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Scenario: In this tutorial, you will set up a visit schedule for a simple Oncology study with two treatment arms: Treatment Arm A - Standard of Care and Treatment Arm B - Standard of Care Plus Active Drug. The visit schedule begins with two standard visits, a Screening visit and a Baseline visit. After completing the screening and baseline, the visit schedule continues with two distinct visit branches. These branches are based on the treatment arms used in this study and the visit schedule described in each branch cycles for a total of two years. Once the treatment completes, subjects enter a new branch schedule for a Follow Up visit that cycles every 8 weeks for an indefinite period. The visit schedule concludes with a completion visit.

Note: The study design might also include other types of visits and events, such as Adverse Events or unscheduled visits, but in this tutorial we are focusing on the feature of branching and cycling visit schedules.

Tutorial workflow

1. Create and schedule the Screening and Baseline visits	2. Create the Standard of Care branch	3. Add visits to the Standard of Care branch	4. Define the visit schedule for the Standard of Care branch	5. Create the Standard of Care Plus Active Drug branch	6. Add visits to the Standard of Care Plus Active Drug branch	7. Define the visit schedule for the Standard of Care Plus Active Drug	8. Create branch Follow Up	9. Add visits to the Follow Up branch	10. Define the visit schedule for the Follow Up branch	11. Complete the study
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Prerequisites: To create and schedule visits branches you must first create a study and define the treatment arms that are used to randomize the subjects. For more details see <u>Create a study</u> and <u>Define a treatment arm</u>.

1 Create and schedule the Screening and Baseline visits

- 1. On the Home page, click the pencil (🌈) button for the study you want to edit.
- **2.** Below Draft, click the study version.
- **3.** Make sure the **Data Collection** tab is selected.
- **4.** In the right pane, in the **Scheduled Visits** section, click the **+** button and select **Add Visit**.
- 5. In the Create Scheduled Visit dialog, fill in the fields and click Save & Add Another:
 - Title: Enter Screening.
 - ID: Enter SCR.
 - Type: Select Screening Visit.
 - **Required:** Select Yes.
- **6.** In the new **Create Scheduled Visit** dialog, fill in the fields and click **Save**:
 - **Title:** Enter Baseline.
 - ID: Enter BASE.
 - Type: Select Scheduled Visit.
 - **Required:** Select Yes.
- 7. To schedule the Baseline visit, click the **Add Schedule** button above the visit.
- **8.** Fill in the fields in the top section:
 - **Scheduled From**: The system defaults to the first visit in the study Screening visit.
 - Days: Enter 7. This means that the Baseline visit will occur 7 days days after the Screening visit.
 - **Hours** is always grayed out.
- **9.** Fill in the fields in the **Visit Window** sections and click **Save**:
 - **Before Days**: Specify 3. This is the number of days before the scheduled date and time that the visit can occur.
 - After days: Specify 3. This is the number of days after the scheduled date and time that the visit can occur.
 - Hours is always grayed out.

Read the detailed instructions for creating and scheduling a visit.



The Standard of Care branch

- 1. In the right pane, in the **Scheduled Visits** section, click the **+** button and select **Add Branch to Bottom**.
- 2. In the **Create Branch** dialog, fill in the fields as needed and click **Save**:
 - Title: Enter Standard of Care.
 - **ID:** Enter SOC.
 - Cycle the Branch: Select Yes.
 - Count of Cycles: Enter the number of times visits in the branch should be repeated throughout the study, in this case 24.
 - Assign Subjects Using: Select Treatment Arm.
 - Treatment Arm Settings: Select Treatment Arm A Standard of Care.

Note: The Standard of Care branch appears below the last scheduled visit, in this case the Baseline visit.

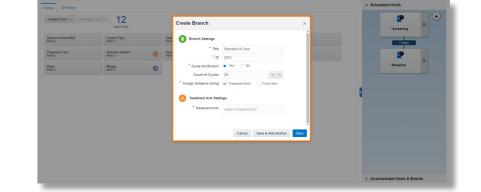
Read the detailed instructions

3 Add scheduled visits to the Standard of Care branch

In this branch, you create two visits: Day 1 and Day 22.

- 1. In the branch section, click **Create scheduled visit**. Alternatively, next to the branch title, click the menu icon and select **Add Scheduled Visit**.
- 2. Fill in the fields and click **Save & Add Another** to add another visit:
 - Title: Enter Day 1.
 - ID: Enter DAY1.
 - Required: Select Yes.
- **3.** Repeat steps 1 and 2 to create the Day 22 visit and click **Save**.

Read the detailed instructions



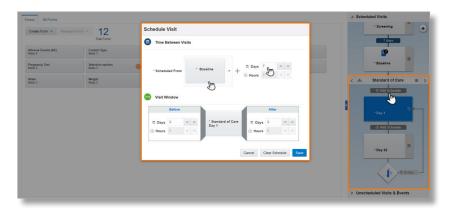


4

Define the visit schedule for the Standard of Care branch

- 1. In the branch, click **Add Schedule** above the first visit.
- **2.** Fill in the fields in the top section:
 - **Scheduled From**: By default, the system auto-selects the last visit that was scheduled prior to the branch start, in this case the Baseline Visit.
 - Days: Enter 7. This means that the Day 1 visit will occur 7 days after the Baseline visit.
 - Hours is always grayed out.
- **3.** Fill in the fields in the **Visit Window** sections and click **Save**:
 - Before Days: Specify 3. This is the number of days before the scheduled date and time that the visit can occur.
 - After days: Specify 3. This is the number of days after the scheduled date and time that the visit can occur.
 - Hours is always grayed out.
- **4.** To schedule visit Day 22 click **Add Schedule** above the visit.
- **5.** Fill in the fields in the top section:
 - Scheduled From: Because this visit is part of a cycle, the system defaults to the first visit within the cycle Day 1.
 - Days: Enter 21. This means that the Day 22 visit will occur 21 days after the Day 1 visit.
 - **Hours** is always grayed out.
- **6.** Fill in the fields in the **Visit Window** sections and click **Save**:
 - **Before Days**: Specify 3. This is the number of days before the scheduled date and time that the visit can occur.
 - After days: Specify 3. This is the number of days after the scheduled date and time that the visit can occur.
 - Hours is always grayed out.
- 7. Because this branch cycles, you need to schedule when the cycle should start again. Below the Day 22 visit click **Add**.
- **8.** Fill in the fields in the top section:
 - **Scheduled From**: By default, the system displays the last visit in the cycle, in this case, Day 22.
 - Days: Enter 21. This means that visit the Day 1 visit will re-occur 21 days after visit the Day 22 visit.
 - **Hours** is always grayed out.
- **9.** Fill in the fields in the **Visit Window** sections and click **Save**:
 - **Before Days**: Specify 3. This is the number of days before the scheduled date and time that the visit can occur.
 - After days: Specify 3. This is the number of days after the scheduled date and time that the visit can occur.
 - **Hours** is always grayed out.

Read the detailed instructions

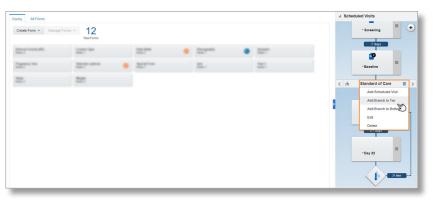




5 Create the Standard of Care Plus Active Drug branch

- 1. On the Data Collection tab, in the right pane, next to the branch title, click the menu icon and select Add Branch to Tier.
- 2. In the **Create Branch** dialog, fill in the fields and click **Save**:
 - Title: Enter Standard of Care Plus Active Drug.
 - ID: Enter SOCPLUS.
 - Cycle the Branch: Select Yes.
 - Count of Cycles: Enter the number of times visits in the branch should be repeated throughout the study, in this case 24.
 - Assign Subjects Using: Select Treatment Arm.
 - Treatment Arm Settings: Select Treatment Arm B Standard of Care Plus Active Drug.

Read the detailed instructions



6 Add scheduled visits to the Standard of Care Plus Active Drug branch

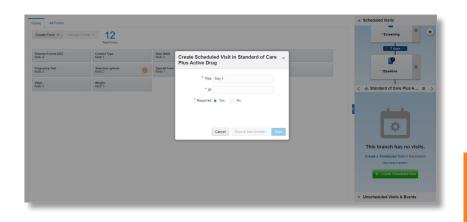
Subjects that are assigned to Treatment Arm B - Standard of Care Plus Active Drug need to be monitored more often. So, in this branch, you create 4 weekly visits: Day 1, Day 8, Day 15, and Day 22.

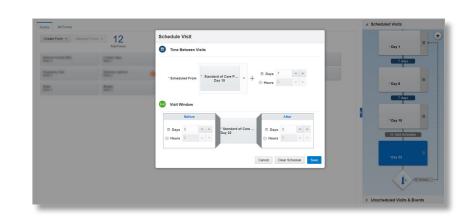
- Next to the branch title, click the menu icon and select Add Scheduled Visit.
- 2. Fill in the fields and click **Save & Add Another** to add another scheduled visit:
 - Title: Enter Day 1.
 - ID: Enter PLUSDAY1.
 - Required: Select Yes.
- **3.** Repeat steps 1 and 2 to create the Day 8, Day 15, and Day 22 visits. When you are finished adding the last visit, click **Save**.

Read the detailed instructions

7 Define the visit schedule for the Standard of Care Plus Active Drug branch

- In the branch, click Add Schedule above the first visit.
- **2.** Fill in the fields in the top section:
 - **Scheduled From**: By default, the system auto-selects the last visit that was scheduled prior to the branch start, in this case the Baseline Visit.
 - Days: Enter 7. This means that the Day 1 visit will occur 7 days after the Baseline visit.
 - **Hours** is always grayed out.
- Fill in the fields in the Visit Window sections and click Save:
 - **Before Days**: Specify 3. This is the number of days before the scheduled date and time that the visit can occur.
 - After days: Specify 3. This is the number of days after the scheduled date and time that the visit can occur.
 - **Hours** is always grayed out.
- **4.** To schedule the Day 8 visit click **Add Schedule** above the visit.
- **5.** Fill in the fields in the top section:
 - **Scheduled From**: Because this visit is part of a cycle, the system defaults to the first visit within the cycle Day 1.
 - Days: Enter 7. This means that the Day 8 visit will occur 7 days after the Day 1 visit.
 - **Hours** is always grayed out.
- **6.** Fill in the fields in the **Visit Window** sections and click **Save**:
 - **Before Days**: Specify 3. This is the number of days before the scheduled date and time that the visit can occur.
 - After days: Specify 3. This is the number of days after the scheduled date and time that the visit can occur.
 - **Hours** is always grayed out.
- 7. Repeat steps 6, 7, and 8 to schedule the Day 15 and Day 22 visits. Each visit is scheduled 7 days from the previous visit in the branch.





- **8.** To schedule the cycle to start again, below visit the Day 22 visit click **Add**.
- **9.** Fill in the fields in the top section:
 - Scheduled From: By default, the system displays the last visit in the cycle, in this case, Day 22.
 - Days: Enter 7. This means that the Day 1 visit will re-occur 7 days after the Day 22 visit.
 - **Hours** is always grayed out.
- **10.** Fill in the fields in the **Visit Window** sections and click **Save**:
 - **Before Days**: Specify 3. This is the number of days before the scheduled date and time that the visit can occur.
 - After days: Specify 3. This is the number of days after the scheduled date and time that the visit can occur.
 - **Hours** is always grayed out.

Read the detailed instructions



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8 Create the Follow Up branch

After two years, treatment is discontinued and all subjects enter a long follow up period. Subjects are allocated to this branch based on the treatment arm to which they are assigned.

- 1. On the **Data Collection** tab, in the right pane, next to the branch title (Standard of Care Plus Active Drug), click the menu icon and select **Add Branch to Bottom**.
- 2. In the **Create Branch** dialog, fill in the fields and click **Save**:
 - Title: Enter Follow Up.
 - **ID:** Enter LTF.
 - Cycle the Branch: Select Yes.
 - Count of Cycles: Select Unlimited.
 - Assign Subjects Using: Select Treatment Arm.
 - Treatment Arm Settings: Select Treatment Arm A Standard of Care and Treatment Arm B Standard of Care Plus Active Drug.

Read detailed instructions

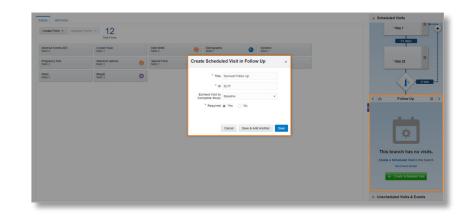
9 Add scheduled visits to the Follow Up branch

In this branch you create one visit: Survival Follow Up.

- 1. Next to the branch title, click the menu icon and select **Add Scheduled Visit**.
- **2.** Fill in the fields and click **Save**:
 - Title: Enter Survival Follow Up.
 - ID: Enter SLTF.
 - Required: Select Yes.

Read the detailed instructions





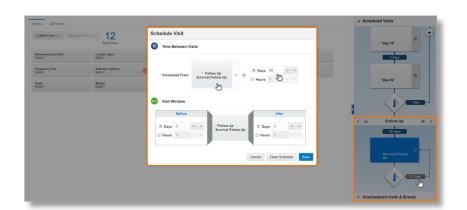
10 Define the visit schedule for the Follow Up branch

The Survival Follow Up visit needs to be scheduled twice, once from the Standard of Care branch and once from the Standard of Care Plus Active Drug branch, because subjects from both branches are included in this third branch. The visit occurs 28 days after the last visit in the previous branch. From then on, the Survival Follow Up visit repeats every 8 weeks.

- Make sure the Standard of Care branch is selected above the Follow Up branch.
- 2. In the Follow Up branch, click **Add Schedule** above the Survival Follow Up visit.
- **3.** Fill in the fields in the top section:
 - **Scheduled From**: By default, the system auto-selects the previous visit that was scheduled, in this case Day 22 from the Standard of Care branch.
 - Days: Enter 28.
 - **Hours** is always grayed out.
- **4.** Fill in the fields in the **Visit Window** sections and click **Save**:
 - **Before Days**: Specify 3. This is the number of days before the scheduled date and time that the visit can occur.
 - After days: Specify 3. This is the number of days after the scheduled date and time that the visit can occur.
 - **Hours** is always grayed out.
- **5.** To schedule the Survival Follow Up visit from the Standard of Care Plus Active Drug branch repeat steps 1 through 5, but this time ensure the Standard of Care Plus Active Drug branch is selected above the Follow Up branch (use the arrows next to the branch name).
- **6.** Because the branch cycles, you need to specify when the cycle should start again. Below the Survival Follow Up visit click **Add**.
- **7.** Fill in the fields in the top section:
 - **Scheduled From**: By default, the system displays the last visit in the cycle, in this case, Survival Follow Up.
 - Days: Enter 56.
 - Hours is always grayed out.
- **8.** Fill in the fields in the **Visit Window** sections and click **Save**:
 - **Before Days**: Specify 3. This is the number of days before the scheduled date and time that the visit can occur.
 - After days: Specify 3. This is the number of days after the scheduled date and time that the visit can occur.
 - **Hours** is always grayed out.

Read the detailed instructions

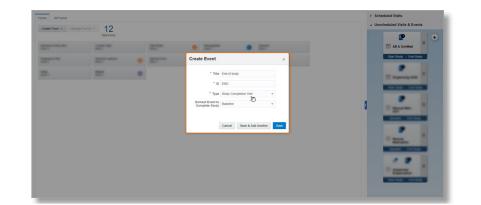




Complete the study

11 Create the Study Completion Visit

- 1. Bellow the Follow Up branch, click **Unscheduled Visit & Events**.
- 2. In the upper right of the **Unscheduled Visit & Events** section, click the **+** sign.
- **3.** Fill in the fields in the **Create Event** dialog:
 - **Title:** Enter End of Study.
 - ID: Enter END.



- Type: Select Study Completion Visit.
 Earliest Event to Complete Study: Select Baseline.
- 4. Click Save.

Read the detailed instructions

Note: After all visits are created, you can start adding forms to your visits and define kits and dispensation. For more details see Create a form, Add a form to a visit, and Define kits for investigational products.



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