_R1" Name="Drug Administration Date must be greater than Informed Consent Date">
        <Description>If drug administration date is less than date of informed consent a discrepancy note must be logged.</Description>
        <Expression>I_ADMIN_DT lt SE_REGISTRATION.F_CONSENT.IG_INFORMEDCONSENT.I_CONSENT_DT</Expression>
    </RuleDef>
</RuleImport>
```

Reference the Rule (RuleRef)

In the RuleRef portion of the Template, reference the Expression you wrote in the RuleDef and

execute the Rule.

Copy the OID of the Rule that you created in the RuleDef portion of the Template into the **RuleRef OID**.

In our example it would appear as follows: <RuleRef OID="I_ADMIN_DT_R1">

Identify when the Rule should run as follows:

A Rule Expression can either evaluate to true or false. It is best practice to write your Rules to trigger when the expression evaluates to true. There will be times when you will need to write Rules to evaluate to false, but that should be the exception.

For our example, if the Expression is true, a discrepancy note should be created. As such, ensure the first line of the DiscrepancyNoteAction tag is as follows: ***IfExpressionEvaluates="true"*** *Note that "true" must be in lower case.*

The <Run> tag allows you to specify when you want the Rule to be executed. For each option specify true or false (must be in lower case).

For a DiscrepancyNoteAction, you must specify the message that the data entry person will see if the Rule is triggered. Type that message between the opening and closing <Message> tags.

For our example, the RuleRef (and the completed Rule) would be as follows:

```
<RuleImport>
    <RuleAssignment>
        <Target Context="OC_RULES_V1">SE_VISIT1.F_DRUGADMIN.IG_DRUGADMINISTRATION.I_ADMIN_DT</Target>
        <RunOnSchedule Time="17:00"/>
        <RuleRef OID="I_ADMIN_DT_R1">
            <DiscrepancyNoteAction IfExpressionEvaluates="true">
                <Run AdministrativeDataEntry="true" InitialDataEntry="true" DoubleDataEntry="true" ImportDataEntry="true" Batch="true" />
                <Message>Drug Administration Date is less than Date of Informed Consent. Please check both dates and either make a correction or create a discrepancy note.</Message>
            </DiscrepancyNoteAction>
        </RuleRef>
    </RuleAssignment>
    <RuleDef OID="I_ADMIN_DT_R1" Name="Drug Administration Date must be greater than Informed Consent Date">
        <Description>If drug administration date is less than date of informed consent a discrepancy note must be logged.</Description>
        <Expression>I_ADMIN_DT lt SE_REGISTRATION.F_CONSENT.IG_INFORMEDCONSENT.I_CONSENT_DT</Expression>
    </RuleDef>
</RuleImport>
```

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

6.4.1 Rule Assignment and Rule Definition

RuleAssignment

A Rule Assignment executes a Rule Expression for a specific target. It contains the following entities.

- **Target**: The item that will be affected by the Rule or for which the RuleAction is being performed.

- **RuleRef**: The RuleOID that will be executed and specifications for when the Rule should be run.

  Within a RuleAssignment you may have one or more RuleRefs.

  A RuleRef also specifies the Action(s) you want the Rule to perform.
  Out of the box actions by OpenClinica currently include

o DiscrepancyNoteAction

o EmailAction

o NotificationAction

o InsertAction

o ShowAction

o HideAction

o EventAction

- **Run**: This specifies when the Rule should be executed. Specify "true" or "false" (must be in lower case) for each possible status as follows:

  If "false" for any of the following options, the Rule will not execute for the specified setting.

  - **AdministrativeDataEntry**
    If "true" the Rule will run if a user saves a change to the data after the form has been marked "complete."

  - **InitialDataEntry**
    If "true" the Rule will run when the user clicks Save after initial data entry.

  - **DoubleDataEntry**
    If "true" the Rule will run when the user clicks Save after double data entry.

  - **ImportData**
    If "true" the Rule will run when data is imported into the form.

  - **Batch**
    If "true" the Rule will run if a user runs the Rule in batch mode (via Tasks>Monitor and Manage Data>Rules and then click the Run icon OR via Tasks>Monitor and Manage Data>CRFs>View the CRF and click the link Run All Rules for This CRF).

RuleDef

Rule Definitions in OpenClinica are independent entities. The same Rule definitions could be used in multiple assignments. Rule Definition elements are themselves made of multiple elements.

- **RuleOID**
  A user-defined, unique OID for the Rule. This must be entered in all upper-case alphanumeric characters. Underscores are also allowed.

- **Name**
  A brief, user-provided description of what the Rule does. This is only visible on the Manage Rules screen (Tasks>Monitor and Manage Data>Rules).

- **Description**
  A detailed, user-provided description of what the Rule does. This is only visible on the Manage Rules screen if the user clicks the Show More link above the table. (Tasks>Monitor and Manage Data>Rules, and then click Show More).

- **Expression**
  The condition that triggers the Rule action. Expressions can include logical operators, mathematical operators, and can be performed using dates. For more information see Expression Element and Rule Expressions.

6.4.2 Expression Element

The expression element appears in RuleDef Element. It is an expression that evaluates to a result when it is run. For example the expression below might evaluate to true or false depending on the value of ITEM_OID.

<Expression> ITEM_OID eq 50</Expression>

OpenClinica defines a specific language for creating these expressions. This language supports Logical, Arithmetic, and Conditional operators. We will list those in tables below. Alongside operators OpenClinica supports the user of Integers, Strings and OpenClinica variables in order to do the evaluation.

The expression above is using ITEM_OID, which is an OpenClinica variable and 50, which is a number, with the operator being an equal. OpenClinica out of the box supports the following operators

The Equality and Relational Operators		
eq	Equal to	Variables used with this operator could be of any type
ne	Not Equal to	Variables used with this operator could be of any type
ct	Contains	Variables used with this operator could be of any type
gt	Greater Than	Variables used with this operator should be of a number type
gte	Greater Than or Equal to	Variables used with this operator should be of a number type
lt	Less Than	Variables used with this operator should be of a number type
lte	Less Than or Equal to	Variables used with this operator should be of a number type

Some example expressions using the above operators

- ITEM_OID eq YELLOW
- ITEM_OID lt (-15)
- ITEM_OID gt 5

- 5 gte ITEM_OID
- YELLOW ne GREEN
- ITEM_OID ct "2014"

The Conditional Operators

and	and	Variables used with this operator should be of a boolean type
or	or	Variables used with this operator should be of a boolean type

Some example expression using the above operators

- ITEM_OID eq YELLOW and ITEM_OID_2 gt 5
- (ITEM_OID eq YELLOW) and (ITEM_OID_2 gt 5)
- (YELLOW neq GREEN) or (ITEM_OID_2 gt 5)

The Arithmetic Operators

+	Addition	Variables used with this operator should be of a number type
-	Subtraction	Variables used with this operator should be of a number type
*	Multiplication	Variables used with this operator should be of a number type
/	Division	Variables used with this operator should be of a number type

Some example expression using the above operators

- ITEM_OID + 35 eq 50
- ITEM_OID 10 eq 34 AND ITEM_OID_2 gt 45
- ((ITEM_OID 10) eq 34) AND (ITEM_OID_2 gt 45)

Statements can be used in these expressions. Now OpenClinica utilizes what is known as contextual statements, meaning as in the examples above you can put

ITEM_OID and OpenClinica will automatically complete the statement so to make it legal. Lets use an example

```
<Target Context="OC_RULES_V1">SED_OID[ALL].CRF_OID.GROUP_OID.ITEM_OID</Target>
<Expression> ITEM_OID eq 50</Expression>
```

What will actually happen here when this expression is being evaluated is that ITEM_OID will be substituted by

```
SED_OID[ordinal].CRF_OID.GROUP_OID.ITEM_OID
```

In order to support cross form edit checks we actually include a complete statement. One side not regarding that is we cannot use ALL in the expressions.

Dates within Rules

Rules supports the following operators to be used with dates

The Equality and Relational Operators

eq	Equal to	ITEM_OID eq 2008-12-12
ne	Not Equal to	ITEM_OID ne 2008-12-12
gt	Greater Than	ITEM_OID gt 2008-12-12
gte	Greater Than or Equal to	ITEM_OID gte 2008-12-12
lt	Less Than	ITEM_OID lt 2008-12-12
lte	Less Than or Equal to	ITEM_OID lte 2008-12-12

The format of the date included in an expression should be **yyyy-MM-dd .**

Example: January 01, 2010 should be written as : 2010-01-01

You can also use _CURRENT_DATE to compare values against the current server date. For example, with a NotificationAction, to notify Participants of a Form that must be completed on the next day, you could use an expression such as:

<Expression>**SE_OID.STARTDATE eq (_CURRENT_DATE +1) and SE_OID.STATUS ne "complete"**</Expression>

This would send a notification one day in advance of the expected form completion date as long as the form was not already completed by the Participant.

6.4.3 Target Element

We will further explain how the Target element is setup.

Rules are assigned to a particular data item in a CRF, via the Target element. The Target must be a valid Item OID, and can be a full or relative OID path. The full OID path would include Event Definition, optional ordinal, CRF, CRF Version, Group, optional ordinal, and Item. A relative path can also be specified by providing only part of the path, normally just the Item OID. Each RuleAssignment may have multiple RuleRefs.

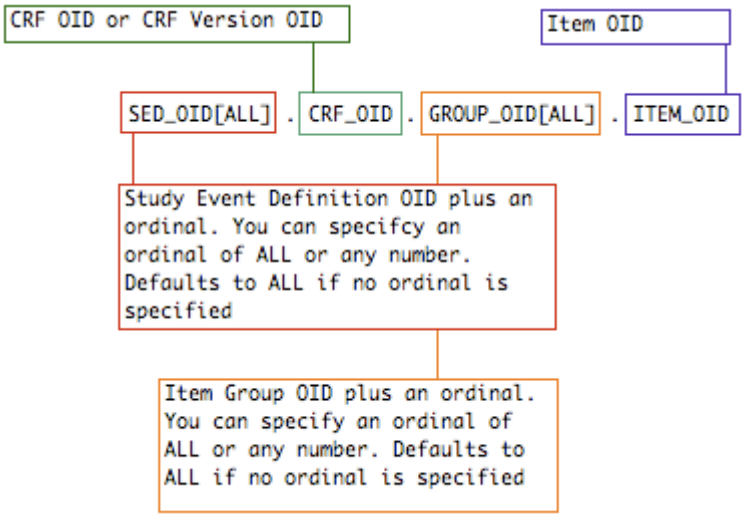
```
<Target
Context="OC_RULES_V1">SED_OID[ALL].CRF_OID.GROUP_OID[ALL].ITEM_OID</Target>
```

As mentioned above the Target element will specify which item the rules will be evaluated against. Although your expression may be evaluating multiple variables, you must specify one variable on which the error message will appear and the action will occur for. Every one of the OIDs must be in upper case. To specify the exact item we need to provide the following information.

- SED_OID[ALL] We need to tell OpenClinica which Study Event definition the Item were after is going to be. We can also specify an ordinal if this happens to be a repeating event, this could be set to ALL or an integer. If you set it to ALL then all event repeats will evaluated. If you specify a specific integer then only that specific event will be evaluated.
- CRF_OID We specified which Event Definition this item is in, now we need to specify which CRF or CRF Version this item is in. Specifying a CRF Version OID will allow the rules to be evaluated against only that specific version. Whereas specifying a CRF OID will allow evaluating against all CRF versions.

- GROUP_OID[ALL] We specified the Study Event Definition and the CRF where the item is, now we need to specify the Group this item is in. This is important because a group might be a repeating or a non-repeating one. If it is a repeating Group OpenClinica allows you to specify if you want the rule to be evaluated against all of the repeats for the variable or a specific ro one of the repeats (a specific row in the repeating group-table) by setting the ordinal to ALL or an integer.
- ITEM_OID Finally we specify which item this rule will be evaluated against. If you have specified a DiscrepancyNoteAction or EmailAction, this is the also the variable that will be specified in the Discrepancy Note or the Email.

As you see we identify the entities by using their OIDs (unique identifiers). You can deduce from the example above that OpenClinica defines its own syntax to create these statements. The separator used throughout all these statements is the .



6.4.4 Action Types

An ActionType is specified in the RuleAssignment and determines what should happen when the expression executes. ActionTypes include DiscrepancyNoteAction, EmailAction, NotificationAction, HideAction, InsertAction, ShowAction, and EventAction. A parameter must always be provided that defines when the action will be triggered to execute - either when the expression evaluates to true or to false.

DiscrepancyNoteAction

The DiscrepancyNoteAction is used to automatically log discrepancy notes on the target item.

When triggered, this action provides a message, specified in the rule definition, to the data entry user. The user can choose to update the value(s) he has provided that caused the rule to fire, or he may proceed with the values unchanged by clicking save on the information again. In this case the DiscrepancyNoteAction will log a discrepancy note on the Target with a status of New and a type of Failed Validation Check. The color of the discrepancy note flag will turn to red.

In the Description field of the discrepancy note, the text will start with the RuleDef OID followed by a colon. After the colon the Message defined by the rule creator will display.

DiscrepancyNoteAction is executed after CRF validations are executed and as the data is being saved to the database.

If a DiscrepancyNoteAction has already been executed on a given target, and the value has not changed, a second discrepancy note will not be logged on the item again.

EmailAction

The EmailAction is used to send email to an email address or list of addresses.

When triggered, this action provides a message, specified in the rule definition, to the data entry user. The user can choose to update the value(s) he has provided that caused the rule to fire, or he may proceed with the values unchanged by clicking save on the information again. In this case the EmailAction will send an email to the list of addresses specified in the rule definition. These addresses are specified when the Rule is created. No record of the email action is saved in OpenClinica.

EmailAction is executed after CRF validations are executed and as the data is being saved to the database.

NotificationAction

The NotificationAction is used to send an SMS and/or email notification to a Study Participant (when used in conjunction with OpenClinica Participate), or to send an email notification to any specified email address.

When triggered, this action provides a notification to the specified recipients. To send a notification to Study Participants, address the message to **${participant}**. OpenClinica replaces ${participant} with the communication means for the Participant as specified when the Participant was connected to OpenClinica. The means of communication for Participants can be SMS, email, or both based on the connection information provided. (For more information, see Connect Participants.

The elements of a NotificationAction include the following:

To: ${participant} and/or a specific email address to whom you're addressing the notification. Separate multiple addresses with a comma.

Subject: The subject of the notification (similar to the Subject line of an email)

Message: The content of the notification.

Parameters can be passed to the "To" and "Message" elements as follows:

Parameter	Description	To	Message
${participant.firstname}	Participant first name		**x**
${participant.loginurl}	Participant URL with automatic login		**x**
${participate.url}	Participant URL without automatic login (requires an access code)		**x**
${study.name}	The name of the Study as defined in OpenClinica.		**x**

${participant.accessCode}	The single-use code the Participant must use to access OpenClinica Participate.		**x**
${event.name}	The name of the Event as specified in the Build Study task in OpenClinica.		**x**
${participant}	The Participant contact information as provided when the Participant was connected to the Study. This may have been a mobile phone number (for SMS notification), email address, or both. OpenClinica automatically sends the notification to any and all means that were provided for the Participant.	**x**	

For example, the following Rule will send a notification to any Participant who has an Event scheduled for the following day:

```
<?xml version="1.0" encoding="UTF-8"?>
<RuleImport>
    <RuleAssignment>
        <Target>SE_INITIALTREATMENT.STARTDATE</Target>
        <RunOnSchedule Time="17:00"/>
        <RuleRef OID="INITIAL_NOTIFICATION1">
            <NotificationAction IfExpressionEvaluates="true">
                <To>${participant}</To>
                <Subject>Forms for ${study.name} ${event.name} are due tomorrow</Subject>
                <Message>Dear ${participant.firstname},\n
                    have forms to complete for ${study.name} ${event.name} \n
                    that are due tomorrow. Please visit${participant.loginurl} \n
                    to complete them. \n
                    You may also go to ${participant.url} and enter your \n
                    private access code: ${participant.accessCode}. \n
                    Thank you.\n
                    Sincerely, \n
                    Your Study Team</Message>
            </NotificationAction>
        </RuleRef>
    </RuleAssignment>
    <RuleDef OID="INITIAL_NOTIFICATION1" Name="INITIAL_NOTIFICATION1">
        <Description>INITIAL_NOTIFICATION1</Description>
        <Expression>_CURRENT_DATE eq SE_INITIALTREATMENT.STARTDATE -1
            and SE_INITIALTREATMENT.STATUS ne "completed"</Expression>
    </RuleDef>
</RuleImport>
```

Notice that the Rule Expression uses _CURRENT_DATE and compares it to SE_INITIALTREATMENT.STARTDATE to determine that the Event is scheduled for the next day. (In other words, if TODAY is equal to the day BEFORE the visit and the status is not yet "completed", send a notification. If you want to send a reminder one day AFTER the visit, you would use _CURRENT_DATE eq SE_INITIALTREATMENT_STARTDATE +1, meaning that the rule will trigger if _CURRENT_DATE is one day AFTER the visit was scheduled and the status is not yet "completed".)

To force a line break, use n at the end of a line.

ShowAction

The ShowAction is used to show previously hidden CRF items or groups.

Note: A ShowAction Rule must be written in combination with a HideAction Rule. A Rule with a ShowAction will not work properly if there is no HideAction associated with it. Both actions must be created under the same Rule OID.

Within this action type is a DestinationProperty. This property is an OID of either an item or a group. When action is triggered, the items or groups specified will be shown.

To specify more than one item, or more than one group, there must be multiple DestinationProperty OIDs. This can not be a comma separated list of OIDs.

When triggered, and when the CRF items to be shown are in the same section of the CRF, this action provides a message, specified in the rule definition, to the data entry user. The message is used to alert the data entry person of new fields that are shown on their current section. Also, the items that are currently shown will be highlighted in yellow.

If the items are in a different section of the CRF, or another CRF entirely, the user will not see the message nor will they see the items highlighted in yellow to indicate they have been shown.

The Show action is not supported across event definitions.

ShowAction is executed after CRF Validations, and DiscrepancyNote, Email, Insert and Hide actions have been executed. Data has already been saved into the database before the new hidden items are shown.

Note: If the Rule XML ifExpressionEvaluates parameter equals blank (i.e. ifExpressionEvaluates = ""), once imported, the value will default to FALSE.

HideAction

The HideAction is used to hide previously shown CRF items or groups.

Note: A HideAction Rule must be written in combination with a ShowAction Rule. A Rule with a HideAction will not work properly if there is no ShowAction associated with it. Both actions must be created under the same Rule OID.

Within this action type is a DestinationProperty. This property is an OID of either an item or a group. When the action is triggered, the items or groups specified will be hidden. To specify more than one item, or more than one group, there must be multiple DestinationProperty OIDs. This can not be a comma separated list of OIDs.

Items that contain a value in the database can not be set to hidden and will always be shown.

The Hide action is not supported across event definitions.

HideAction is executed after CRF Validations, and DiscrepancyNote, Email and Insert actions have been executed. Data has already been saved into the database before the items are hidden.

InsertAction

The InsertAction is used to insert data into CRF items.

Within this action type is a DestinationProperty. This property is an OID of an item. When the action is triggered, the specified item(s) will have a value inserted. To specify more than one item, there must be multiple DestinationProperty OIDs. This can not be a comma separated list of OIDs.

Within the DestinationProperty OID is the option to provide either a Value or a ValueExpression.

- **Value** is a static value you want inserted into the DestinationProperty. To insert a date, the format must be yyyy-mm-dd (e.g., 2014-12-24).
- **ValueExpression** allows you to calculate a new value or copy a value from one field to another. To use another items value as part of the ValueExpression you must provide a valid Item OID. ValueExpression supports all data types, including date and partial date (pdate).

The Insert action is not supported across event definitions.

EventAction

The EventAction is used to schedule a future event or events. This is also known as scheduling or calendaring, and allows you to schedule one or multiple events based on the current event.

Within this action, the Target is the trigger that fires the rule. There is an EventDestination, which is the STARTDATE of the future event that the rule will schedule, and there is a ValueExpression that calculates the STARTDATE for the future event.

To define an EventAction, you must identify the Target, define the EventDestination, and ValueExpression, and specify the conditions for when to run the Rule (RunOnStatus). Following are three different techniques for implementing an EventAction:

- Schedule all subsequent events based on the date of the first event (**View a sample**)
  - There is ONE Target (trigger) in this option - the Rule is triggered only for that Target
  - If an Event STARTDATE is changed, this Rule does not update future Events

- Schedule all subsequent events based on the date of the current event (**View a sample**)
  - There are MULTIPLE Targets (triggers) in this option - the Rule is triggered for any of the Targets
  - If an Event STARTDATEis changed, this Rule dynamically updates all subsequent events

- Schedule the next event (and only the next event) based on the status of the current event (**View a sample**)
  - This option does not display the entire visit schedule. Initially it only displays the first event. Once the first Event is started or completed, it displays the next event - and only the next event. Once the next Event data entry is started or completed, it displays the next event, and so on.

6.4.5 Testing Expressions

To ensure the logic you provided in a rule is correct, there is a Test Rule feature. This feature simply allows you to confirm that the rule is actually testing the feature you wanted to test. To fully test your rules, it is best practice to enter test data for a test subject.

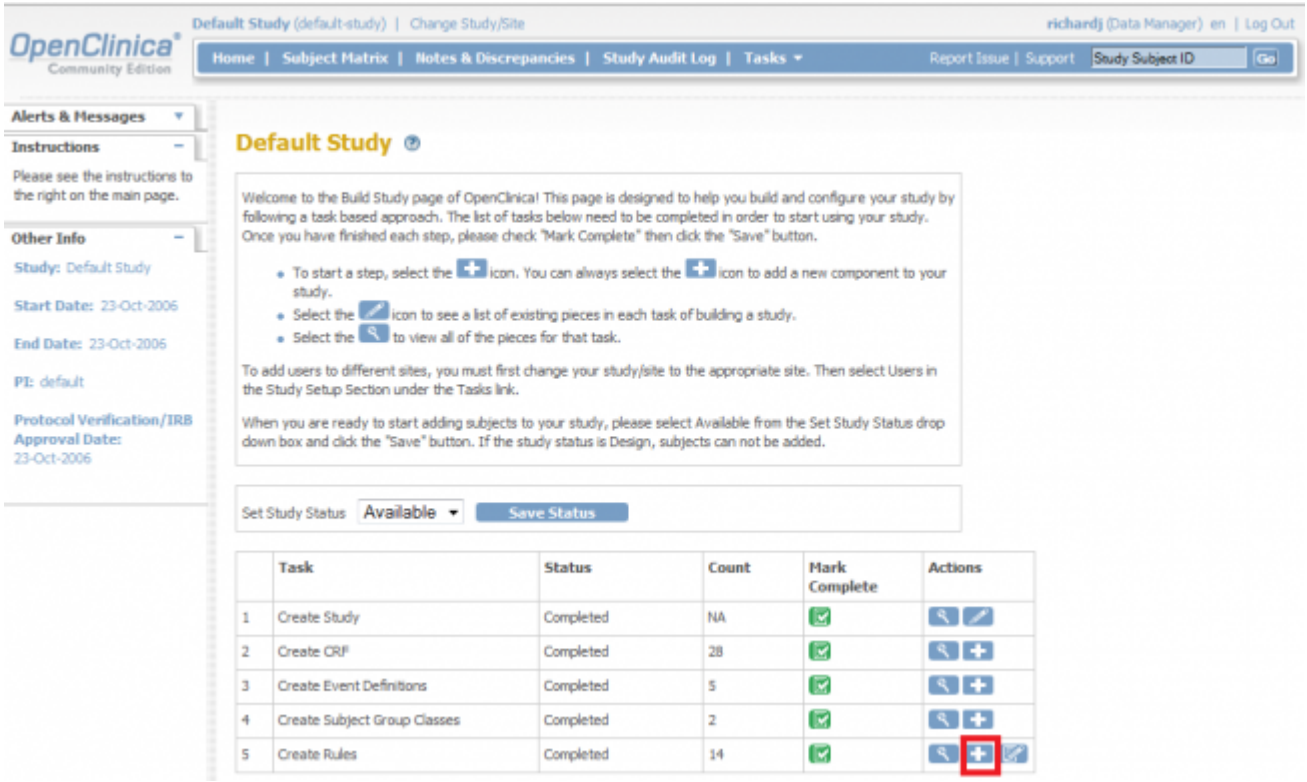
Ensure the rule is uploaded to OpenClinica:

1. Complete writing the rule

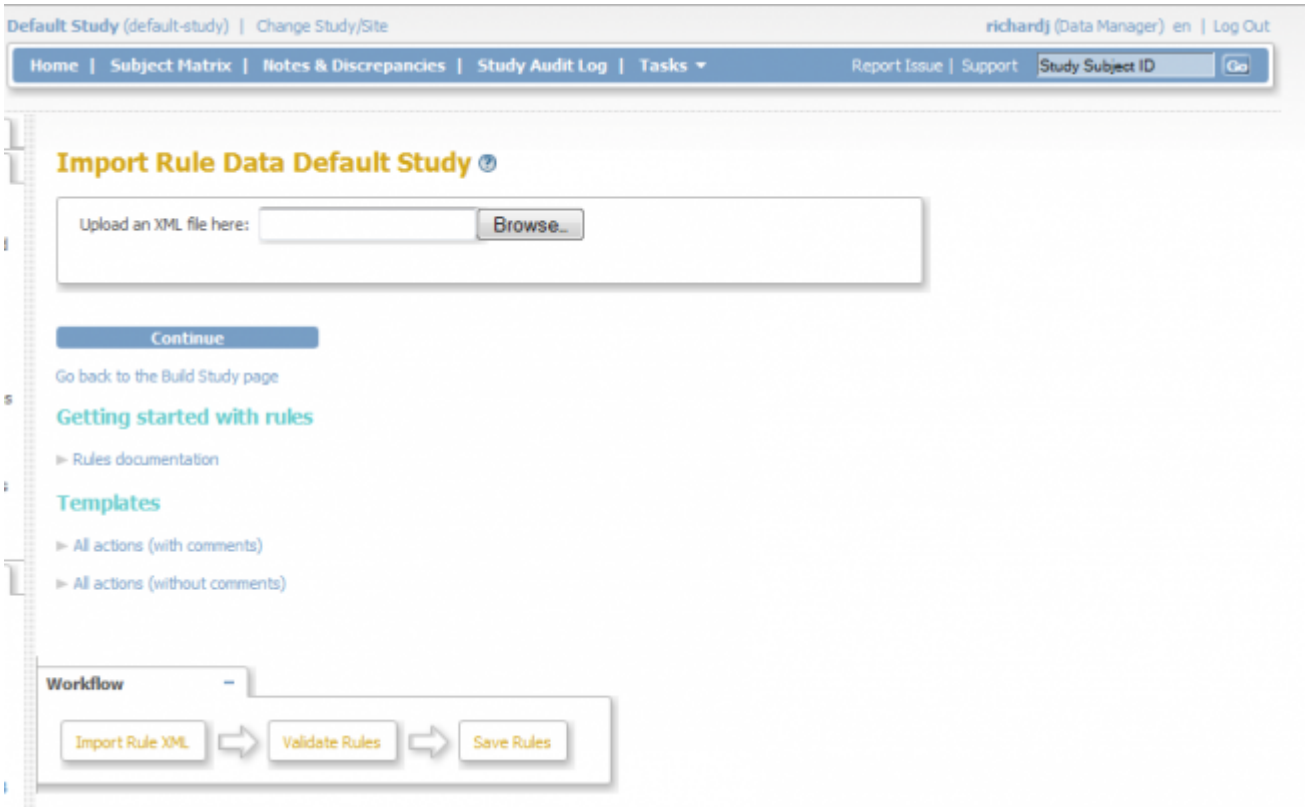
2. Log into OpenClinica

3. Select **Tasks > Build Study**

4. On the Create Rules row of the Build Study page, click



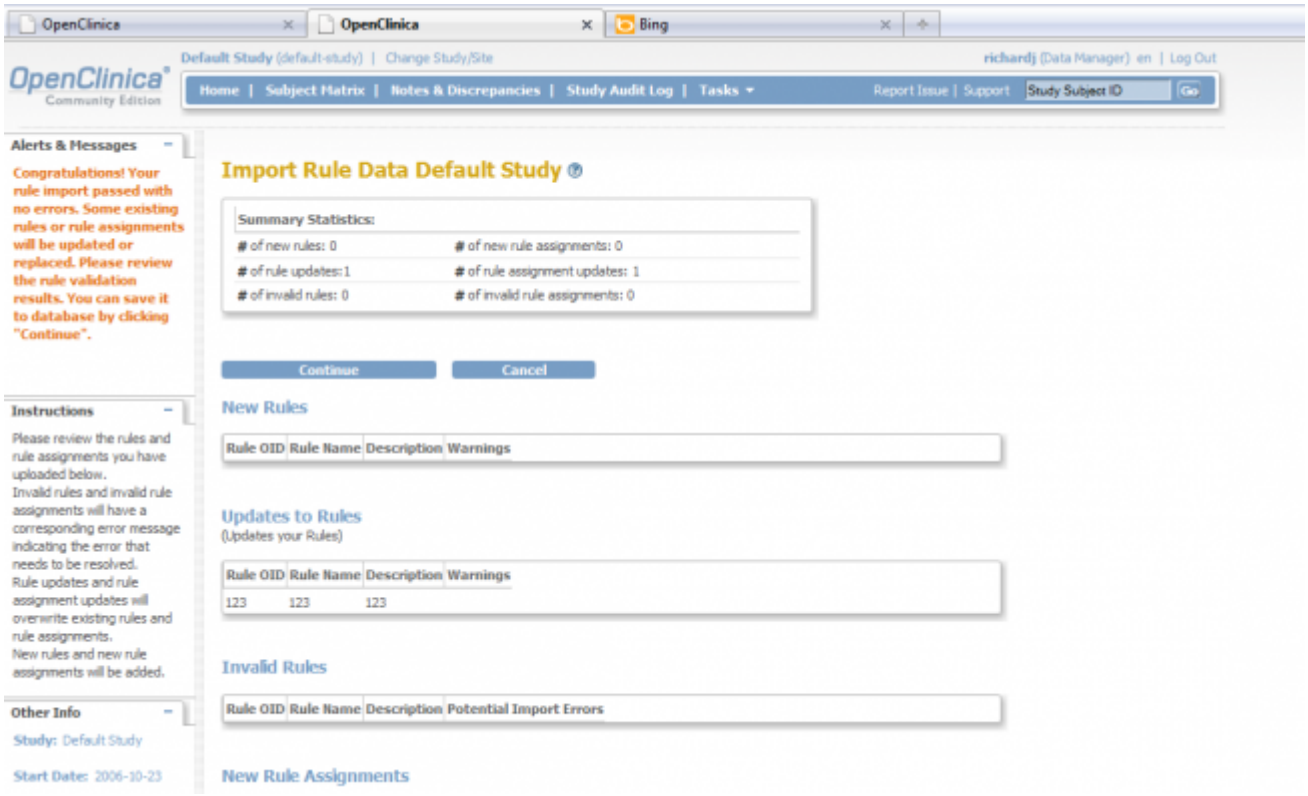
The following window displays:



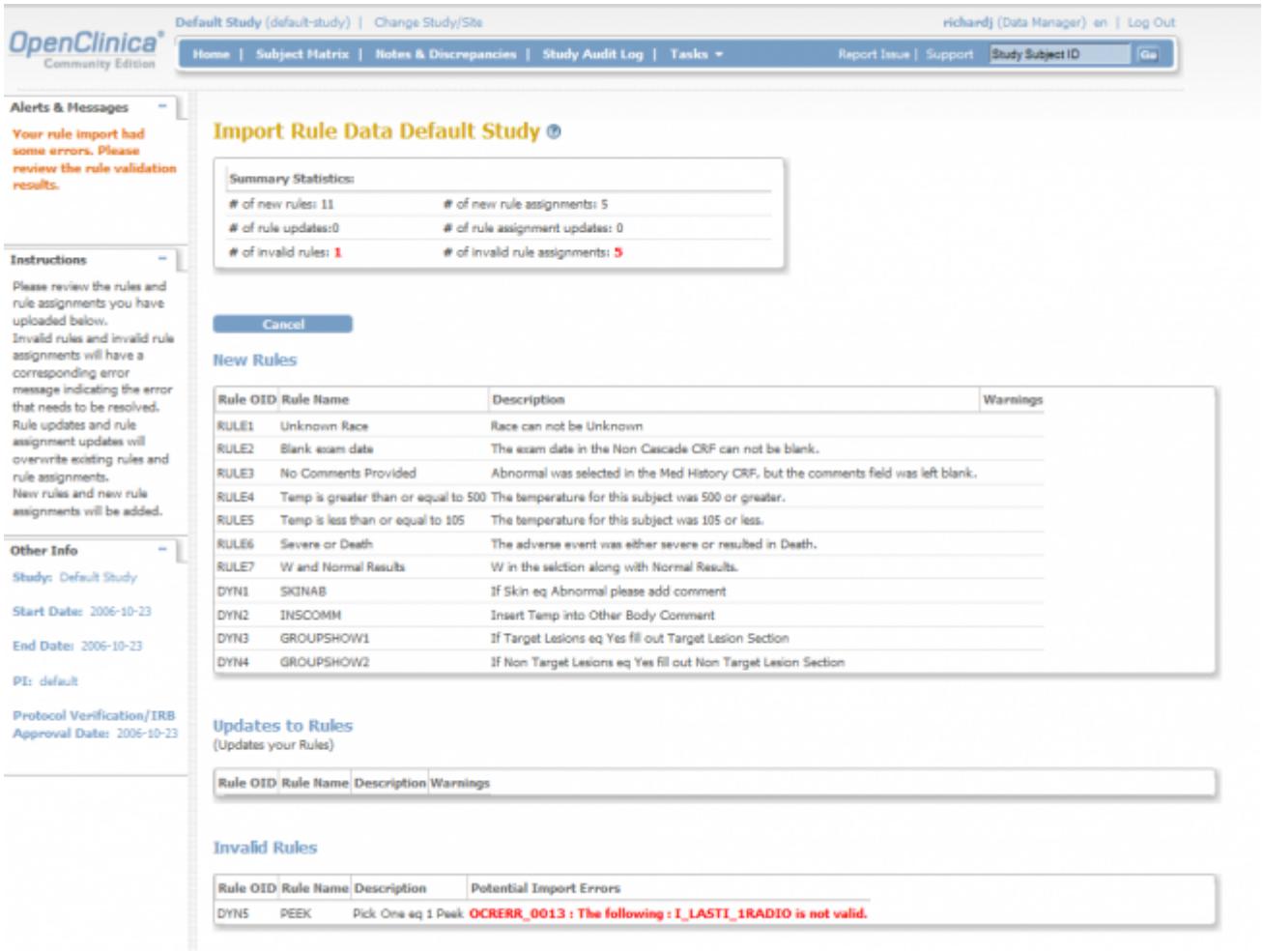
5. Click **Browse**, then locate and **Open** the XML file containing the rule to be uploaded. You may only upload one file at a time.

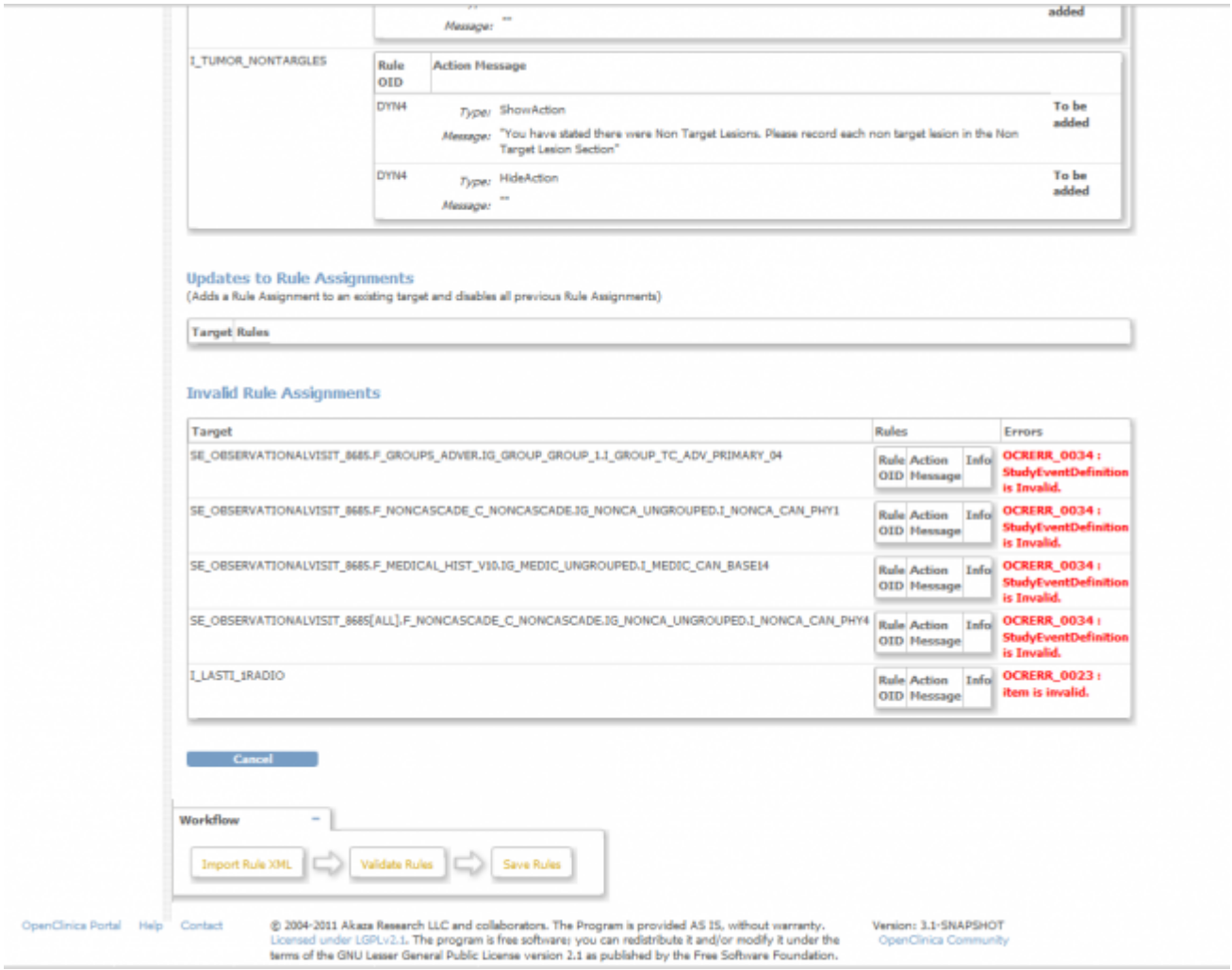
6. Click **Continue**, this will prompt the system to check the validity of the rule

7. If the rule is valid, a successful confirmation message is displayed. To save the rule in OpenClinica, you must select "Continue." Otherwise, click "Cancel."



8. If the rule in invalid, the system displays an error message containing the source of errors. Note that for invalid rules there is no "Continue" button; "Cancel" is the only option at the bottom of the page.


OpenClinica
Community Edition
Default Study (default-study) | Change Study/Site
richardj (Data Manager) en | Log Out
Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks
Report Issue | Support
Study Subject ID
Go
Alerts & Messages
Your rule import had some errors. Please review the rule validation results.
Instructions
Please review the rules and rule assignments you have uploaded below.
Invalid rules and invalid rule assignments will have a corresponding error message indicating the error that needs to be resolved.
Rule updates and rule assignment updates will overwrite existing rules and rule assignments.
New rules and new rule assignments will be added.
Other Info
Study: Default Study
Start Date: 2006-10-23
End Date: 2006-10-23
PI: default
Protocol Verification/IRB Approval Date: 2006-10-23
Import Rule Data Default Study
Summary Statistics:
# of new rules: 11
# of new rule assignments: 5
# of rule updates:0
# of rule assignment updates: 0
# of invalid rules: 1
# of invalid rule assignments: 5
Cancel
New Rules
Rule OID
Rule Name
Description
Warnings
RULE1
Unknown Race
Race can not be Unknown
RULE2
Blank exam date
The exam date in the Non Cascade CRF can not be blank.
RULE3
No Comments Provided
Abnormal was selected in the Med History CRF, but the comments field was left blank.
RULE4
Temp is greater than or equal to 500
The temperature for this subject was 500 or greater.
RULE5
Temp is less than or equal to 105
The temperature for this subject was 105 or less.
RULE6
Severe or Death
The adverse event was either severe or resulted in Death.
RULE7
W and Normal Results
W in the selction along with Normal Results.
DYN1
SKINAB
If Skin eq Abnormal please add comment
DYN2
INSCOMM
Insert Temp into Other Body Comment
DYN3
GROUPSHOW1
If Target Lesions eq Yes fill out Target Lesion Section
DYN4
GROUPSHOW2
If Non Target Lesions eq Yes fill out Non Target Lesion Section
Updates to Rules
(Updates your Rules)
Rule OID
Rule Name
Description
Warnings
Invalid Rules
Rule OID
Rule Name
Description
Potential Import Errors
DYN5
PEEK
Pick One eq 1 Peek
OCRERR_0013 : The following : I_LASTI_1RADIO is not valid.



9. Repeat step 1-7 as necessary to upload a new file/ update an invalid rule.

Testing Rules Expression in OpenClinica

In order to make creating/managing Rules easier, OpenClinica provides you with a tool to execute rules in a test environment. With the Test Rule page you will be able to modify, edit and run the rules for the desired results. You will be presented with a real time response on the validity of your test rules before uploading them into OpenClinica.

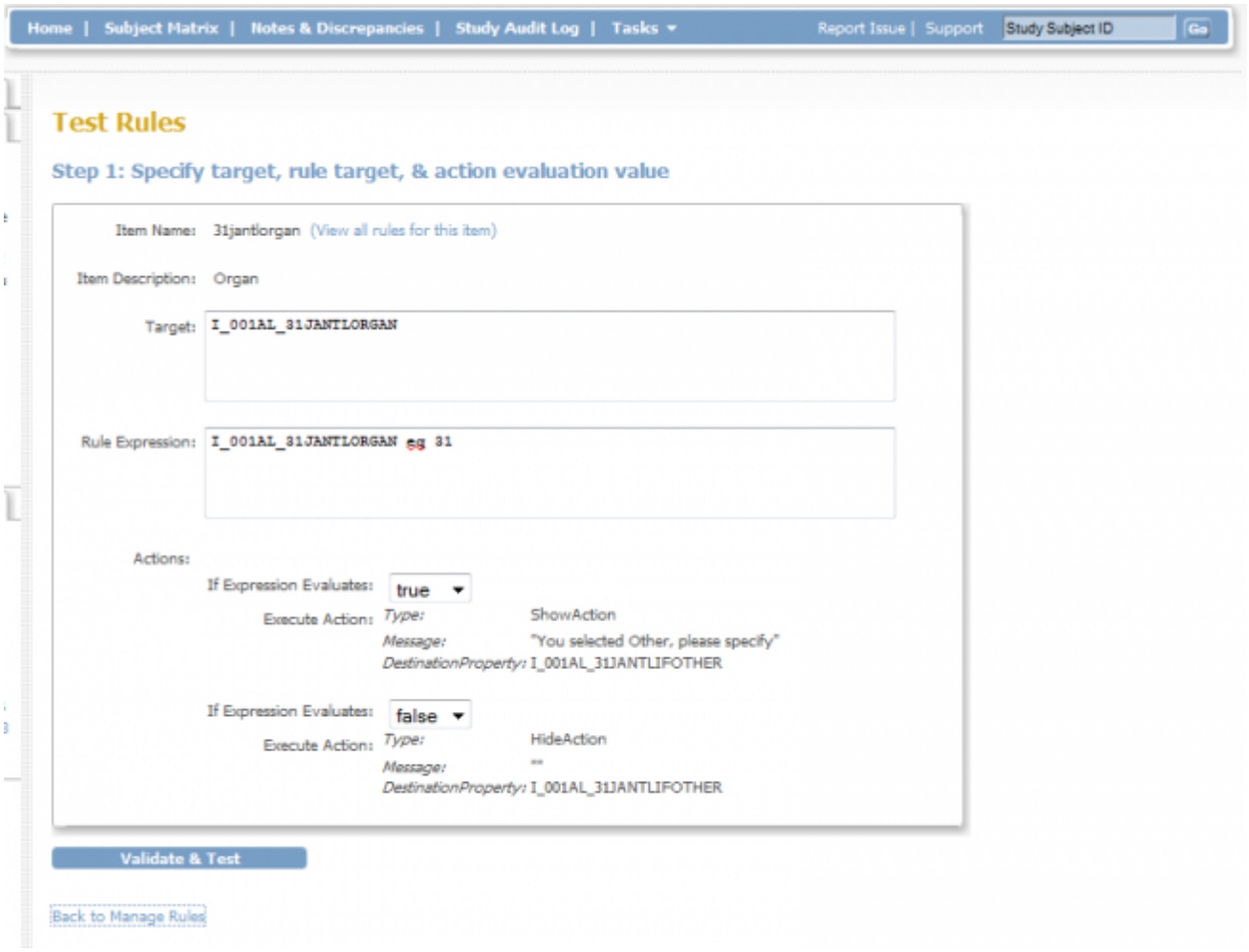
Once the rules get uploaded successfully to OpenClinica, you can verify the validity of the rule by:

1. On the Build Study page, click the View icon to access the Manage Rules for <<Study Name>> page. Click here for more information regarding the Manage Rules page.

2. Locate the rule that you wish to validate and test

3. Under the "Actions" column of that rule, click the "Test" icon

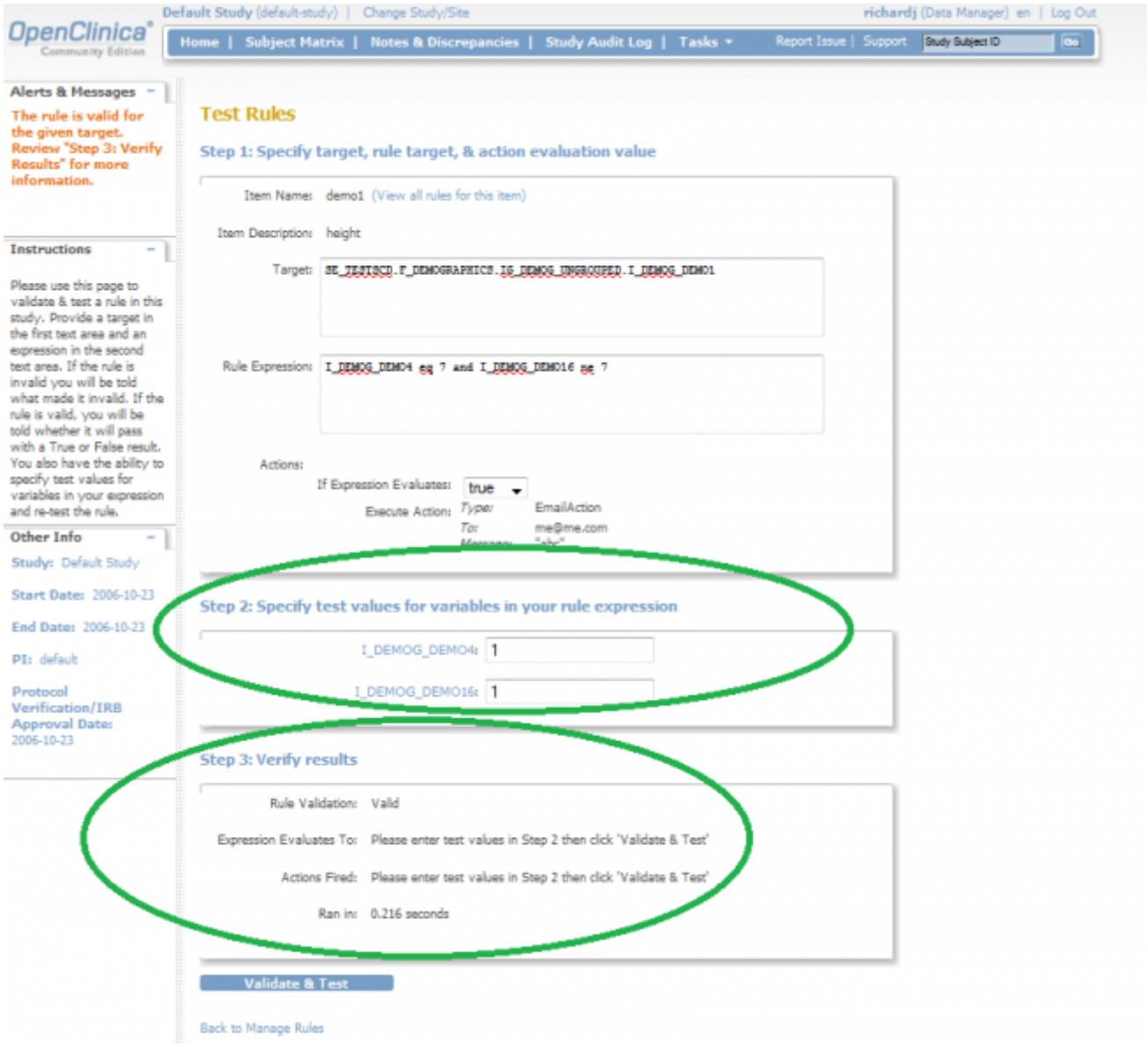
4. You will be prompted to the Test Rules page (see below). The Test Rules page allows you to enter specific information about the rule you want to test.



- Enter Target Name: This would be the same statement element as the Target element in RuleAssignment in the XML file
- Enter the Rule Expression: This would be the same element as the expression element in the RuleDef element in the XML file.
- Select the evaluation action from the drop-down true or false

5. Click Validate and Test

6. **Note**: If the rule is valid, you will be told whether it will pass with a True or False result. You also have the ability to specify test values for variables in your expression and re-test the rule. If the rule is valid, then a successful confirmation message is displayed. Also, addditional sections named "Step 2" and "Step 3" are displayed (see below). If a rule is invalid, OpenClinica will provide you with feedback in the form of an error message with information on why your rule was considered invalid.



7. Now, you can specify the test values for variables in the rule expression at your discreton and verify if the rule functions as expected by clicking "Validate and Save". Repeat this step as necessary.