

2.2.6 Rules

Definition: A rule is a logical expression used to automate a task.

Examples:

• A rule might be used to automatically schedule an event when the Enrollment event has a **status** of **completed**.

• A rule might be used to notify participants about forms that are due when using OpenClinica Participate.

Data Managers can create rules to automatically schedule events (**EventAction**) or automatically send notifications by email or SMS (**NotificationAction**).

You can download the Rules Template and edit it to create a rule to perform either an **EventAction** or a **NotificationAction**.

Note: You can only write rules based on the statuses in the table below. You cannot be written based on an event being *Removed* or *Archived*.

Event Status	Text for Rule (case sensitive)
Not Scheduled	not_scheduled
Scheduled	scheduled
Data Entry Started	data_entry_started
Completed	completed
Skipped	skipped
Stopped	stopped
Signed	signed
Locked	locked

Despite the use of the new data model, with **Statuses** and **Independent Status Attributes**, rules that use the old data model will still work correctly.

Quick Start Guide

To Create a Rule:

Step 1: Access the Manage Rules screen.

- 1. Click Tasks in the header bar of Study Runner.
- 2. Select Rules.
 - a. The **Rules** option does not display when logged in at the Site level. Change to Study level to see the Rules option.

Step 2: To Download the Rules Template.

Click the Download Rules Template link at the top of the table.

Enter Participant ID	View	w					Hom	e Participant Matrix	Queri	ies	Study Audit Log	Tasks 🔻
Alerts & Messages 🔸	Manage	e Rules f	for CAR-T	Study								
Instructions This page allows you to view and manage your study rules.	Add Rules	H 15	🗸 🗐 📓 🗐 SI	now More Dow	nload Rules Template							
OpenClinica rules	CRF	Item Name	Rule Name	Rule OID	Expression	Execute On	Action Summary		Action	s		
provide edit check,									Apply	Filter	Clear Filter	
email action and other capabilities during the course of			ST_BASELINE	ST_BASELINE	SE_ENROLLMENT.STATUS eq "completed"	true	Type:	EventAction	Q	×	≛ ⊟	
data capture and in batch mode.					completed		Run On:	Not Scheduled, Scheduled				
You may click on the action icons to view, test, execute and manage these rules. By default the table is							DestinationProperty:	STARTDATE				
filtered by Rule Status (Available) and sorted			ST_ARM	ST_ARM	SE_BASELINE.STATUS eq "completed"	true	Type:	EventAction	Q	×	* 🖻	
by Item Name. Use the column headers and filter fields (gray					completed		Run On:	Not Scheduled, Scheduled				
boxes) to sort and filter, or filter by Event CRF by using the tree in the 'Info' panel below							DestinationProperty:	STARTDATE				
Info 👻			ST_BQOL	ST_BQOL	SE_BASELINE.STATUS eq "completed"	true	Type:	EventAction	Q	×	≛ ⊕	
Study: CAR-T Study - Study XML:					completes		Run On:	Not Scheduled, Scheduled				
- Unique CRFs: 40 - Unique Items: 1146 - Unique Rule Assignments: 2							DestinationProperty:	STARTDATE				?
	Results 1 - 3	of 3.										

Step 3: Open the Rules Template in an XML editor, such as **Notepad ++** for **Windows** or **TextWrangler** for **Mac**.

Step 4: Find and record OIDs to reference Events and Forms.

- 1. Click **Tasks** in the header bar of Study Runner, and select **View Study**.
- 2. Click the **Download the Study Metadata** link at top of the screen and record OIDs, or scroll down on the screen and record OIDs from there.

See <u>Locate Object Identifiers in a Study</u> for more information on finding OIDs.

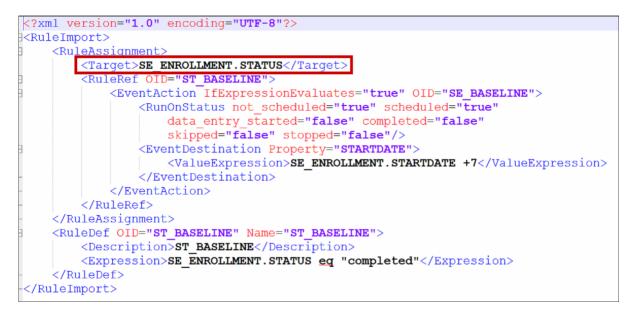
Step 5: In the Rules Template, delete any actions you do not want the rule to perform.

- If you are making an **EventAction** rule, delete the lines starting from **<NotificationAction >** to **</NotificationAction>** tags.
- If you are making a **NotificationAction** rule, delete the lines starting from **<EventAction>** to **</EventAction>** tags.

Step 6: Define the Target.

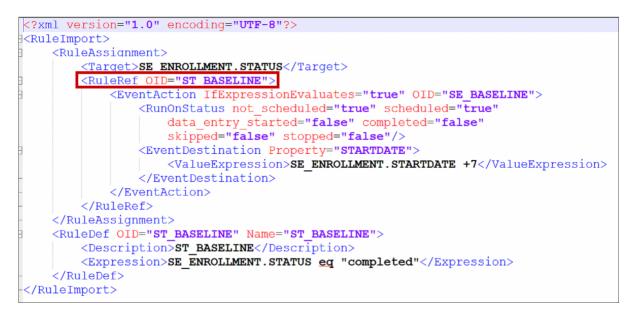
Any time a value changes, the rule evaluates the target. For example, you can use:

- Event Status: SE EVENTOID.STATUS
- Event Start Date: SE_EVENTOID.STARTDATE



Step 7: Define an OID for the rule.

It must be entered in all capital letters. You can include numbers and underscores. It must be unique within the study and can only be 40 characters long.



(Optional): If you want the rule to run at a certain time, specify the time in 24-hour format.



Step 8: Enter the expression.

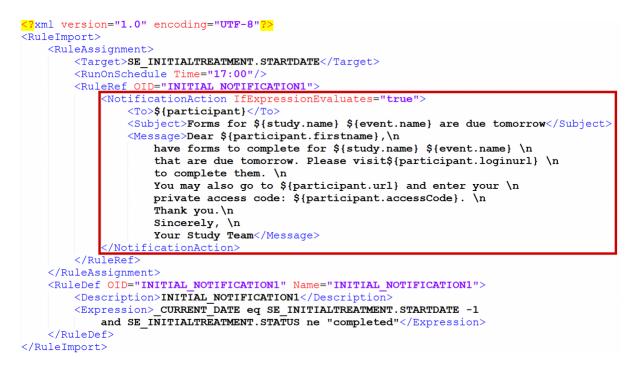
Expressions are the conditions that cause the rule to run.

```
<?xml version="1.0" encoding="UTF-8"?>
<RuleImport>
    <RuleAssignment>
        <Target>SE ENROLLMENT.STATUS</Target>
        <RuleRef OID="ST BASELINE">
            <EventAction IfExpressionEvaluates="true" OID="SE BASELINE">
                <RunOnStatus not scheduled="true" scheduled="true"
                    data entry started="false" completed="false"
                    skipped="false" stopped="false"/>
                <EventDestination Property="STARTDATE">
                   <ValueExpression>SE ENROLLMENT.STARTDATE +7</ValueExpression>
                </EventDestination>
            </EventAction>
        </RuleRef>
    </RuleAssignment>
    <RuleDef OID="ST BASELINE" Name="ST BASELINE">
        <Description>ST BASELINE</Description>
        <Expression>SE ENROLLMENT.STATUS eg "completed"</Expression>
    </RuleDef>
</RuleImport>
```

Event Action: If you want the rule to run when the event reaches a certain **status**, specify all of the **statuses** as **true** or **false**.

NotificationAction: Specify the recipient(s), subject of the notification, and message next to the corresponding tags. You can include multiple email addresses separated by commas. To use this rule, **Openclinica Participate** must be active.

Note: See syntax below, in the tables.



Step 9: Make sure all tags are closed, and save the file as an XML file.

Enter Participant ID	View					Ноп	ne Participant Matrix	Queri	es s	Study Audit Lo	g Tasks 🔻
Alerts & Messages →	Manage Rules f	for CAR-T S	Study								
Instructions 👻	Add Rules										
o view and manage our study rules.	HK K H H 15 V	🖌 🗐 💼 Sh	ow More Dow	nload Rules Template							
OpenClinica rules	CRF Item Name	Rule Name	Rule OID	Expression	Execute On	Action Summary		Actions	;		
orovide edit check, email action and								Apply	Filter	Clear Filter	
other capabilities during the course of		ST_BASELINE	ST_BASELINE	SE_ENROLLMENT.STATUS eq "completed"	true	Type:	EventAction	Q	×	≛ 🕀	
data capture and in batch mode.						Run On:	Not Scheduled, Scheduled				
You may click on the action icons to view, test, execute and manage these rules. By default the table is						DestinationProperty:	STARTDATE				
iltered by Rule Status Available) and sorted by Item Name. Use		ST_ARM	ST_ARM	SE_BASELINE.STATUS eq "completed"	true	Type:	EventAction	۹	×	≜ 😑	
the column headers and filter fields (gray						Run On:	Not Scheduled, Scheduled				
and filter fields (gray boxes) to sort and filter, or filter by Event CRF by using the tree in the 'Info' panel below						DestinationProperty:	STARTDATE				
nfo 👻		ST_BQOL	ST_BQOL	SE_BASELINE.STATUS eq "completed"	true	Type:	EventAction	Q	×	* 🗄	
Study: CAR-T Study - Study XML:						Run On:	Not Scheduled, Scheduled				
Download - Unique CRFs: 40 - Unique Items: 1146 - Unique Rule Assignments: 2						DestinationProperty:	STARTDATE				?
	Results 1 - 3 of 3.										

Step 10: Click the Add Rules link at the top of the Manage Rules screen.

Step 11: Click **Choose file**, and select a file to upload. Then click the **Continue** button.

To View a Rule:

Click the **View** button next to the rule you want to view.

Manage	e Rules f	or CAR-T	Study					
Add Rules								
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CRF	Item Name	Rule Name	Rule OID	Expression	Execute On	Action Summary		Actions
								Apply Filter Clear Filter
		ST_BASELINE	ST_BASELINE	SE_ENROLLMENT.STATUS eq "completed"	true	Туре:	EventAction	Q 🗙 🛓 🗄
						Run On:	Not Scheduled, Scheduled	
						DestinationProperty:	STARTDATE	

To Remove a Rule:

Click the $\ensuremath{\textbf{Remove}}$ button next to the rule you want to remove.

Manage Rules for CAR-T Study											
Add Rules											
HK H	M M 15	🗸 📄 🗃 🗐 si	how More Dow	nload Rules Template							
CRF	Item Name	Rule Name	Rule OID	Expression	Execute On	Action Summary		Actions			
								Apply Filter Clear Filte	er		
		ST_BASELINE	ST_BASELINE	SE_ENROLLMENT.STATUS eq "completed"	true	Туре:	EventAction	Q 🗙 🛓 🖻			
							Not				
						Run On:	Scheduled, Scheduled				
						DestinationProperty:	STARTDATE				

To Download a Rule:

Click the **Download** button next to the rule you want to download.

Manag	e Rules	for CAR-T	Study						
Add Rules	5								
HI H	H H 15 V	- 🗉 🗟 🕘 Sł	now More Dow	nload Rules Template					
CRF	Item Name	Rule Name	Rule OID	Expression	Execute On	Action Summary		Actions	
								Apply Filter Clear	Filter
		ST_BASELINE	ST_BASELINE	SE_ENROLLMENT.STATUS eq "completed"	true	Туре:	EventAction	Q 🗙 🛓 🗄	Ð
						Run Oni	Not Scheduled,		
						Run On:	Scheduled, Scheduled		
						DestinationProperty:	STARTDATE		

To Test a Rule:

1. Click the ${\bf Test}$ button next to the rule you want to test.

Manag	e Rules	for CAR-T	Study						
Add Rules									
H H I	M M 15 V	🗸 📄 📓 🎒 Sł	how More Dow	nload Rules Template					
CRF	Item Name	Rule Name	Rule OID	Expression	Execute On	Action Summary		Actions	
								Apply Filter	Clear Filter
		ST_BASELINE	ST_BASELINE	SE_ENROLLMENT.STATUS eq "completed"	true	Туре:	EventAction	Q X	≛ 🗄
							Not		
						Run On:	Scheduled, Scheduled		
						DestinationProperty:	STARTDATE		

- 2. Check that the Target, Rule Expression, and Actions are displayed correctly on the screen.
- 3. Click the **Validate & Test** button.

Test Rule

Step 1: Specify target, rule expression and action evaluation value

Item Name:	Enrollment (View	all rules for this item)	
Item Description:				
Target:	SE_ENROLLMENT.STATU	IS	/	
Rule Expression:	SE_ENROLLMENT.STATU	IS eq "completed"		
Actions:				
If Exp	pression Evaluates:	true 🗸		
Exec	ute Action:	Type: DestinationProperty:	EventAction	
Validate & Test				

- 4. Specify test values for variables in your rule expression.
- 5. Click the **Validate & Test** button again.
- 6. Review the results of the test. On the left-hand sidebar under **Alerts & Messages**, you will see a statement about whether the test was valid or invalid. Scroll down to **Verify** results for more details.

Actions

[table id=32 /]

Rule Components

[table id=33 /]

Expressions

[table id=34 /]

Example:

SE.ENROLLMENT.STARTDATE eq completed

Conditional Operators

[table id=35 /]

Example:

CURRENT_DATE -1 and SE.SCREENING.STATUS ne completed

Arithmetic Operators

[table id=36 /]

Example:

SE.ENROLLMENT.STARTDATE + 7

Dates within Rules: Equality and Relational Operators

[table id=37 /]

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

Example:

January 01, 2020 should be written as: 2020-01-01

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.

Notification Action Parameters

[table id=38 /]

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 {\rm 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**.)

Functional approval by Riley Bianchi. Signed on 2023-03-21 3:23PM

Approved for publication by Paul Bowen. Signed on 2023-03-21 5:59PM

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