Forte EDC Developer Overview
Protocol Setup

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Create a Protocol

The Protocols menu lists all of the protocols to which you have access and allows you to create new protocols locally in the application or import them from OnCore via the Import Protocol functionality. Click the **Protocol Number** link to open the Summary page for an existing protocol.

**Protocols Menu**

<table>
<thead>
<tr>
<th>Protocol Number</th>
<th>NCT Number</th>
<th>Protocol Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAR1086</td>
<td>NCT00363095</td>
<td>Rajavithi Health Promotion Project (Population Base Cohort)</td>
</tr>
<tr>
<td>CAR1087</td>
<td>NCT00121550</td>
<td>The CLARICOR Trial: Effect of Clarithromycin on Mortality and Morbidity in Patients With Ischemic Heart Disease</td>
</tr>
<tr>
<td>CAR1088</td>
<td>NCT01405091</td>
<td>Markers of Coronary Artery Disease During Exercise Testing - R</td>
</tr>
<tr>
<td>CAR1089</td>
<td>NCT01520311</td>
<td>The eSVS77 Mesh Post-Marketing Trial</td>
</tr>
</tbody>
</table>

The Summary page displays basic information about the protocol. Navigate to each section using the links in the left pane or make changes directly from the Summary page.
Protocol Summary

On the Summary page, you will see:

- The Protocol Details: Protocol Number and Title, as well as two protocol-specific settings:
  - Allow Recalculation of Planned Visit Dates
  - Auto-Generate Subject Number
- Study Sites
- Protocol Users
- Protocol Calendar Versions
- Subjects enrolled at your Study Sites
• Protocol Documents, which are documents that need to be shared with all sites working on the protocol.

From the Summary page, you can:

• Select study sites
• Create the protocol calendar
• Add new subjects to the protocol in the Development environment
• Add new protocol documents (either a document or a URL) or updated versions of these documents

Create a New Protocol – Import from OnCore

1. From the Protocols Menu, click Import Protocol.

2. In the Import Protocol window:
   • Enter the Protocol or NCT Number for the protocol that you want to import from the linked OnCore environment.
   • Select the protocol you want to import.
   • Decide whether you want to allow the recalculation of planned visit dates by selecting Yes or No. When this field is set to Yes, data entry personnel can recalculate planned dates for the current calendar segment or for all visits going forward. The value for this setting can be changed until a calendar is deployed to production.
   • **Auto-Generate Subject Number** will be automatically set to No for linked protocols. This is because the Forte EDC Subject Number and the OnCore Subject Sequence Number need to be the same in order to preserve the subject link between Forte EDC and OnCore.

3. Click Save.

When you import the protocol, the protocol’s study site information is also imported.

When you import a protocol via Hub integration:

• If there isn’t already a protocol in Forte EDC, the protocol study site records for that protocol are created in Forte EDC.
• If there is a protocol already in Forte EDC with that protocol number, the system identifies the protocol study site records on that protocol in Hub, compares them to what exists in Forte EDC, and then acts based on the results. If the protocol study site already is included on the Forte EDC protocol, the system links the
record to the one in Hub. If it is not in use on the protocol, the protocol study site record is created. If there are calendar versions deployed to Production, subjects for that study site are imported as well.

**Add Protocol Users**

You can add protocol users from the Summary page or Protocol Users page within the protocol. Here, you can add the staff member’s start and stop date, effectively determining when they should have access to this study. You must also include the study sites that the individual has access to on this study. Finally, you can enter the staff’s protocol roles, which are the permissions and access that the staff member has for this particular study.

By selecting **Add Protocol Users**, you can add additional staff to the study.

*Protocol Summary > Protocol Users*

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Study Sites</th>
<th>Protocol Roles</th>
<th>Start Date</th>
<th>Stop Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ajay</td>
<td>Indrajit</td>
<td>Great Hospital, Outstanding Research Organization</td>
<td>CRA, Data Manager, Principal Investigator and 4 more</td>
<td>01 Jan 2014</td>
<td></td>
</tr>
<tr>
<td>Angela</td>
<td>Dooley</td>
<td>Great Hospital</td>
<td>CRA, Data Manager, Principal Investigator and 3 more</td>
<td>30 May 2013</td>
<td></td>
</tr>
</tbody>
</table>

1. On the Summary page, in the Protocol Users table, select your user’s name (first or last is fine)
2. In the Study Site search field, add the appropriate study sites.
3. In the Protocol User Roles search field, add the relevant role and select **Add Protocol Role**.
Create the Protocol Calendar

The Calendar Versions page is where the bulk of the setup work is done for a protocol. The protocol calendar is built once and then deployed to one of three environments where subjects can be added.
Here’s an overview of the sections of the protocol and what actions you take in them:

A. Enter a description to help users differentiate between calendar versions.
B. Determine whether timepoint tolerances should be evaluated for this protocol.
C. Deploy the calendar for use with subjects.
D. Select forms, designate forms that can be used as additional forms or ongoing forms, and add usage-specific constraints.
E. Define visits/timepoints and associate forms.
F. Create additional segments if needed.
G. Define the source field for any cross-form variables.
H. Preview the calendar and make it available to specific study sites.

When you create a new protocol, Version 1 of the calendar is automatically created for you. If changes need to be made later in the study, you can create a new version of the calendar.
**Timepoint Tolerances**

Each calendar version can be configured to use timepoint tolerances to compare dates and times of assessments, such as a PK blood sampling, to an anchor, such as Study Drug Administration, that has been defined for the calendar version. This is used to enforce the approved schedule of treatment administration and subsequent assessments per the protocol document.

When configured, Forte EDC will check the assessment date and time on the form against the tolerances when the form is saved. If either form is In Progress, a warning is displayed on the assessment date and time. If both forms have a status of at least Data Entry Complete, a query is automatically generated.

In order for timepoint tolerances to be evaluated, you must configure the protocol as follows:

- **Evaluate Timepoint Tolerances** must be set to Yes.
- One or more forms for the protocol must have a timepoint tolerance constraint.
- A ‘0 Hour’ timepoint must exist within the calendar.
- Tolerances (+/- Minutes/Hours/%) must be defined at the timepoint (default) or form (override) level.
- An Anchor must be defined in the Variable Mappings table.

For practice setting up timepoint tolerances, see the example protocol calendar at the end of the manual.

In your Version 1 calendar, one segment is automatically created for you. A segment is a collection of visits that apply to a group of subjects. If it makes sense for your protocol, you can create additional segments. The auto-created segment, called Primary, is automatically added to all subjects for the protocol.

There are six basic steps to creating a calendar in Forte EDC:
1. Select the forms to be used on the protocol and add any usage-specific constraints.
2. Define visits and timepoints within the Primary segment.
3. Create additional segments if necessary based on the protocol study schedule.
4. Associate forms with visits and timepoints within each segment.
5. Complete Variable Mappings for any cross-form or timepoint tolerance constraints.
6. Deploy the calendar.

Building a Calendar, Step 1: Select Forms for the Protocol

1. Click the Version 1 link to open the Calendar Summary page.
2. In the Forms section, click the Add/Remove Forms link.
3. Click Add in the list of Available Forms to move each relevant form to the list of Selected Forms.
4. Click the Remove button to remove forms from the list of Selected Forms if necessary.
5. Click Save to save your selections and return to the Calendar Summary page.

Add/Remove Forms
What if I don’t see the form I am looking for?

The list of Available Forms includes all form templates with a status of Released. Check the status of the form template in Forms > Forms Designer if you don’t see what you’re looking for.

How can I confirm that I have selected the correct forms?

On the Calendar Summary page, use the Name links in the Forms section to preview each form. You can add protocol-specific constraints here as well.
Designating Forms as Ongoing or Additional

After you’ve selected the forms you want to use for the calendar version, you can also choose how forms are used in the Forms section:

- **Ongoing forms** are forms that are not usually associated with a visit, but they are instead used to collect a running log of data throughout a study (such as an Adverse Event form). By default, the Ongoing Form field is set to No for forms (unless the form has already been set up as an ongoing form based on a conditional form constraint). There are some situations in which you can’t designate a form as ongoing:
  o If the form is already scheduled on a calendar segment.
  o If the form is already conditionally associated with a calendar segment due to a conditional form constraint.
  o If the form is listed as an additional form, it can’t be both an ongoing and an additional form.
  o If a form can’t be designated as ongoing, you’ll see text that says "Scheduled" or "Conditional" below the Yes and No buttons in the Ongoing Forms column.

- **Additional forms** are forms that can be added to subject visits. You must specify which forms are available to add in the Allow Additional Form column. Only the forms where Allow Additional Form is set to Yes appear in the list of forms in the Add a Form field in the subject visit. When you add a new form to a calendar version, Allow Additional Form is set to No by default.
Can I change the order of the forms in the calendar?

Yes! On the Calendar Summary page, click **Edit** in the Forms section and reorder the forms by dragging and dropping the rows. Click **Save** to preserve this order in the Calendar Preview and Subject Calendar.

Can I add constraints at the protocol level?

Yes! On the Calendar Summary page, click the name of the form to which you need to add a constraint. (If you don’t see your form, click the **Forms** link in the left navigation pane.) Click the Constraints tab, and then click **Add Constraint** and add the necessary logic. Constraints added here are enforced only on the selected protocol. Use the Preview tab to test your constraints.

Add Usage Specific Constraints

We can include constraints to enforce protocol-specific logic within the forms. We will create a conditional form constraint, a cross-form validation constraint, and a timepoint tolerance constraint.

1. Click the form’s name in the Forms table to create a conditional form constraint.
   - On the Constraints tab, click **Add Constraint**.
   - In the Create Constraint window, select a **Constraint Type** of Conditional Form.
   - In the **Label** field, type your constraint, for example: “If Female, add Pregnancy Test.”
• In the **Expression** field, select your variables to create your expression. For example: select “Sex” and “Female” as your variables so that the expression reads **Sex = Female**.

• In the **Forms** field, choose the form you wish to add. For example, choose Pregnancy Test (you will have needed to associate this form with the calendar beforehand).

• In the **Visits / Timepoints** field, choose the visit or timepoint to which this constraint should apply.

• Click **Create**.

2. Create a cross-form validation constraint on a selected form.

   • On the Constraints tab, click **Add Constraint**.

   • In the Create Constraint window, select a **Constraint Type** of Validation.

   • In the **Label** field, type a description of the constraint. If you’re using the Adverse Events_Severity Scale form, an example of this would be: Onset Date must be > ICF Date and < Study Completion Date.

   • In the **Expression** field, use CTRL+SPACE to select your variables. In the AE form example, this would be: (AESTDT < Informed Consent) or (AESTDT > Study Complete).

   • In the **Targets** field, choose the variable that determines whether or not the user’s entry is valid. In this example, that variable would be AESTDT.

   • In the **Error Message** field, type a message that will show up for the user if they enter something that is not valid. For example, “Start Date and Time must be greater than Informed Consent and less than Study Completion. Please reconcile.”

   • In the **Enforcement Action** field, choose Query.

3. A timepoint tolerance constraint example follows, using the Vital Signs_Single Assessment form:

   • Click the **Vital Signs** link in the Forms navigation pane to create a timepoint tolerance constraint to ensure that vital signs assessments are performed within the protocol-specified window (timepoint tolerances must be set to yes for the protocol in question for this to work).

   • On the Constraints tab, click **Add Constraint**.
• In the Create Constraint window, select a **Constraint Type** of Timepoint Tolerance.

• In the **Label** field, type VSDatTime.

• In the **Targets** field, choose VSDatTim.

• In the **Error Message** field, type “Date and Time of Vital Signs is outside the protocol-specified tolerance. Please reconcile.”

• Click **Create**.

### Building a Calendar, Step 2: Define Visits and Timepoints for the Primary Segment

1. In the Segments section, click the **Primary** link.
   - The Screening visit is created by default, and you can edit the name if necessary by clicking the visit name.

2. Click the **New Visit** button to bring up the Visit Details window.

3. Enter the name of the visit (i.e. Baseline) in the **Name** field and specify the tolerance.

4. Click **Save** to create the visit and return to the Segment Summary page.

5. Click the **Timepoints** button for any visit requiring the use of timepoints. Click **Add** after each timepoint entered.

6. Click **Save** to return to the Segment Summary page.
Specifying Visit Tolerances

Creating Timepoints
Does my calendar need to include timepoints?

Not necessarily. Timepoints offer an additional level of organization within the subject’s calendar, which can be useful if an assessment is performed multiple times during a specific visit. If assessments are performed only once per visit, you do not need to add timepoints. The timepoint is also included in Data Export, which allows you to use the same form multiple times without the need for a Timepoint field in the form.

Building a Calendar, Step 3: Create Additional Segments

1. In the Segments section of the Calendar Summary page, click Add.
2. Enter Follow Up in the Name field.
3. Set Repetitions to Recurring if relevant.
4. Use the Repetitions field to indicate whether the visits in this segment can happen only once (Non-recurring), as many times as needed (Open Ended), or a predefined number of times (Recurring).
5. In the Follows Segments field, enter the name of the segment that this new segment should follow (i.e. Primary). The Follows Segments field allows you to select the segments after which this segment can be added to the subject calendar by the Protocol Coordinator.
6. Click Create to open the Segment Summary page.
7. Click New Visit to bring up the Visit Details window. Enter Follow Up in the Name field and specify the visit tolerance. This tolerance applies when following the Primary segment.
8. Click Save to create the visit and return to the Segment Summary page.
9. Click Save to return to the Segment Summary page.
Create New Segment

Create New Segment

Name • Follow-up
Repetitions • Non-recurring Open Ended Recurring
Number of Repetitions • 4
Follows Segments • Primary

Does my calendar need additional segments?

Generally speaking, additional segments are created when visits apply only to a subset of subjects on the protocol. Even in this scenario, it is possible to create all visits within a single segment, but that means the Protocol Coordinator will need to mark some visits as Not Applicable. If multiple segments are created, the Protocol Coordinator can add them to each subject’s calendar as needed.

Building a Calendar, Step 4: Associate Forms with Visits and Timepoints

1. Click the Edit button above the Form Associations grid for the primary segment.
2. Select the appropriate checkboxes based on the protocol study schedule. Timepoint anchors are indicated by a clock icon. Because ongoing forms aren’t scheduled, they appear in a list at the bottom of the section.
3. Click Save to return to read-only mode.
4. Repeat this process to associate forms with the visits and timepoints in any additional segments
# Form Associations

<table>
<thead>
<tr>
<th>Ongoing Forms</th>
<th>Screening</th>
<th>Baseline&lt;sup&gt;A&lt;/sup&gt;</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 14 +/-3</th>
<th>Follow-up&lt;sup&gt;C&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eligibility</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographics</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine Pregnancy Test&lt;sup&gt;D&lt;/sup&gt;</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical History</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vital Signs&lt;sup&gt;G&lt;/sup&gt;</td>
<td>X</td>
<td>X</td>
<td>X&lt;sup&gt;B&lt;/sup&gt;</td>
<td>X&lt;sup&gt;B&lt;/sup&gt;</td>
<td>X&lt;sup&gt;B&lt;/sup&gt;</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Body Measurements</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Exam</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety Laboratory Tests&lt;sup&gt;G&lt;/sup&gt;</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Oral Dose Administration</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X&lt;sup&gt;E&lt;/sup&gt;</td>
</tr>
<tr>
<td>PK Blood Sampling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X&lt;sup&gt;F&lt;/sup&gt;</td>
</tr>
<tr>
<td>Adverse Events</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study Completion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

<sup>A</sup> – Within 28 Days after Screening.
<sup>B</sup> – Vital Signs must be performed Predose and at 4, 12, 24, and 48 Hours Postdose with a tolerance of +/- 5 minutes.
<sup>C</sup> – Every 3 months for 1 year beginning 3 months +/- 3 days after Day 14.
<sup>D</sup> – Females only.
<sup>E</sup> – Oral Dose Administration should be performed at Dosing Hour.
<sup>F</sup> – PK Blood Sampling must be performed Predose and at 4, 12, 24, and 48 Hours Postdose with a tolerance of +/- 2 minutes.
<sup>G</sup> – Repeat as clinically indicated.
Can I add forms to the calendar that are not associated with a visit or timepoint?

Yes! You can designate a form as an ongoing form (so that it is always available for data entry throughout the study) or as an additional form (so that it can be added for a particular subject visit).
Need to add forms based on data entered for the subject?

You can use a Conditional Form constraint to add one or more forms to one or more visits based on data entered for the subject. For example, you can add a Pregnancy Test form to Screening and Baseline when the Gender is equal to Female on the Demographics form.

Forms added from Conditional Form constraints are represented by a “C” instead of a check mark in the Form Associations grid.

Note that you can use ongoing forms in conditional form constraints by selecting the Ongoing Forms option. When you set up the constraint, the Forms field can’t include forms that are scheduled in a visit or timepoint, ongoing, allowed as additional forms, or already used in another conditional form constraint.
Building a Calendar, Step 5: Map Variables

This step applies to calendars that include forms with cross-form validation constraints and/or timepoint tolerance constraints. When these types of constraints are included, you must map any Protocol Variables (Informed Consent, Study Complete, First Dose, Date of Birth, Gender) and define the Timepoint Anchor. Forte EDC automatically detects the use of Protocol Variables and Timepoint Anchors, and the Variable Mappings table is updated as appropriate.

1. Click the Edit button above the Variable Mappings grid.
2. Select the Visit or Timepoint, Form, and Field for each Protocol Variable. The Timepoint Anchor must be mapped to a DateTime field.
3. Click Save to return to read-only mode.

Note that you can use ongoing forms in variable mappings by selecting the Ongoing Forms option in the Visit or Timepoint field. After you select that option, you can choose an ongoing form (as long as the variable is not a timepoint anchor).

Variable Mappings
Building a Calendar, Step 6: Preview the Protocol Calendar

You can use the calendar Preview feature to review the setup before deploying the calendar. In the preview:

- If you include ongoing forms, they appear in their own column.
- Conditional forms appear with a “C” instead of an “X” in the cell.
- Forms that can be included as additional forms have a superscript “A” next to their name.

**Protocol Summary > Calendar Versions**

1. In the Calendar Versions table, click **Preview** for the appropriate version.
2. Select the appropriate segments using the checkboxes at the top.
3. Select the **Show Tolerance Details** checkbox to include visit tolerances.
4. Click **Export** to generate an Excel export of the protocol calendar.
Building a Calendar, Step 7: Deploy the Protocol Calendar and Associate Sites

After the forms and segments are defined for the protocol, the calendar can be deployed for testing. Forte EDC allows calendars to be deployed to three environments:

- **Development** - Intended for use by the Developer for initial testing.
- **Test** - Intended for use by the Data Manager, CRA, Protocol Coordinator, and/or Principal Investigator for more formal testing.
- **Production** - Intended for use by the clinical sites to capture all production subject data.

After the calendar is deployed to an environment, it can be applied to subjects in that environment. Keep in mind that all of the setup work for a protocol is done only once. The only difference between environments in Forte EDC is subjects.
1. Click **Deploy** for the Development row in the Deployments table.
2. Complete the necessary testing with a subject in Development.
3. If no changes are required, click **Deploy** for Test and/or Production.
4. If changes are required, click **Demote** to enable edits to the segments and visits.
5. Repeat this process until you're ready to deploy the calendar in Production.
6. Click the **Site Associations** link in the left pane and select the checkboxes for each study site for which the calendar version should be available.
All study sites are automatically associated with calendar versions deployed to Development and Test. When deploying the calendar to Production, you must select the study sites for which the calendar version should be available. The study site association can happen before or after the calendar is deployed, but at least one study site must be associated prior to adding subjects to the protocol.

**Site Associations > Calendar Versions section**

<table>
<thead>
<tr>
<th>Study Site</th>
<th>V1</th>
<th>V2</th>
<th>V3</th>
<th>V4</th>
<th>V5</th>
<th>V6</th>
<th>V7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Great Hospital</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>Madison Clinic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outstanding Research Organization</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
</tr>
</tbody>
</table>

**Can I make changes to the protocol calendar after it has been deployed?**

After the calendar has been deployed to an environment, the forms and segments can’t be edited. If changes are necessary, the calendar can be demoted unless:

- Production data has been recorded. If Production data has been recorded, a new version of the calendar must be created.
- A more recent version of the calendar exists.
To demote the calendar and enable edits to the segments and visits, click **Demote** in the Deployments table. All subjects and associated subject data are deleted when the calendar is demoted.

**Can subject data be restored if I demote the calendar?**

No. Demoting a calendar deletes all subject data in the selected environment, and this action can’t be undone.

---

**Need to switch environments?**

You can move between the Development, Test, and Production environments using the toggle in the top menu. Remember that the only difference between environments is **subjects**. If you don’t see the subject you are looking for, make sure you have selected the correct environment.
Create a New Version of the Protocol Calendar

After Production data has been recorded, you must create a new version of the Protocol Calendar to make changes to the segments, visits, and forms.

If a new version of a form has been created, you can create a new calendar version and upgrade to the new form version. On the Calendar Summary page, click the name of the form you need to upgrade. (If you don’t see your form, click the Forms link in the left navigation pane.) From the Preview tab, select the appropriate version and click Upgrade to Version to move to the new version of the form.

1. Click New Version in the Calendar Versions section.
2. Enter a Description in Calendar Details to indicate what is different in this version of the calendar.
3. Make the necessary changes to the segments, visits, and forms.
4. Click Deploy for Development in the Deployments table.
5. Complete the necessary testing with a subject in Development.
6. If no changes are required, click Deploy for Test and/or Production.
7. If changes are required, click Demote to enable edits to the segments and visits.
8. Repeat this process until you’re ready to deploy the new version of the calendar in Production.

Can I apply the changes in the new version of the calendar to existing subjects?

If existing subjects need to be moved to the new version of the calendar, you can use the Migrate Subjects link in the Calendar Versions table. See the following image.
To add a subject from the Available Subjects list to the Selected Subjects list, click the **Add** button. To remove a subject from the Selected Subjects list and return it to the Available Subjects list, click the **Remove** button. Once the appropriate subjects have been selected, click **Save** to migrate the subjects to the new calendar version or **Cancel** to return to the Protocol Summary page without performing the migration.

The list of Available Subjects is limited to subjects on a previous version of the calendar in the selected environment. When a subject can't be migrated, the [Add] button is inactive; if you hover your mouse over the button, you'll see a message indicating what's preventing the migration.
## When can subjects be migrated?

<table>
<thead>
<tr>
<th>Subject Details</th>
<th>Can Be Migrated</th>
<th>Additional Migration Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects on a previous version of the calendar in the selected environment.</td>
<td>Yes</td>
<td>This migration can occur even if the forms do not have the Allow Additional Forms field set to Yes on the new calendar version. After the subject is migrated, all previous additional forms remain. Any new additional forms available are based on the current calendar's specified additional forms.</td>
</tr>
<tr>
<td>Subjects with an additional form on their current calendar version that IS associated with the new calendar version.</td>
<td>Yes</td>
<td>In order to migrate the subjects to the new calendar version, one of the following actions must be taken: · The additional form must be included with the calendar version (even if it isn't associated with any visits). · The form must be deleted from the subject's current calendar visit.</td>
</tr>
<tr>
<td>Subjects with an additional form on their current calendar version that IS NOT associated with the new calendar version.</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Subjects with an ongoing form with data entered on their current calendar version that IS also associated as an ongoing form with the new calendar version.</td>
<td>Yes</td>
<td>The ongoing form is removed during subject migration and its data is audited. The form is present as a scheduled or additional form in the new calendar version, but no data is populated on it based on values from the previous ongoing version of the form.</td>
</tr>
<tr>
<td>Subjects with an ongoing form with data entered on their current calendar version that IS associated with the new calendar version, BUT the form is scheduled or additional on the new calendar version (not ongoing).</td>
<td>Yes</td>
<td>The ongoing form is removed during subject migration and its data is audited. The form is not accessible after the migration.</td>
</tr>
<tr>
<td>Subjects with an ongoing form with data entered on their current calendar version that IS associated with the new calendar version, BUT the form is NOT scheduled or designated as an additional form.</td>
<td>Yes</td>
<td>The ongoing form is removed during subject migration and its data is audited.</td>
</tr>
<tr>
<td>Subjects with an ongoing form with data entered on their current calendar version that IS NOT associated with the new calendar version.</td>
<td>Yes</td>
<td>The ongoing form is removed during subject migration and its data is audited.</td>
</tr>
<tr>
<td>Subjects with a visit form with data entered on their current calendar version, and that form is designated as an ongoing form in the new calendar version.</td>
<td>Yes</td>
<td>The visit form is no longer present in the new calendar version and its data is audited. The ongoing form is available but not populated based on values from the previous visit version of the form.</td>
</tr>
<tr>
<td>Subjects with open or responded queries.</td>
<td>No</td>
<td>All queries must first be closed before the subjects can be migrated.</td>
</tr>
<tr>
<td>Subjects with visits and/or forms in the Locked, Approved, or Frozen Status.</td>
<td>No</td>
<td>The appropriate users must undo the Frozen/Approved/Locked statuses before the subjects can be migrated.</td>
</tr>
</tbody>
</table>