

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 | <i>not_scheduled</i> |
| Scheduled | <i>scheduled</i> |
| Data Entry Started | <i>data_entry_started</i> |
| Completed | <i>completed</i> |
| Skipped | <i>skipped</i> |
| Stopped | <i>stopped</i> |
| Signed | <i>signed</i> |
| Locked | <i>locked</i> |

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

Home Participant Matrix Queries Study Audit Log Tasks

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: CAR-T Study
- Study XML:
Download
- Unique CRFs: 40
- Unique Items: 1146
- Unique Rule Assignments: 2

Manage Rules for CAR-T Study

Add Rules

Download Rules Template

| CRF | Item Name | Rule Name | Rule OID | Expression | Execute On | Action Summary | Actions |
|-------------|-------------|-------------------------------------|----------|------------|---|---------------------------|---------|
| ST_BASELINE | ST_BASELINE | SE_ENROLLMENT.STATUS eq "completed" | | true | Type: EventAction Run On: Not Scheduled, Scheduled DestinationProperty: STARTDATE | Apply Filter Clear Filter | |
| ST_ARM | ST_ARM | SE_BASELINE.STATUS eq "completed" | | true | Type: EventAction Run On: Not Scheduled, Scheduled DestinationProperty: STARTDATE | | |
| ST_BQOL | ST_BQOL | SE_BASELINE.STATUS eq "completed" | | true | Type: EventAction Run On: Not Scheduled, Scheduled 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 [Locate Object Identifiers in a Study](#) 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

```

<?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 eq "completed"</Expression>
  </RuleDef>
</RuleImport>

```

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.

```

<?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 eq "completed"</Expression>
  </RuleDef>
</RuleImport>

```

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

```

<?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>

```

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 eq "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.

```

<?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>

```

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

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

The screenshot shows the 'Manage Rules for CAR-T Study' interface. On the left, there's a sidebar with 'Alerts & Messages', 'Instructions', and 'Info'. The main area has a header with 'Enter Participant ID' and 'View' buttons. Below the header, there's a section titled 'Manage Rules for CAR-T Study' with an 'Add Rules' link highlighted by a red box. Below this, there's a table of rules. The table has columns: CRF, Item Name, Rule Name, Rule OID, Expression, Execute On, Action Summary, and Actions. There are three rules listed, all with 'SE_BASELINE.STATUS eq "completed"' as the expression and 'EventAction' as the action type. The 'Run On' status is 'Not Scheduled, Scheduled' and the 'DestinationProperty' is 'STARTDATE'.

| CRF | Item Name | Rule Name | Rule OID | Expression | Execute On | Action Summary | Actions |
|-----|-----------|-------------|-------------|-------------------------------------|------------|---|---------------------------|
| | | ST_BASELINE | ST_BASELINE | SE_ENROLLMENT.STATUS eq "completed" | true | Type: EventAction Run On: Not Scheduled, Scheduled DestinationProperty: STARTDATE | Apply Filter Clear Filter |
| | | ST_ARM | ST_ARM | SE_BASELINE.STATUS eq "completed" | true | Type: EventAction Run On: Not Scheduled, Scheduled DestinationProperty: STARTDATE | Apply Filter Clear Filter |
| | | ST_BQOL | ST_BQOL | SE_BASELINE.STATUS eq "completed" | true | Type: EventAction Run On: Not Scheduled, Scheduled DestinationProperty: STARTDATE | Apply Filter Clear Filter |

Results 1 - 3 of 3.

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 Rules for CAR-T Study

Add Rules

| 15 Show More Download Rules Template | | | | | | | |
|--------------------------------------|-----------|-------------|-------------|-------------------------------------|------------|---|---|
| CRF | Item Name | Rule Name | Rule OID | Expression | Execute On | Action Summary | Actions |
| | | ST_BASELINE | ST_BASELINE | SE_ENROLLMENT.STATUS eq "completed" | true | Type: EventAction Run On: Not Scheduled, Scheduled DestinationProperty: STARTDATE | Apply Filter Clear Filter [Search] [X] [Download] [Test] |

To Remove a Rule:

Click the **Remove** button next to the rule you want to remove.

Manage Rules for CAR-T Study

Add Rules

| 15 Show More Download Rules Template | | | | | | | |
|--------------------------------------|-----------|-------------|-------------|-------------------------------------|------------|---|---|
| CRF | Item Name | Rule Name | Rule OID | Expression | Execute On | Action Summary | Actions |
| | | ST_BASELINE | ST_BASELINE | SE_ENROLLMENT.STATUS eq "completed" | true | Type: EventAction Run On: Not Scheduled, Scheduled DestinationProperty: STARTDATE | Apply Filter Clear Filter [Search] [X] [Download] [Test] |

To Download a Rule:

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

Manage Rules for CAR-T Study

Add Rules

| 15 Show More Download Rules Template | | | | | | | |
|--------------------------------------|-----------|-------------|-------------|-------------------------------------|------------|---|---|
| CRF | Item Name | Rule Name | Rule OID | Expression | Execute On | Action Summary | Actions |
| | | ST_BASELINE | ST_BASELINE | SE_ENROLLMENT.STATUS eq "completed" | true | Type: EventAction Run On: Not Scheduled, Scheduled DestinationProperty: STARTDATE | Apply Filter Clear Filter [Search] [X] [Download] [Test] |

To Test a Rule:

1. Click the **Test** button next to the rule you want to test.

Manage Rules for CAR-T Study

Add Rules

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Show More

Download Rules Template

| CRF | Item Name | Rule Name | Rule OID | Expression | Execute On | Action Summary | Actions |
|-----|-----------|-------------|-------------|-------------------------------------|------------|--|---|
| | | ST_BASELINE | ST_BASELINE | SE_ENROLLMENT.STATUS eq "completed" | true | <i>Type:</i> EventAction <i>Run On:</i> Not Scheduled, Scheduled <i>DestinationProperty:</i> STARTDATE | <div> <div>Apply Filter</div> <div>Clear Filter</div> </div> <div> <div></div> <div></div> <div></div> <div></div> </div> |

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.STATUS

Rule Expression:

SE_ENROLLMENT.STATUS eq "completed"

Actions:

If Expression Evaluates:

true

Execute Action:

Type:

EventAction

DestinationProperty:

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 ${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**.)

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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