

Rave 5.6.3 Gap Training for Study Builders

Leader Guide to Participant Guide 1.1 [10 Dec 09]



ACKNOWLEDGMENTS

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Version	1.1
Document Date	10 Dec 09
Amendment History	

Cover Photo Patient Profiles (left to right)

Ben, Pulmozyme® Patient

At birth Ben weighed in at over nine pounds and, by all accounts, seemed to be a healthy baby. At six months old and after two hospitalizations for pneumonia, Ben was diagnosed with cystic fibrosis (CF). At 18 months old Ben had a two-week hospital stay for CF, and at the age of two Ben started Pulmozyme therapy as part of his treatment regimen. Now 13, Ben is a lively seventh-grader with a voracious appetite for life. He has a passion for math, movies, computer games and wizard stories. An avid snowboarder and surfer, Ben is also a right defender and right mid-fielder on his competitive soccer team. Ben's family reports that his daily treatment regimen is under an hour and, with the assistance of Pulmozyme therapy, Ben enjoys the life of an active teenage boy.

Samantha and Alison, Nutropin® Patients

Nutropin is indicated for growth hormone deficiency in children and adults, growth failure associated with chronic renal insufficiency, and short stature associated with Turner Syndrome.

Jane, Rituxan® Patient

Six years ago, in 1998, Jane discovered a lump on her collarbone. Thinking it was some type of muscular inflammation, she went to the doctor to have it examined. The doctors performed a biopsy on the lump and discovered that she had non-Hodgkin's lymphoma. After telling her family that she had non-Hodgkin's lymphoma, her daughter, who had just started working at Genentech, mentioned that her company had recently launched a new drug for non-Hodgkin's lymphoma, Rituxan. Jane started taking Rituxan and soon discovered that her tumor was shrinking. After a year, she was in remission and went off of Rituxan. Jane credits her daughter's new job at Genentech for helping her find the drug that helped treat her disease.

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CLASS PREPARATION

At least three weeks prior to the day of the class, reserve a training facility with:

- › Instructor's computer that is connected to an overhead projector
- › Internet access from all attendees' computers

Prior to the day of the class, obtain a sufficient number of copies of the training materials (described below).

On the day of the class, you need the following:

- › Dry erase agenda poster and pen
- › Participant name placards
- › *Rave 5.6.3 Gap Training for Study Builders Instructor Guide*
- › *Rave 5.6.3 Gap Training for Study Builders Participant Guides*
- › Rave 5.6.3 Gap Training for Study Builders - PowerPoint Presentation
- › Rave 5.6.3 Gap Training for Study Builders - Handouts (Mock eCRFs, SLACs, and Visit Form Matrix for the training sample study; Publish in Place list)

On the day of the class, you will need to complete the following tasks:

- › Assign each attendee a unique training user number that correlates with the user accounts that they will use to log into Rave. Assign yourself a blank subject (to demo submitting data), and assign all learners a blank subject in a specific site.
- › From the leader's machine:
 - › Open the PowerPoint presentation. On the title page, specify your leader name, role, and the class date. Verify that the title page is displayed overhead.
 - › Confirm that you can view the Rave login screen by entering the training URL (<https://gentrn563.mds01.com>) into the browser address window.
 - › Confirm that you can log into Rave with each of the user accounts (CASA role only) that you will be using during the training.
 - › Verify that the data in the training sample study are correct (refreshed).
- › From each learner's machine:
 - › Confirm that you can view the Rave login screen by entering the training URL (<https://gentrn563.mds01.com>) into the browser address window.
 - › Confirm that you can log into Rave with the user account (CASA role) that the attendee will be using during the training.

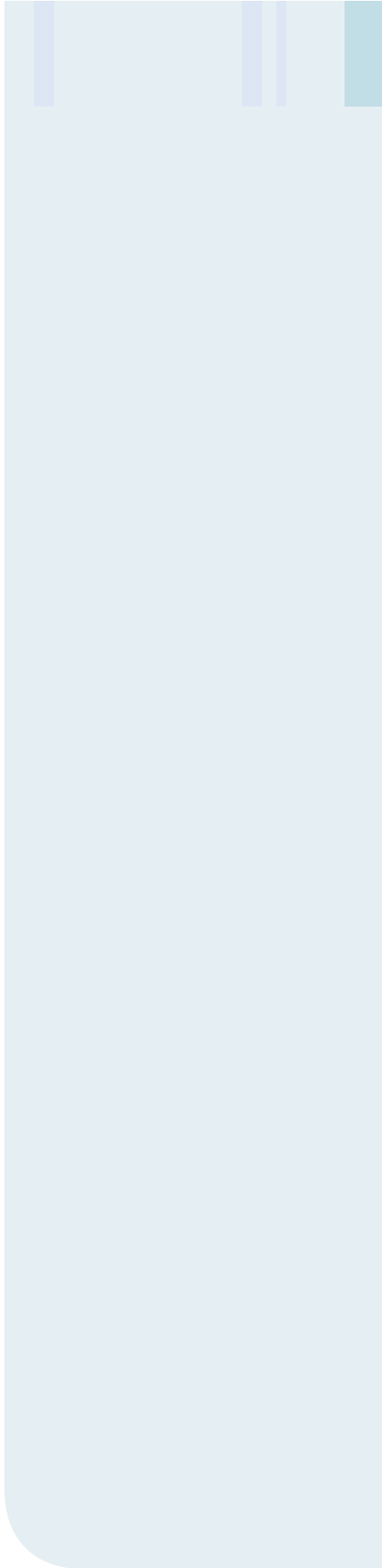
After the class, send out an electronic survey to all participants.

Timing Estimates

Estimated duration for attendees:
about 4-5 hours (4.25 hours + breaks).

The following timeline provides an approximation of the time needed to complete each lesson. Individual classes may vary based on the size of the group, time to answer questions and provide extra assistance, length of breaks, and other factors.

- › Start the class [8 mins]
- 1. Introduction [10 mins]
- 2. Log Lines [20 mins]
- 3. Navigation and Radio Buttons [10 mins]
- 4. PDF Generator [15 mins]
- 5. Edit Checks
 - > Lecture [30 mins]
 - > Timepoint Demo [10 mins]
 - > Exercises [100 mins (25 mins ea)]
- 6. Amendment Manager and Study Migration [12 mins]
- 7. Architect Loader [5 mins]
- 8. Publish in Place [30 mins]
- › Conclusion and Wrap Up [5 mins]



RAVE 5.6.3 GAP TRAINING FOR STUDY BUILDERS

Lessons in this training include:

- › [Introduction \(see page 2\)](#)
- › [Log Lines \(see page 5\)](#)
- › [Navigation and Radio Buttons \(see page 7\)](#)
- › [PDF Generator \(see page 11\)](#)
- › [Edit Checks and Derivations \(see page 13\)](#)
- › [Amendment Manager and Study Migration \(see page 23\)](#)
- › [Architect Loader \(see page 30\)](#)
- › [Publish in Place \(see page 32\)](#)
- › [Conclusion \(see page 36\)](#)



LESSON 1

INTRODUCTION

This lesson introduces Medidata Rave. It covers the following topics:

- › [Purpose of this Training \(see page 2\)](#)
- › [Changes in Medidata Rave v5.6.3 \(see page 3\)](#)
- › [What You Will Learn in the Rave 5.6.3 Gap Training for Study Builders \(see page 3\)](#)
- › [Sample Study Used in this Training \(see page 4\)](#)
- › [Training Prerequisites \(see page 4\)](#)
- › [Rave 5.6.3 Resources \(see page 4\)](#)

Purpose of this Training

The goal of the Rave 5.6.3 Gap Training for Study Builders is to provide gap training on new features for Study Builders who have already been trained on Rave 5.6.1.

The objective is to provide Study Builders with business process and EDC training relative to the new and changed features of the Rave software (Architect and other Rave modules related to study building) to enable Study Builders to use these features successfully in their contributions to the CDM organization.

This gap training will be scheduled to occur around the Rave 5.6.3 Go-Live. This is designed to be a one-time training event rather than a recurring, ongoing training course.

Changes in Medidata Rave v5.6.3

Rave 5.6.3 represents an upgrade from Rave 5.6.1. The Rave 5.6.3 environment offers new and changed functionality that will affect how studies are built for Genentech-sponsored clinical trials. The following list summarizes changes in Rave 5.6.3 that pertain to study builders:

- › Reactivation of log lines and setting restrictions using the default value delimiter
- › New Architect navigation features such as copy preview and Go Back links
- › New vertical radio buttons and radio buttons that EDC users can deselect
- › New Publish in Place functionality, including the ability to overwrite, restore, and lock a CRF version
- › New configuration settings in PDF Generator
- › Enhancements such as the new Quick Edit editor, new check functions, and other changes that affect both edit checks and derivations
- › New Amendment Manage Scheduler used in study migration
- › New Subset download functionality in Architect Loader

What You Will Learn in the Rave 5.6.3 Gap Training for Study Builders

This training covers the following topics:

- › log line changes
- › Architect navigation changes
- › radio button changes
- › Publish in Place (new)
- › PDF Generator changes
- › Edit check and derivation changes
- › Amendment Manager Scheduler (new)
- › Architect Loader changes

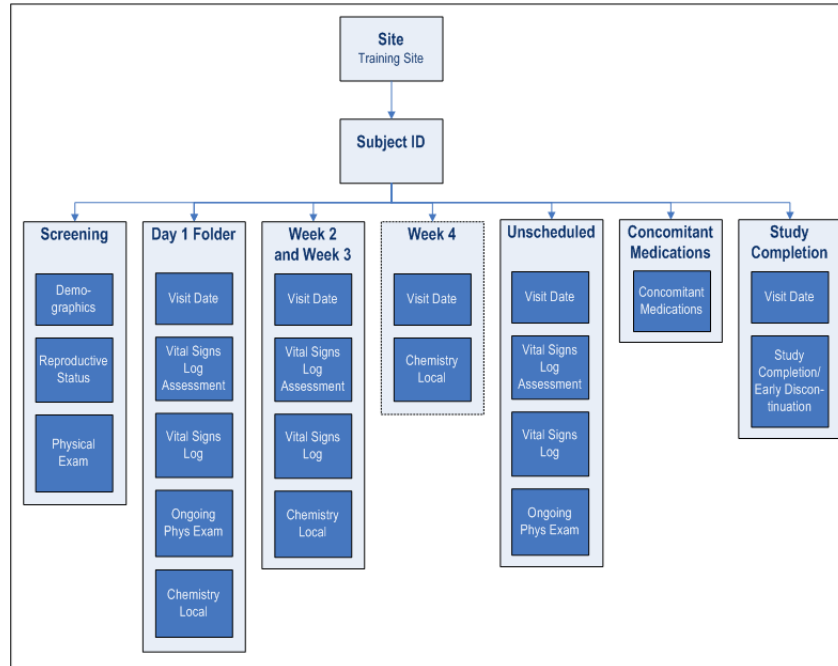
In-class Discussions

During the course of this training, certain topics might trigger in-class discussions about how best to use certain Rave features, business process implications, and so on.

It is up to the leader's discretion to decide whether to use class time to pursue the conversation, or to defer the topic to a post-training discussion.

Sample Study Used in this Training

This training uses a sample project that consists of the following folders and eCRFs (the Week 4 folder will be added during an exercise later in this class):



Training Prerequisites

This training requires prior completion of the following training:

- › Must be a functioning Study Builder (CASA role)
- › Should have attended a Medidata sponsored Architect training course on Rave v5.6.1 or higher

Rave 5.6.3 Resources

Information about Rave 5.6.3 is published on Livelink. Livelink is being reorganized, but as of 12/1/09, this information was located in the following path:

Genentech Livelink > Departments > Genentech Informatics > CIT Product Development IT > Projects > Rave > Rave-EDC > Docs > Rave 5.6.3

Among these documents are two important resources for Rave 5.6.3 Study Builders:

- › Medidata *Rave 5.6.3 Release Notes*
- › Medidata's Cumulative Rave 5.6.3 *Known Issues* list

LESSON 2

LOG LINES

This lesson discusses changes to log lines in Rave 5.6.3. It covers the following topics:

- › [Reactivation of Log Lines \(see page 5\)](#)
- › [Default Value Delimiters for Log Fields \(see page 5\)](#)

Reactivation of Log Lines

In Rave 5.6.3, EDC users who have sufficient privileges to inactivate a log line will now have the ability to reactivate it. When a log line is reactivated, all relevant edit checks (including any custom functions associated with those edit checks) will be run automatically.

This feature is automatic (cannot be turned off) once the environment is upgraded to Rave 5.6.3. For log lines that were inactivated in the previous environment, the Reactivate link will be displayed automatically.

Default Value Delimiters for Log Fields

This section describes how to configure default value delimiters for log fields.

About Default Value Delimiters

For log fields, you can use a *default repeat* to create a log form with multiple records, with each record containing a different default value. To do this, you specify a set of delimiter-separated values in the Default Value Attribute of the field. The delimiter character is a pipe (|).

Restricting Log Lines by Appending a Delimiter

With Rave 5.6.3, for default repeat log forms, you must restrict the number of log lines by adding a pipe delimiter as the terminating character in the list of default values. For example, if you have the following list of default values:

```
1|2|3|4|5
```

You add a terminating delimiter character:

```
1|2|3|4|5|
```

Doing this has the following implications for EDC users:

- › EDC users cannot add new log lines to a default repeat form.
- › EDC users cannot inactivate or reactivate log lines in a default repeat form.

Leader Note

Demonstrate the inactivation and reactivation of a log line. Show the results in the Audit Trail after each operation.

Leader Note

Briefly mention that, if ever there were a need for a study, we could write edit check code that conditionally executed or skipped actions if the edit check was fired due to a reactivation event (as opposed to an edit).

Study Builder Conventions

Beginning with Rave 5.6.3, adding a terminating delimiter character is now *required* for all default repeat log forms. All new studies will be configured in this way.

Rave 5.6.1 Studies with Default Repeat Log Forms

For existing studies running in the Rave 5.6.1 environment, if a default repeat log form was configured with a terminating delimiter character, the character was ignored.

When the study is migrated to Rave 5.6.3:

- › the terminating character will be stripped out automatically during the upgrade process
- › existing default repeat log forms will behave exactly as they did in the Rave 5.6.1 environment (that is, without restrictions)
- › any inactivated log lines will remain inactivated

A user with the appropriate role will be able to reactivate inactivated log lines manually.



IMPORTANT! In general, this change will not be retroactively implemented in existing studies. However, if you want to retroactively add the log line restrictions to existing studies with default repeat log forms, you must submit an EDC Amendment and Study Migration form. Requests will be assessed on a study-by-study basis. If the request is approved, then you will need to manually add the terminating delimiter to the list of default values to enable the log line restrictions.

Hands-on Exercise

1. Log onto Rave using your assigned login credentials. Here is the training URL:
<https://gentrn563.mdso1.com/>
2. Navigate to the draft of your training study.
3. For the Vital Signs Log form, observe the configuration of the defaulted values for the TMPTC field.
4. Publish and push the existing version.
5. Navigate to the EDC module and create a subject in your study.
6. Using the Visit Form Matrix, enter data to add the Vital Signs Log form at the visit of your choice. Enter data and observe the behavior of the defaulted log field.
7. Return to Architect and, in the TMPTC Field properties, go to the Default Value attribute and add a pipe (default value delimiter) at the end of the field, then publish and push.
8. Return to the EDC module, create a subject and enter data as before. Observe the change in behavior due to the change in configuration.

LESSON 3

NAVIGATION AND RADIO BUTTONS

This lesson describes various changes to the Architect module in Rave 5.6.3. It covers the following topics:

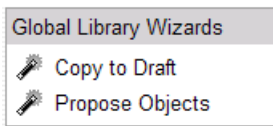
- › [Previewing Forms Before Copying to the Global Library Copy Wizard \(see page 7\)](#)
- › [Go Back Link \(see page 9\)](#)
- › [Radio Buttons \(see page 9\)](#)
- › [Hands-on Exercise \(see page 10\)](#)

Previewing Forms Before Copying to the Global Library Copy Wizard

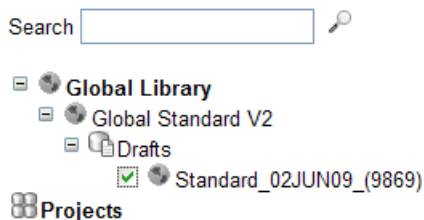
Rave 5.6.3 allows you to preview forms before you copy them to the Global Library. The preview works for selected fields and dictionary entries.

Preview a form

1. In Global Copy Wizards, click **Copy to Draft**.



2. Select the Global Library and click **Next**.



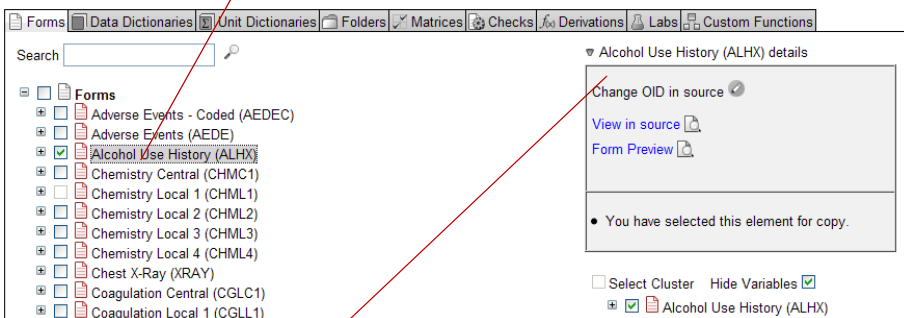
3. On the Forms tab, click the check box next to the form you want to preview.

Instructor Demo

Demonstrate the use of the Copy Preview feature.

4. Click the name of the form to display the form details.

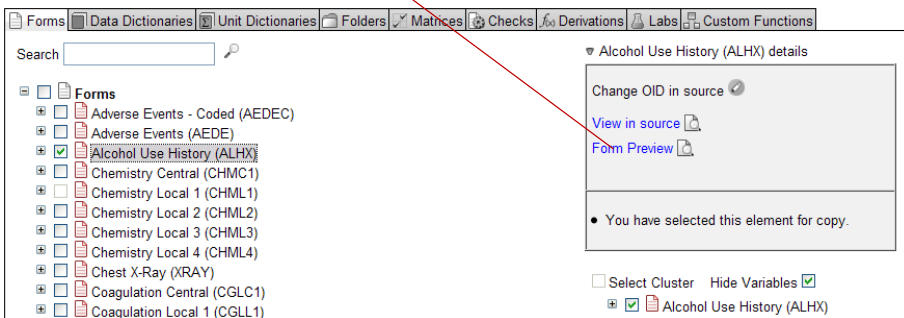
Click the name of a form



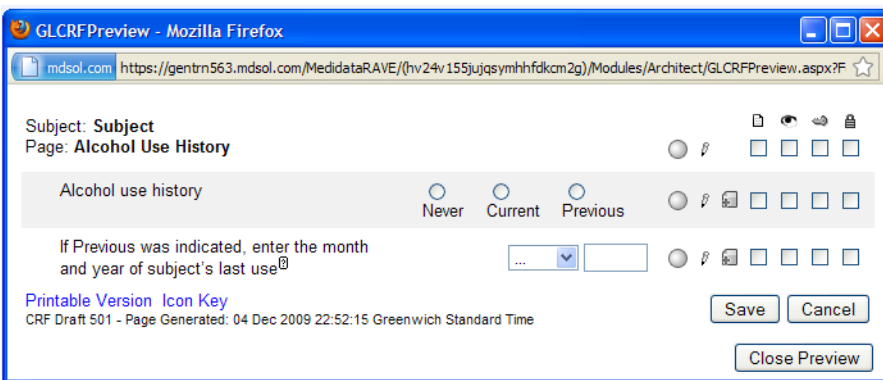
Form Details

5. Click **Form Preview**.

Click Form Preview



6. Architect displays the form in a separate preview window.



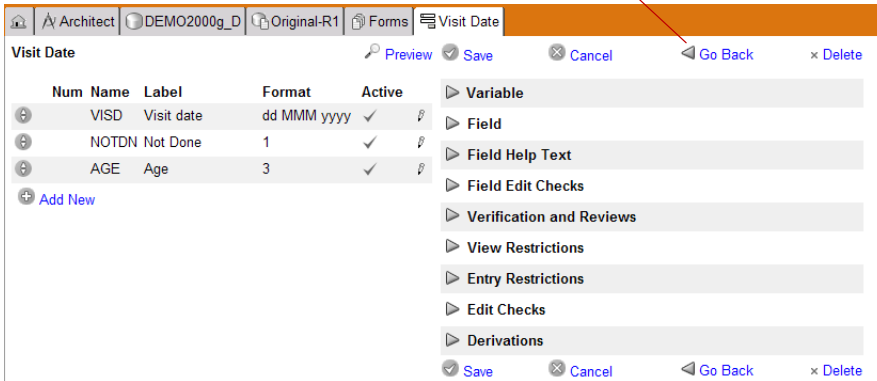
7. Click **Close Preview** when finished.

Go Back Link

◀ Go Back

A new Go Back link takes you back to the previous screen. Use it as an alternative to clicking the tab. In the Form Details screen, click **Go Back** to get to the Forms summary screen.

Go Back link



Radio Buttons

This section describes changes to radio buttons in Rave 5.6.3.

Deselectable Radio Buttons

In prior Rave releases, once an EDC user selected a single radio button, then at least one radio button in the group needed to be selected. In Rave 5.6.3, EDC users can now *deselect* any radio button on any form. This change applies to all radio buttons in the Rave 5.6.3 environment.

Instructor Demo

Demonstrate the use of the Go Back link on the Form Details screen and Edit Check screen.

Instructor Demo

Demonstrate deselectable radio buttons.

The field is “empty” when no radio button is selected. If there is a requirement to have at least one radio button selected, an edit check can be configured to check for empty values and fire a query to prompt the user to make a selection.

Vertical Radio Buttons

In Rave 5.6.3, you now have two options for displaying radio buttons: horizontal or vertical (new).

Male Female

Male
 Female

In previous Rave versions, all radio buttons were horizontal, and these settings were migrated from Rave 5.6.1 into the Rave 5.6.3 environment.

To configure vertical radio buttons, in the Form Details screen, you simply choose the RadioButton (Vertical) control type.

Field

Field Name:

Field OID:

Field Num:

Indent Level:

Active Log data entry

Requires Translation Is visible field

Can Set Record Date Can Set DataPage Date

Can Set Instance Date Can Set Subject Date

Show Previous Visit Values Does not participate in Signature

Header Text:

Field Label:

Fixed Unit:

Control Type:

Accept files with extensions:

Lab Analyte:

Default Value:

SAS Label:

SAS Format:

RadioButton (Vertical)

CheckBox

DateTime

DropDownList

Dynamic SearchList

File Upload

LongText

RadioButton

RadioButton (Vertical)

SearchList

Signature

Text

Vertical radio button

Hands-on Exercise

1. Start the process of copying a form from the Global Library and preview the form using Form Preview.
2. Refer to the Demographics form in the mock eCRFs handout.
3. Look at the Radio buttons in the SEX field.

In the Rave 5.6.1 environment, all radio buttons were horizontal, and these settings were migrated into the Rave 5.6.3 environment.

4. Change this field to vertical radio buttons.
5. Publish and push the existing version. Verify the change on the Demographics form.

LESSON 4

PDF GENERATOR

This lesson discusses changes to PDF Generator settings in Rave 5.6.3. It covers the following topics:

- › [New Configuration Settings \(see page 11\)](#)
- › [Profile Changes to PDF Generator \(see page 11\)](#)

New Configuration Settings

The following new configuration settings were added to PDF Generator in Rave 5.6.3:

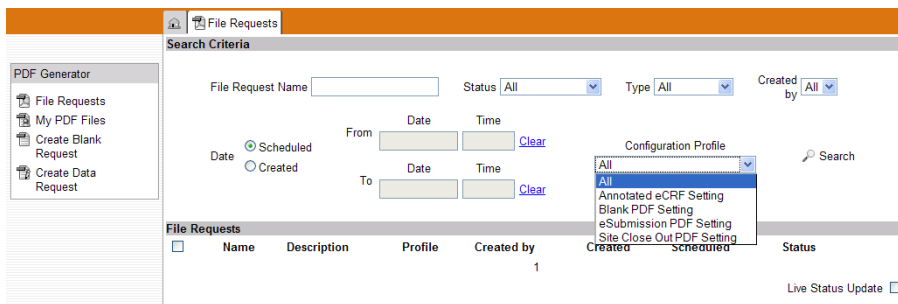
- › Option to display the full folder path in the PDF header for blank and data PDFs
- › Ability to include the Field OID in an annotated PDF
- › Only include inactive records in the PDF when “Include Inactive Records” is selected, regardless of whether “Include Blank Forms” is selected
- › Allow for both Folders (Visits) and Forms to be shown in the same Bookmark tree.
- › There is now one bookmark per log form, not one bookmark per log line.

Profile Changes to PDF Generator

PDIT provides two profiles for PDF Generator:

- › **Blank PDF Setting**—uses settings from Rave 5.6.1
- › **Annotated eCRF Setting**—uses new settings available in Rave 5.6.3

You select the profile you want to use when you configure a PDF file:



Using Old Group Names

While organization names are still being revised, this training uses old names that are familiar to training participants.

Proposed Rave 5.6.3 Settings

These proposed settings have not yet been approved.

Leader Note

Demonstrate PDFs generated in 5.6.1 and 5.6.3, showing how the new options are different.

The Annotated eCRF setting uses the following proposed items that PDM wants selected:

- Field Label
- SAS Label
- Values (Data Dictionary Values)
- Pre-Filled Values (defaulted fields)
- Field OID

How Configuration Settings Affect PDFs

The following example shows a generated PDF for the Subject Identification form in the Rave 5.6.1 environment (Blank PDF Setting):

DEV_R1_006_04DEC09_CPS: Primary Matrix Form: Subject Identification Generated On: 06 Dec 2009 00:18:58	For reference purpose ONLY, this CRF should NOT be used as Source Documentation
<hr/>	
Subject Number	<hr/>
Subject Initials	<hr/>
Subject Name	<hr/>

The following example shows a generated PDF for the Subject Identification form in the Rave 5.6.3 environment (Annotated eCRF Setting):

DEV_R1_006_04DEC09_CPS: Primary Matrix Form: Subject Identification Generated On: 06 Dec 2009 00:19:18	For reference purpose ONLY, this CRF should NOT be used as Source Documentation
<hr/>	
Subject Number	<hr/> 1
Subject Initials	<hr/> 2
Subject Name	<hr/> 3

DEV_R1_006_04DEC09_CPS: Primary Matrix Form: Subject Identification Generated On: 06 Dec 2009 00:19:18	For reference purpose ONLY, this CRF should NOT be used as Source Documentation				
<hr/>					
Field Name	Field Label	SAS Label	Values	Pre-Filled Values	Include Field OID
1 PTNUM	Subject Number	Subject Number			PTNUM
2 PTINIT	Subject Initials	Subject Initials			PTINIT
3 PTID	Subject Name	Subject Name			PTID

Proposed items

LESSON 5

EDIT CHECKS AND DERIVATIONS

This lesson discusses changes to edit check and derivation functionality in Rave 5.6.3. It covers the following topics:

- › [Quick Edit Editor \(see page 13\)](#)
- › [New Check Functions \(see page 17\)](#)
- › [Other Edit Check Changes \(see page 18\)](#)
- › [Hands-on Exercise \(see page 22\)](#)

Quick Edit Editor

Quick Edit

In Rave 5.6.3, a new Quick Edit Editor has been added that allows you to directly modify the code in edit checks—check functions, check steps, and so on. As a text editor, you can use the Clipboard to copy and paste code between edit checks and between projects. You can also use this feature to rapidly copy edit checks and then subsequently modify each one.



Note: The Quick Edit link is available for any edit check that you can modify, including inactive edit checks in a draft. It is not displayed for system edit checks or for edit checks in a CRF version (where nothing is editable).

Opening the Quick Edit Editor

Open the Quick Edit Editor for an edit check

1. On the Edit Checks tab, click the Check Steps drill-down icon next to the edit check that you want to change.

This feature is not available if your role has Read Only Architect security for Stage 2.

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Messages My Profile Help Home Logout
User: Eric Ivory-Chambers

Architect DEMO2000g_D Original-R1 Edit Checks GE_BPS_GREATER_BPD

Go Back

Quick Edit

If BPS IsLessThanOrEqualTo BPD And BPS IsNotEmpty And BPD IsNotEmpty then... open a query to Site on BPS, displaying "Systolic Blood Pressure is less than or equal to the Diastolic Blood Pressure. Please review your entries."

Check Steps

Type	Step	Edit
Data Value	...>...>BPS>...>...>None	✓
Data Value	...>...>BPD>...>...>None	✓
Check Function	IsLessThanOrEqualTo	✓
Data Value	...>...>BPS>...>...>None	✓
Check Function	IsNotEmpty	✓
Data Value	...>...>BPD>...>...>None	✓
Check Function	IsNotEmpty	✓
Check Function	And	✓
Check Function	And	✓

Add Check Step

Check Actions

Data Point	Action	Edit
...>...>BPS>...>...>	Open Query: Site: Systolic Blood Pressure is less than or equal to the Diastolic Blood Pressure. Please review your entries.	✓

Add Check Action

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2. On the Check Steps page, click the **Quick Edit** link to open the Quick Edit tab.

Architect DEMO2000g_D Original-R1 Edit Checks GE_BPS_GREATER_BPD Quick Edit

```

|GE_BPS_GREATER_BPD|True|False

||StandardValue|BPS|
||StandardValue|BPD|
IsLessThanOrEqualTo|
||StandardValue|BPS|
IsNotEmpty|
||StandardValue|BPD|
IsNotEmpty|
And|
And|

||BPS|||OpenQuery|Systolic Blood Pressure is less than or equal to the
Diastolic Blood Pressure. Please review your entries.|Site|

```

Specify delimiter.

Save Cancel

About the Quick Edit Editor

The Quick Edit Editor displays the code for an edit check. The code is divided into three sections: Edit Check Name, Check Steps, and Check Actions. Details in each section are formatted with a specific syntax that uses a pipe (|) delimiter. This syntax parallels the columns in Architect Loader, with the delimiter representing a cell boundary.

Below is a code example:

```
|GE_BPS_GREATER_BPD|True|False

||StandardValue|BPS|
||StandardValue|BPD|
IsLessThanOrEqualTo|
||StandardValue|BPS|
IsNotEmpty|
||StandardValue|BPD|
IsNotEmpty|
And|
And|

||BPS|||OpenQuery|Systolic Blood Pressure is less than or equal to the Diastolic
Blood Pressure. Please review your entries.|Site|
```

The following table describes which lines belong to which section.

Section	Code Example
Edit Check Name	GE_BPS_GREATER_BPD True False
Check Step(s)	<pre> StandardValue BPS StandardValue BPD IsLessThanOrEqualTo StandardValue BPS IsNotEmpty StandardValue BPD IsNotEmpty And And </pre>
Check Action	<pre> BPS OpenQuery Systolic Blood Pressure is less than or equal to the Diastolic Blood Pressure. Please review your entries. Site </pre>

The following table shows the syntax and format used for edit checks in the Quick Edit Editor.

Section	Syntax
Edit Check Name	CheckName CheckActive BypassDuringMigration
Check Step(s)	CheckFunction StaticValue DataFormat VariableOID FolderOID FormOID FieldOID RecordPosition CustomFunction LogicalRecordPosition FormRepeatNumber FolderRepeatNumber
Check Action	CheckName FolderOID FormOID FieldOID VariableOID RecordPosition PageRepeatNumber InstanceRepeatNumber ActionType ActionString ActionOptions ActionScript

Pipe Delimiter (|)

Although the delimiter can be customized for default values, Genentech uses only the pipe delimiter.

Syntax Checker

Architect will generate an error if a change is invalid, such as a non-existent field OID or a pipe delimiter that was accidentally deleted.

Modifying an Edit Check

Modify an edit check in the Quick Edit Editor

1. Open the Quick Edit page for an edit check.
2. Edit the code for the edit check.



IMPORTANT! Make your edits carefully. Because this is free-form text editing, you must make sure that you do not introduce errors into the syntax. The values and delimiters must be consistent with the columns in Architect Loader.

3. Click **Save** to save your changes.

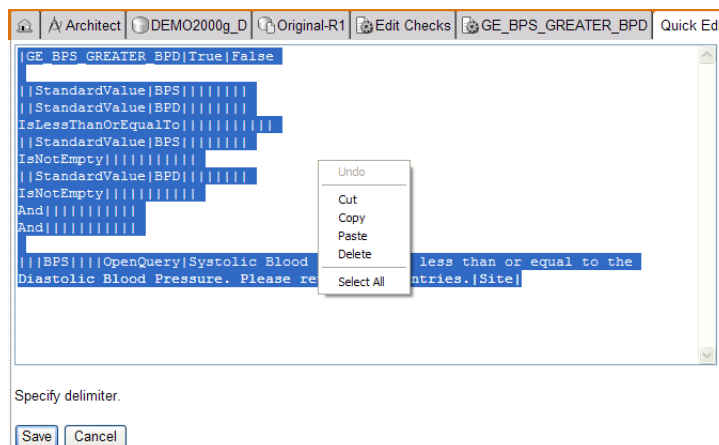
Copying an Edit Check

Make rapid copies of an edit check in the Quick Edit Editor

1. Open the Quick Edit page for an edit check.
2. Change the Edit Check Name. The new name must be unique—it cannot conflict with an existing edit check name, nor can it begin with the following characters: `sys_`.
3. Click **Save** to save it as a new edit check.
4. Make any other changes as required, then click **Save**.

Using the Clipboard to Copy and Paste

Because the Quick Edit Editor is a text editor, you can select text, copy text to the Clipboard, and then paste this text to another edit check—within the same project or between different projects.



This is helpful when you want to copy portions of code to use in other edit checks, or to quickly make identical (or nearly-identical) copies of edit checks.

New Check Functions

The following new check functions in Rave 5.6.3 were previously available only for derivations.

Check Function	Description
Add	Adds the numeric data values and/or numeric constants together.
Age	Calculates the age in years between two date fields.
Subtract	Subtracts a numeric constant or data value from another numeric constant or data value.
Multiply	Multiplies a numeric constant or data value by another numeric constant or data value.
Divide	Divides a numeric constant or data value by another numeric constant or data value.
AddDay	Adds a specific number of days to a date field, returning a new date.
AddMonth	Adds a specific number of months to a date field, returning a new date.
AddYear	Adds a specific number of years to a date field, returning a new date.
AddSec	Adds a specific number of seconds to a date field, returning a new date.
AddMin	Adds a specific number of minutes to a date field, returning a new date.
AddHour	Adds a specific number of hours to a date field, returning a new date.
DaySpan	Calculates the number of days between two date fields.
TimeSpan	Calculates the amount of time (in minutes) between two date/time fields.
StringAdd	Concatenates two character strings together.
IsActive	Returns true if the corresponding data value is active.

New Check Functions in Exercises

You will have the opportunity to write edit checks that use some of these new check functions during the hands-on exercises at the end of this lesson.

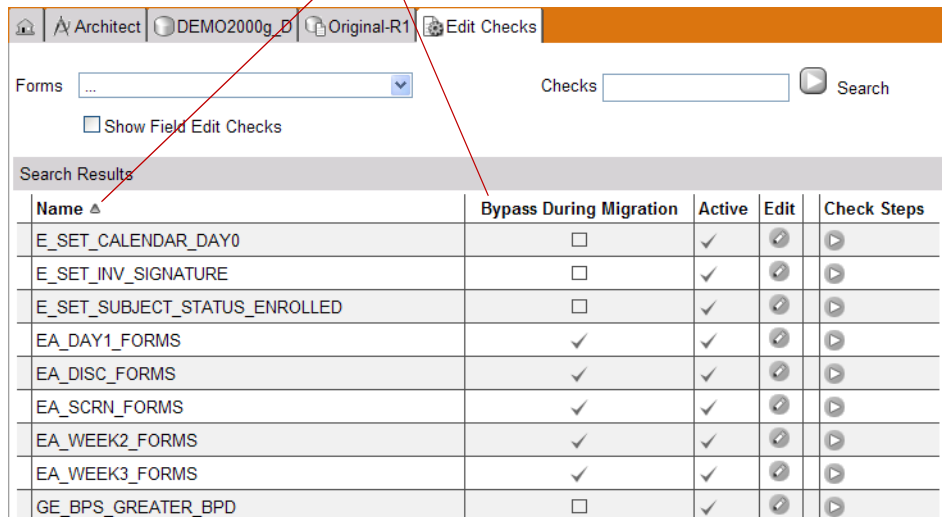
Other Edit Check Changes

This section describes other Rave 5.6.3 enhancements for edit checks.

Sorting Columns for Edit Checks and Derivations

In Rave 5.6.3, you can now sort edit checks by clicking the column header in the Name or Bypass during Migration columns. Click again to reverse the sort order.

Click column header to sort



Forms Checks Search

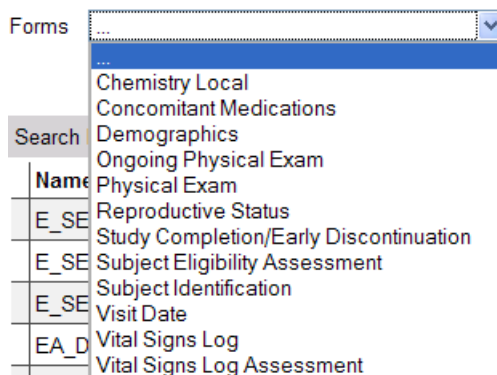
Show Field Edit Checks

Search Results

Name ▲	Bypass During Migration	Active	Edit	Check Steps
E_SET_CALENDAR_DAY0	<input type="checkbox"/>	✓	⊗	▶
E_SET_INV_SIGNATURE	<input type="checkbox"/>	✓	⊗	▶
E_SET_SUBJECT_STATUS_ENROLLED	<input type="checkbox"/>	✓	⊗	▶
EA_DAY1_FORMS	✓	✓	⊗	▶
EA_DISC_FORMS	✓	✓	⊗	▶
EA_SCRN_FORMS	✓	✓	⊗	▶
EA_WEEK2_FORMS	✓	✓	⊗	▶
EA_WEEK3_FORMS	✓	✓	⊗	▶
GE_BPS_GREATER_BPD	<input type="checkbox"/>	✓	⊗	▶

Forms Drop-down List Sorted Alphabetically

The Forms drop-down list is sorted alphabetically.



Forms

Search

Name

E_SE

E_SE

E_SE

EA_D

- Chemistry Local
- Concomitant Medications
- Demographics
- Ongoing Physical Exam
- Physical Exam
- Reproductive Status
- Study Completion/Early Discontinuation
- Subject Eligibility Assessment
- Subject Identification
- Visit Date
- Vital Signs Log
- Vital Signs Log Assessment

Reordering Check Steps



In Rave 5.6.3, you can now easily change the order of check steps using the Reorder button.





Architect | DEMO2000g_D | Original-R1 | Edit Checks | E_SET_CALENDAR_DAY0

Go Back


Quick Edit

If VISD in Visit Date in Screening with record position 0 IsNotEmpty then... set the Time Zero using the value in VISD in Visit Date in Screening with record position 0 and calculate the subject calendar

Check Steps

	Type	Step	Edit
	Data Value	Screening>Visit Date>VISD>VISD>0>...>None	
	Check Function	IsNotEmpty	
Add Check Step			

Check Actions





Data Point	Action	Edit
Screening>Visit Date>VISD>VISD>0>...>...	Set Time Zero	
Add Check Action		

Reorder button

Reorder check steps





1. Click the Reorder button to display a drop-down list:

Check Steps

	Type	Step	Edit
	Data Value	Screening>Visit Date>VISD>VISD>0>...>None	
	Check Function	IsNotEmpty	
Add Check Step			

2. Display the list items and select the new position for this check step.

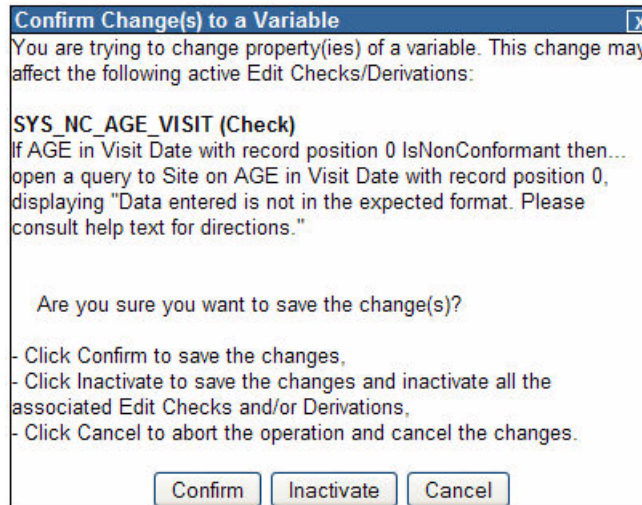
Check Steps

	Type	Step	Edit
	Data Value	Screening>Visit Date>VISD>VISD>0>...>None	
	Check Function	IsNotEmpty	
<div style="border: 1px solid black; padding: 2px;"> <ul style="list-style-type: none"> Top Data Value: Screening>Visit Date>VISD>VISD>0>...>None Check Function: IsNotEmpty Bottom </div>			

Once selected, Architect moves the check step to the selected position.

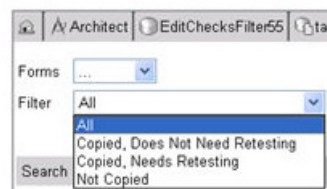
Confirmation Prompt for Changing Variable Attributes

In Rave 5.6.3, if you change an attribute of a variable that is referenced by edit checks and/or derivations, Architect displays a list of any active edit checks and derivations that would be affected by this change, and prompts you to confirm or cancel the change. Changes are committed only after confirmation.



Filtering Based on Test Requirement Levels

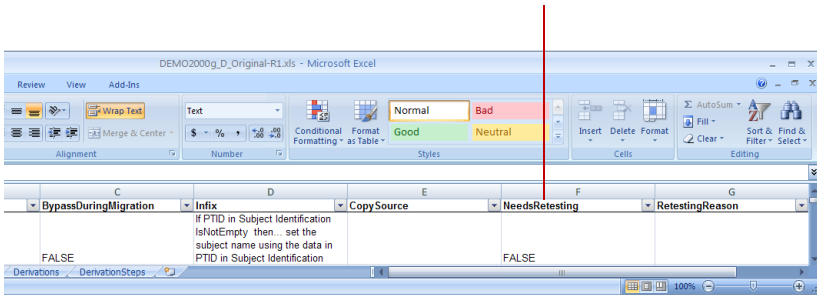
For edit checks and derivations that are stored in the Global Library and which have been copied from another source, you can filter the list of edit checks by the testing level required:



- All
- Copied, Does Not Need Retesting
- Copied, Needs Retesting
- Not Copied

Retesting requirements are included in Architect Loader downloads (NeedsRetesting and RetestingReason columns in the spreadsheet).

NeedsRetesting, RetestingReason




Use Max Add


In Rave 5.6.3, for AddMatrix edit checks, you can use a new Use Max Add option to specify whether the edit check can prohibit (checked) or allow (unchecked) the edit check to add matrices beyond the maximum specified for the matrix.

Edit Check Log Report

A new Edit Check Log Report allows you to track and troubleshoot performance issues for edit checks. In the Configuration module, a Check Execution Threshold setting (30000) controls the output for this report.

 **Note:** This Edit Check Log Report is a Rave standard report that is currently undergoing the validation process. Validation might not be complete in time for the Rave 5.6.3 GoLive date.

Logical Record Position

 **Note:** The new Logical Record Position (LRP) functionality will not be implemented yet. Genentech testing has shown it to be insufficiently reliable.

Instructor Demo

Demonstrate the use of TimeSpan with timepoint fields.

Instructor Demo

Show GDX_BRTHD_VISD derivation as an example of using Age.

Instructor Note

Stop after each edit check and walk through the corresponding pre-built edit check in the demo study. Give students ~15 minutes to do step, then spend 5-10 minutes going over the results. Consider a classroom break after #2.

Instructor Note

Lead a discussion with learners about how best to use the IsActive functionality. What are the nuances?

Hands-on Exercise

When building edit checks during this exercise, refer to the SLACs handout.

1. Build and test an edit check function that uses the **Age** check function.

On the SLACs handout, refer to the edit check for the Visit Date form that uses the Age check function to conditionally execute certain check actions.

2. Build and test an edit check function that uses the **AddYear** check function.

On the SLACs handout, refer to the edit check for the Concomitant Meds form that uses the AddYear check function to prevent users from entering medications and treatments that are older than 10 years (as might be done in an oncology study).

3. Build and test an edit check function that uses the **Divide** check function.

On the SLACs handout, refer to the edit check for the Vital Signs form that use the Divide check function to calculate the Body Mass Index (BMI) from the height and body weight values.

Note: This is a hypothetical example only, provided solely for teaching the use of this check function in this training. For Genentech-sponsored clinical trials, sites would calculate and enter this value themselves—no changes have been made to this business process.

4. Build and test an edit check function that uses the **IsActive** check function.

On the SLACs handout, refer to the edit check that uses the IsActive check function to generate a query if a user inactivates the PE form in the Unscheduled Visit folder. The query instructs users to change their answer to the “Was a physical exam performed?” on the Unscheduled Visit Assessment from “Yes” to “No” (because the PE form was inactivated). The query is resolved when the form is reactivated.

Note: The IsActive check function applies to both inactivated forms and inactivated log lines. It passes in a fieldOID on the form (not the formOID itself), and returns FALSE if the form is inactivated.

LESSON 6

AMENDMENT MANAGER AND STUDY MIGRATION

This lesson discusses study migration and the new Amendment Manager Scheduler in Rave 5.6.3. It covers the following topics:

- › [Amendment Manager \(see page 23\)](#)
- › [Amendment Manager Scheduler \(see page 23\)](#)
- › [Proposed Changes to the Study Migration Business Process \(see page 29\)](#)
- › [Hands-on Exercise \(see page 29\)](#)

Amendment Manager

There is no major change to the Amendment Manager other than fixes to some of the known issues. When preparing to migrate a study in the Amendment Manager, be sure to consult the latest Rave 5.6.3 “Known Issues” list for current problems with the Amendment Manager. For more information, see [“Rave 5.6.3 Resources” on page 4](#). Before you perform an actual migration, review the list so that you can do what’s needed to minimize problems that can occur during migration.

Amendment Manager Scheduler

Rave 5.6.3 introduces the Amendment Manager Scheduler—a new tool within Architect that allows you to schedule CRF *migration jobs* in advance. You use the Amendment Manager to create migration plans, and then use the Amendment Manager Scheduler to schedule a time to execute the plans (or conduct a dry run). You can set up migration job to run anytime, such as during off-peak or off-work hours. Migration jobs wait in a job queue until the configured start time, at which point the Amendment Manager Scheduler fires the job and, when complete, saves the results in a log. The results indicate the job status and whether the job succeeded or failed, which is useful for migration confirmation or failure analysis and resolution.

Automatic Access to AM Scheduler

If you are assigned the CASA-1 role, you have access to the Amendment Manager Scheduler automatically.

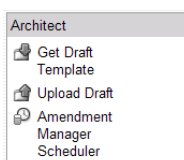
Unattended Migrations

The trade-off for being able to schedule migration jobs is that you might not be present to oversee the job execution in real time and respond immediately to any issues that arise during execution of the migration process.

This is important to remember if you have scheduled a series of migrations. For example, if you have three scheduled migration jobs and the second job fails, the third job will execute regardless. There is currently no way to conditionally execute a job based on the success or failure of a prior job. Therefore, give some thought about how and when you plan to schedule your migration jobs.

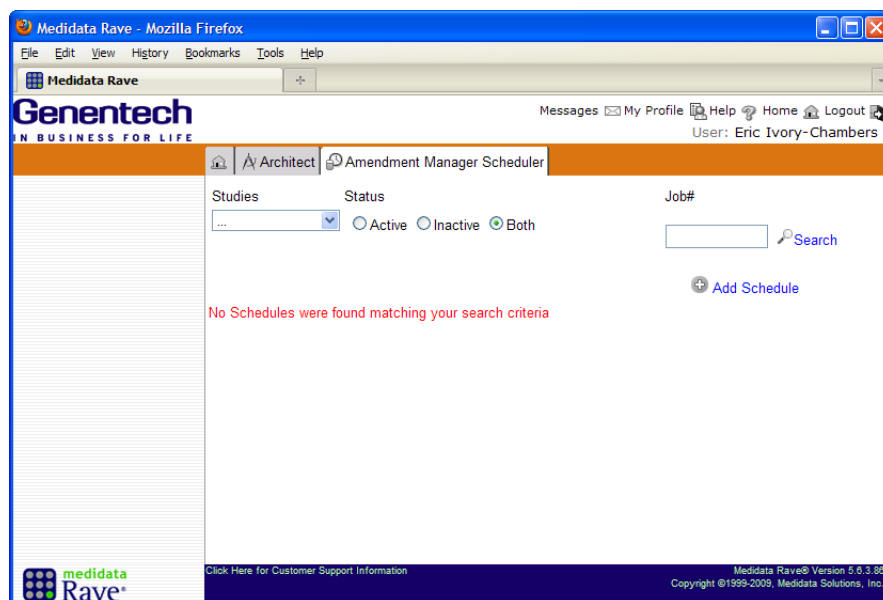
Launching the Amendment Manager Scheduler


Launch the Amendment Manager Scheduler



- In the Architect sidebar, click **Amendment Manager Scheduler**.

Architect displays the Amendment Manager Scheduler main page, which shows the queue of scheduled amendments (pending jobs awaiting execution).



 **Note:** By default, the migration job queue shows only jobs that have not yet completed.

The Amendment Manager Scheduler displays the following information about each migration job:

Field	Description
Study Name	Name of the study and environment.
Job #	Amendment Manager-generated number for this migration plan.
Schedule ID	Amendment Manager Scheduler-generated ID for this job schedule.
Source CRF Version	CRF version from which the data will be migrated. Defined when the migration plan was created.
Target CRF Version	CRF version to which the data will be migrated. Defined when the migration plan was created.
Submitted By	Name of the user who submitted the job.
Start Time	Date and time to start executing the job, or double dashes (--) if a start time is unspecified for this job.
End Time	Date and time by which the job must be stopped, or double dashes (--) if an end time is unspecified for this job. If the End Time for a migration job is reached while it is executing, Rave completes the process of migrating the current subject before stopping.
Active	Indicates whether the job is active (selected) or inactive (cleared).

Filtering the Migration Job Queue

Once you are on the Amendment Manager Scheduler main page, you can filter jobs in the migration job queue by study, job status, job number—individually or in combination. By default, no filters are set. The Amendment Manager Scheduler displays an error message if any of the filter conditions are incorrect, or if no jobs match the specified filter criteria.

Filter by study

- Select a study from the drop-down list.

Filter by job status

- Select **Active**, **Inactive**, or **Both** (displays both active and inactive jobs, the default).

Filter by job number

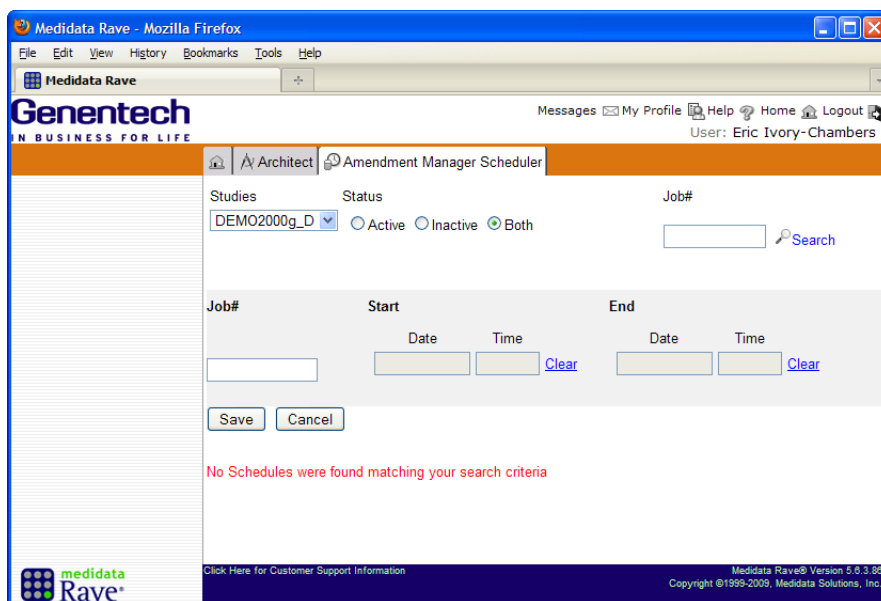
- Enter the job number and click Search.

Adding a Migration Job

You can add a schedule to any migration job that has not already completed.

Add a schedule to a migration job

1. On the Amendment Manager Scheduler main page, click **Add Schedule**.



2. Enter the following schedule information.

Field	Description
Job #	Number associated with the existing migration plan that you want to schedule. This is the job # that the Amendment Manager assigned to the migration plan when it was created.
Start Date / Time	Date and time to start executing the migration job. <ul style="list-style-type: none">➤ If the Start Date is in the past and the Start Time is blank, then the current time is used.➤ If the Start Date is in the future and the Start Time is blank, then 12:00 AM will be the time used.➤ The migration job will run immediately if the Start Date is blank or if the start date is today's date and the Start Time is blank.
End Date / Time	Date and time to end the migration job if it has not already been completed. Must be later than today's date and the Start Date. If the End Time is blank, then the system defaults to 11:59 PM.

If you click on a date field, a Calendar control appears.



You can also click **Clear** to clear the current values.

3. Click **Save** to save your changes.
4. If any fields are blank, Amendment Manager Scheduler prompts you to confirm—accept this message.

Amendment Manager Scheduler saves the new schedule data for the migration plan and displays the migration job in the queue.

Editing a Migration Job

You can edit any migration job in the job queue that has not already completed.

Edit a migration job in the queue

1. On the Amendment Manager Scheduler main page, find the scheduled migration job that you want to edit.
2. Click the **Edit** icon next to the scheduled migration job.
3. Change the settings you want:

Field	Description
Start Date / Time	Date and time to start executing the migration job.
End Date / Time	Date and time to end the migration job if it has not already been completed. Must be later than today's date and the Start Date. If the End Time is blank, then the system defaults to 11:59 PM.

4. Click **Update** to save your changes.

Inactivating a Migration Job

You can inactivate any migration job in the job queue that has not already completed.

Inactivate a migration job in the queue

1. On the Amendment Manager Scheduler main page, find the scheduled migration job that you want to inactivate.
2. Click the **Edit** icon next to the scheduled migration job.
3. Clear (uncheck) the **Active** check box for this migration job.
4. Click **Save** to save your changes.

Any user who has access to the Amendment Manager (Lead CASA) and the study can modify, inactivate, or delete a job in the Amendment Manager Scheduler.

You do not need to be the person who scheduled the migration job.

Deleting a Migration Job

You can delete any migration job in the job queue that has not already completed. However, if there is only one schedule for the job, it cannot be deleted.

Delete a migration job in the queue

1. On the Amendment Manager Scheduler main page, find the scheduled migration job that you want to delete.
2. Click the **Edit** icon next to the scheduled migration job.
3. Click (check) the **Delete** check box for this migration job.
4. Click **Update**.

Showing Migration Job Details

To see migration job details, in the migration jobs list, hover the mouse over one of the data values in the list. The Amendment Manager Scheduler displays the job number, the number of subjects migrated, the total number of subjects, and any errors or warnings that arose during job execution. For migration jobs that have not yet executed, the tooltip indicates that the job has not been started.

Proposed Changes to the Study Migration Business Process

The study migration process is currently undergoing review based on proposed changes that were submitted in September (including an automation script to be validated). Changes to the study migration business process will not be made before the Rave 5.6.3 go-live date. The current business process remains in effect until recommended changes, if any, are approved.

Hands-on Exercise

1. In the Amendment Manager, create a migration plan from one of several versions already published during the class.
2. In the Amendment Manager Scheduler, schedule a migration job to start executing 24 hours from now and to stop executing 25 hours from now.
3. Note how your migration job is added to the queue, along with migration jobs scheduled by others in the class.
4. Delete your migration job in the queue.
5. Watch your leader demonstrate the actual execution of a scheduled migration job.

Leader Note

Schedule an amendment job to occur within one minute after everyone has canceled their amendment jobs.

LESSON 7

ARCHITECT LOADER

This lesson briefly describes the subset load functionality that is now available in Architect Loader for Rave 5.6.3. It covers the following topics:

- › [Subset Download Functionality \(see page 30\)](#)
- › [Results in Excel \(see page 31\)](#)

Subset Download Functionality



For Architect Loader, Rave 5.6.3 now provides the ability to select and download a *partial draft* (a subset of study components). A new Draft Summary / Download section was added to the Draft Summary.

Instructor Demo

Walk through the steps to download a subset of study components, then show the results in Excel.


The screenshot shows the Genentech Architect Loader interface. The main content area is divided into three sections: 'CRF Draft Settings', 'Draft Summary / Download', and 'Upload Trail'. The 'Draft Summary / Download' section contains a table with columns for Item, Count, Updated, and Include in Download. A 'Download' button is located below the table. A red arrow points to the 'Download' button with the label 'Download button'. Another red arrow points to the 'Draft Summary / Download' section with the label 'Draft Summary / Download'.

Item	Count	Updated	Include in Download
Forms	12	09 Oct 2008	<input checked="" type="checkbox"/>
Fields	60	09 Oct 2008	<input checked="" type="checkbox"/>
Variables	54	09 Oct 2008	<input checked="" type="checkbox"/>
Folders	7	09 Oct 2008	<input checked="" type="checkbox"/>
Edit Checks	70	09 Oct 2008	<input checked="" type="checkbox"/>
Valid Checks	70		
Invalid Checks	0		
Derivations	1	09 Oct 2008	<input checked="" type="checkbox"/>
Data Dictionaries	10	09 Oct 2008	<input checked="" type="checkbox"/>
Unit Dictionaries	0		<input checked="" type="checkbox"/>
Matrices	2	09 Oct 2008	<input checked="" type="checkbox"/>
Lab Variable Mappings	0		<input checked="" type="checkbox"/>
Custom Functions	2	09 Oct 2008	<input checked="" type="checkbox"/>

The Download button was moved from Drafts Settings to this new Draft Summary / Download section. The Protect Worksheets option was added to allow you to create a spreadsheet with protected worksheets (to prevent users from changing important data)—you can subsequently remove the protection if necessary.

For example, you could download only edit checks and derivations to a spreadsheet by selecting the appropriate check boxes under **Include in Download**. Unchecked components are *excluded* from the download.

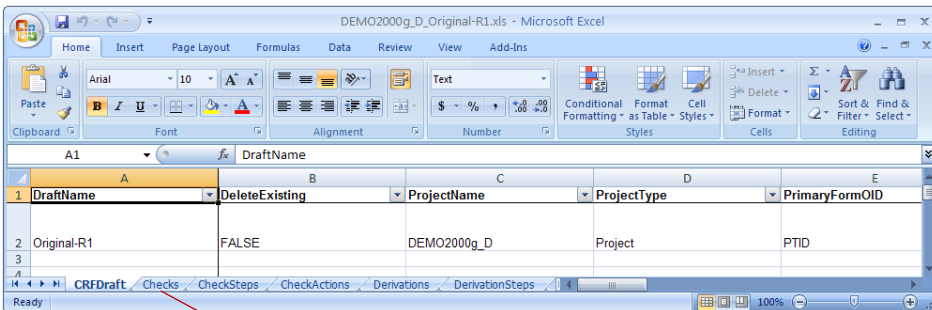
Draft Summary / Download			
Item	Count	Updated	Include in Download
Forms	12	09 Oct 2008	<input type="checkbox"/>
Fields	60	09 Oct 2008	<input type="checkbox"/>
Variables	54	09 Oct 2008	<input type="checkbox"/>
Folders	7	09 Oct 2008	<input type="checkbox"/>
Edit Checks	70	09 Oct 2008	<input checked="" type="checkbox"/>
Valid Checks	70		
Invalid Checks	0		
Derivations	1	09 Oct 2008	<input checked="" type="checkbox"/>
Data Dictionaries	10	09 Oct 2008	<input type="checkbox"/>
Unit Dictionaries	0		<input type="checkbox"/>
Matrices	2	09 Oct 2008	<input type="checkbox"/>
Lab Variable Mappings	0		<input type="checkbox"/>
Custom Functions	2	09 Oct 2008	<input type="checkbox"/>

Protect Worksheets
 Download

Included in Download

Results in Excel

When you download the partial draft, the resulting Microsoft Excel spreadsheet includes only the selected components on separate worksheets (see the tabs along the bottom of the spreadsheet).



Worksheet Tabs for Downloaded Components

LESSON 8

PUBLISH IN PLACE

This lesson introduces the new Publish in Place functionality in Rave 5.6.3. It covers the following topics:

- › [About Publish in Place \(see page 32\)](#)
- › [Overwriting an Existing CRF Version \(see page 32\)](#)
- › [Restoring a CRF Version \(see page 33\)](#)
- › [Locking a CRF Version \(see page 34\)](#)
- › [Recommendations for Using Publish in Place \(see page 34\)](#)
- › [Hands-on Exercise \(see page 35\)](#)

About Publish in Place

Rave 5.6.3 provides a new Publish in Place functionality that allows you to overwrite an existing CRF Version with the contents of an existing CRF Draft. After overwriting, if necessary, you can restore the draft to its original state (under a different name).

Previously, each time you published changes, a separate version was created. Over time, this could result in many CRF versions, almost all of which were superseded by the most recent version. Publish in Place allows you to minimize the number of CRF versions.

Overwriting an Existing CRF Version

Overwrite an existing CRF version from an existing CRF draft

1. In Architect, select a draft to display its details.

On the draft details page, look at the Publish box and notice the Overwrite column next to the Existing Versions list.

Existing Versions	Overwrite
DEV_R1_001_08OCT08_CPS (500)	Overwrite

2. Click **Overwrite** next to the CRF version that you want to overwrite.

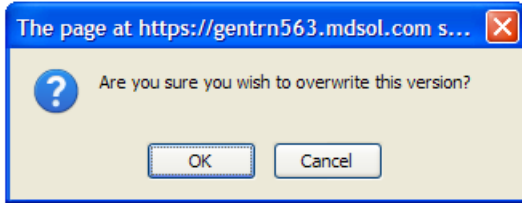


Note: Architect will not overwrite the target CRF version if it is locked.

For more information, see [“Locking a CRF Version” on page 34](#)

Publish in Place at Genentech



A best practices document and a job aid are being developed for this functionality.



3. When prompted to confirm, click **OK**.

Architect overwrites the target CRF version with the source CRF draft, adding new study components from the source that do not yet exist in the target, removing any study components in the target that do not exist in the source, and overwriting properties for study components that exist in both (components share an OID).

When finished, Architect displays a message to notify whether the overwrite process succeeded.

 **Note:** For certain features, changes are not immediately displayed in the EDC module—a brief lag time can occur between when the version was overwritten and when EDC users will see the changes reflected in their existing subjects. Changes are displayed, and all edit checks and derivations are re-run, when an EDC user selects the subject. Until a subject is refreshed, the EDC module displays an “In Doubt” icon () next to affected EDC subjects.



After overwriting a version, Architect adds this event to the Version History.


Restoring a CRF Version

Restore a CRF Version

1. In Architect, select a draft to display its details.

On the Version details page, look at the Version History box and notice Restore as Draft.

Version History		
Published Date	Published By	Restore As Draft
09 Dec 2009 18:13:34	buildsc 11	
09 Dec 2009 18:16:26	buildsc 11	

2. Click the **Restore as Draft** button () next to the CRF version that you want to restore.
3. When prompted, enter a different name (unique within the project) for this draft.

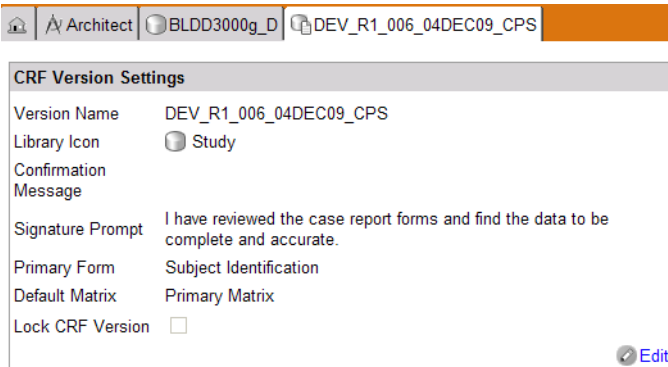
Architect restores the newly-named draft from the source version and updates subjects associate with the overwritten CRF version.

Locking a CRF Version

Lock a CRF version to ensure that it cannot be overwritten with the Publish in Place functionality.

Lock a CRF version

1. Select the CRF version that you want to lock.

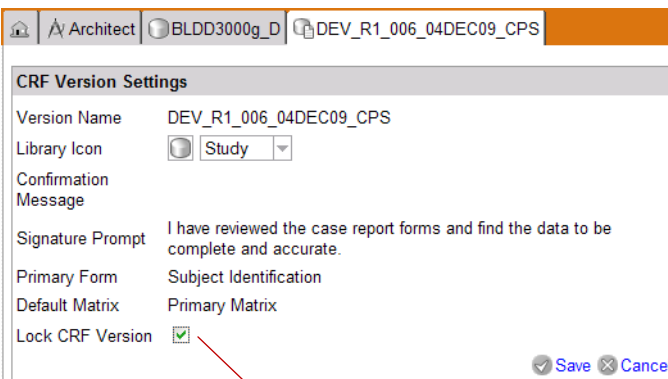


The screenshot shows the 'CRF Version Settings' dialog box. At the top, there is a breadcrumb trail: 'Architect' > 'BLDD3000g_D' > 'DEV_R1_006_04DEC09_CPS'. The dialog box contains the following fields:

Version Name	DEV_R1_006_04DEC09_CPS
Library Icon	<input type="radio"/> Study
Confirmation Message	
Signature Prompt	I have reviewed the case report forms and find the data to be complete and accurate.
Primary Form	Subject Identification
Default Matrix	Primary Matrix
Lock CRF Version	<input type="checkbox"/>

An 'Edit' button is located at the bottom right of the dialog box.

2. Select (check) the **Lock CRF Version** check box.



The screenshot shows the 'CRF Version Settings' dialog box with the 'Lock CRF Version' checkbox checked. The breadcrumb trail is the same as in the previous screenshot. The 'Library Icon' field now shows a dropdown menu with 'Study' selected. The 'Save' and 'Cancel' buttons are visible at the bottom right.

Version Name	DEV_R1_006_04DEC09_CPS
Library Icon	<input type="radio"/> Study
Confirmation Message	
Signature Prompt	I have reviewed the case report forms and find the data to be complete and accurate.
Primary Form	Subject Identification
Default Matrix	Primary Matrix
Lock CRF Version	<input checked="" type="checkbox"/>

Lock CRF Version check box

3. Click **Save**.

Recommendations for Using Publish in Place

A planning group has provided the following recommendations for using Publish in Place at Genentech:

- For UAT, always publish and push a new CRF version.
- In P1 and P2, do not use Overwrite in/during UAT.
- The lead CASA must lock the CRF version that is pushed to UAT.

As a best practice, you should lock and unlock *your* version only.

Hands-on Exercise

1. In Architect, look at a current CRF version in your study.
2. Make and test the following changes to this CRF draft:
 - a. Create the Week 4 folder. Refer to the Visit Form Matrix handout.
 - b. To the Primary matrix, add a new Week 4 folder (which includes a Visit Date and Chemistry Local form). Refer to the Visit Form Matrix handout.
 - c. Overwrite (Publish in Place) and review the results.
 - d. Change the Primary matrix. Deselect the Chemistry Local form and select the PE form instead. Refer to the SLACs and Visit Form Matrix handouts.
 - e. Overwrite (Publish in Place) and review the results.
3. Make and test the following changes to this CRF draft:
 - a. Make a change to an edit check using a custom function. The name of the check to modify is GEXC_VTLREC_NO_VTLS1_COMPLETED_VTLS3. Modify the query text (only) to match the SLACs handout, and then overwrite (publish in place). Verify the query message.
 - b. Change a dictionary of your choosing.
 - c. Change a field property of your choosing.
4. Make and test the following change to this CRF draft:
 - a. Add the CREAT (CREAT) field to the Chemistry Local form by copying it from the Global Library.
 - b. Overwrite (Publish in Place) and review the results.
5. Make and test the following change to this CRF draft:
 - a. Lock this draft.
 - b. Try to execute Publish in Place. Notice what happens.
 - c. Go back and unlock the draft.

CONCLUSION

You have completed the Rave 5.6.3 Gap Training for Study Builders.

Review

In this training, you have learned about new and changed features in the Rave 5.6.3 software related to building Rave studies for Genentech-sponsored clinical trials. It has covered the following information:

- › Reactivation of log lines and setting restrictions using the default value delimiter
- › Architect navigation features such as copy preview and go back links
- › Vertical radio buttons and radio buttons that users can deselect
- › Publish in Place functionality, including the ability to overwrite, restore, and lock a CRF version, and recommendations for using this functionality at Genentech
- › New configuration settings in PDF Generator
- › Enhancements for edit checks such as the Quick Edit editor, new check functions, and other changes that affect both edit checks and derivations
- › Amendment Manage Scheduler for use in study migration
- › Subset download functionality in Architect Loader

Where to Go From Here

Now that you have completed this training, before you leave, be sure to sign the group training record.

You can now apply what you've learned in this course to future study design efforts.

APPENDIX A

EDIT CHECKS IN THE DEMO STUDY

This appendix provides screen shots of edit checks in the demo study that use some of the new check functions in Rave 5.6.3.

E_AGE_OUT_OF_RANGE

This edit check uses the Age check function.

Architect BLDD3000g_D Original - R2 Edit Checks E_AGE_OUT_OF_RANGE

[Go Back](#)

[Quick Edit](#)

If VISD in Visit Date with record position 0 Age BRTHD in Demographics in Screening with record position 0 and form repeat number 0 and folder repeat number 0 IsLessThan 18 Or VISD in Visit Date with record position 0 Age BRTHD in Demographics in Screening with record position 0 and form repeat number 0 and folder repeat number 0 IsGreaterThan 65 then... open a query to Site on VISD in Visit Date with record position 0, displaying "Subject's age is not within the protocol age range. Please review the Date of Birth and Date Subject or Legal Guardian signed protocol informed consent on the Subject Eligibility form."

Check Steps

	Type	Step	Edit
⊖	Data Value	...>Visit Date>VISD>VISD>0>...>...>None	⊕
⊖	Data Value	Screening>Demographics>BRTHD>BRTHD>0>0>None	⊕
⊖	Check Function	Age	⊕
⊖	Constant	18 (2)	⊕
⊖	Check Function	IsLessThan	⊕
⊖	Data Value	...>Visit Date>VISD>VISD>0>...>...>None	⊕
⊖	Data Value	Screening>Demographics>BRTHD>BRTHD>0>0>None	⊕
⊖	Check Function	Age	⊕
⊖	Constant	65 (2)	⊕
⊖	Check Function	IsGreaterThan	⊕
⊖	Check Function	Or	⊕
⊕	Add Check Step		

E_HEIGHT_WEIGHT_BMI

This edit check uses the Divide check function.

Architect BLDD3000g_D Original - R2 Edit Checks E_HEIGHT_WEIGHT_BMI

Go Back

Quick Edit

If WT in Vital Signs Log Assessment with record position 0 Divide HT in Vital Signs Log Assessment with record position 0 Multiply HT in Vital Signs Log Assessment with record position 0 IsGreaterThen 30 then... open a query to Site on HT in Vital Signs Log Assessment with record position 0, displaying "Subject's BMI is not within the BMI range for this protocol. Please review your entries."

Check Steps

Type	Step	Edit
Data Value	...>Vital Signs Log Assessment>WT>WT>0>...>None	✓
Data Value	...>Vital Signs Log Assessment>HT>HT>0>...>None	✓
Data Value	...>Vital Signs Log Assessment>HT>HT>0>...>None	✓
Check Function	Multiply	✓
Check Function	Divide	✓
Constant	30 (2)	✓
Check Function	IsGreaterThen	✓

Add Check Step

Check Actions

Data Point	Action	Edit
...>Vital Signs Log Assessment>HT>HT>0>...>...	Open Query: Site: Subject's BMI is not within the BMI range for this protocol. Please review your entries.	✓

Add Check Action

E_MDED_10YEARS_BEFORE_NOW

This edit check uses the AddYear check function.

Architect BLDD3000g_D Original - R2 Edit Checks E_MDED_10YEARS_BEFORE_NOW

Go Back

Quick Edit

If MDED in Concomitant Medications in Concomitant Medications AddYear 10 IsLessThan Now then... open a query to Site on MDED in Concomitant Medications in Concomitant Medications, displaying "Date Stopped is more than 10 years prior to today's date.This medication should not be recorded per protocol instructions. Please review your entries."

Check Steps

Type	Step	Edit
Data Value	Concomitant Medications>Concomitant Medications>MDED>MDED>...>...>None	✓
Constant	10 (2)	✓
Check Function	AddYear	✓
Check Function	Now	✓
Check Function	IsLessThan	✓

Add Check Step

EX_PEU_NO_PE2_ACTIVE

This edit check uses the IsActive check function.

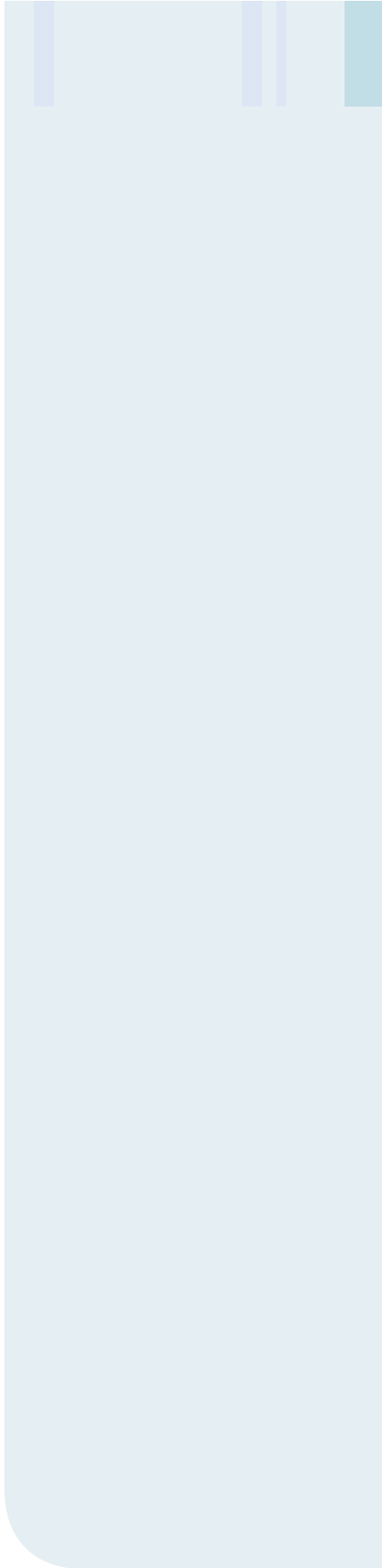
[Home](#) | [Architect](#) | [BLDD3000g_D](#) | [Original - R2](#) | [Edit Checks](#) | **EX_PEU_NO_PE2_ACTIVE**

[Go Back](#)
[Quick Edit](#)

If PEU in Unscheduled Visit Assessment with record position 0 IsEqualTo NO And PEREC in Ongoing Physical Exam with record position 0 IsActive then... open a query to Site on PEU in Unscheduled Visit Assessment with record position 0, displaying "Please inactivate the Ongoing Physical Exam form in the Unscheduled visit folder." (requires manual close)

Check Steps

	Type	Step	Edit
+	Data Point (Coded Value)	...>Unscheduled Visit Assessment>PEU>PEU>0>...>None	
+	Constant	NO (\$3)	
+	Check Function	IsEqualTo	
+	Data Point (Data Point)	...>Ongoing Physical Exam>PEREC>PEREC2>0>...>None	
+	Check Function	IsActive	
+	Check Function	And	
+	Add Check Step		



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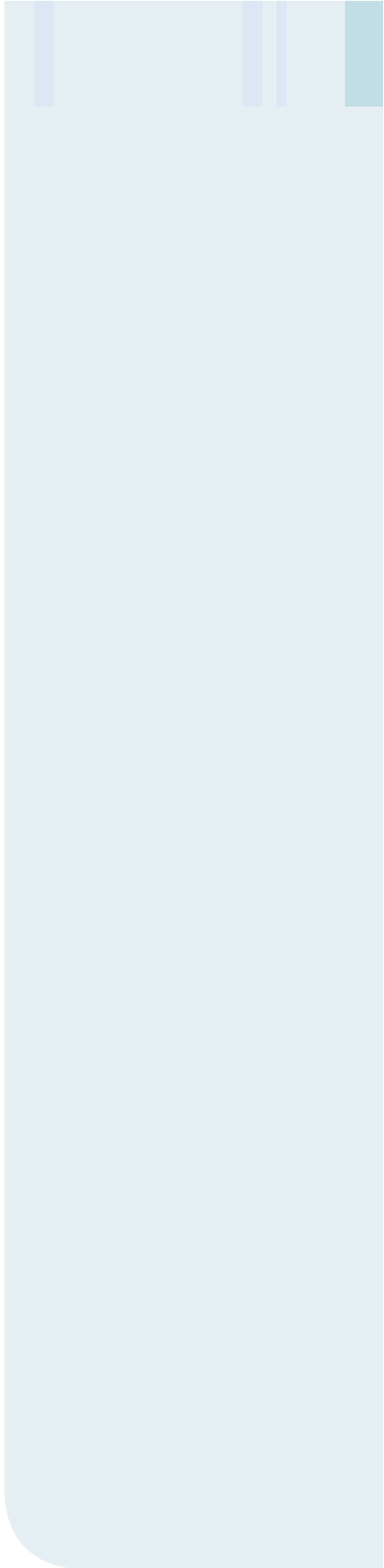
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