

## RAVE KT SESSION DOCUMENTATION

### 1. RAVE val url: <https://avdev.mdsol.com/>

Abbott  
A Promise for Life

English

User Name:

Password:

Enter [Activate New Account](#) [Forgot Password?](#)

Passwords are case sensitive.  
(Example: "AAA" is not the same as "aaa")

Technical Support is available by phone at 866-633-4328.  
For international tech support, please click the Customer Support Information link below.  
Upon calling the support desk, please enter the Abbott Vascular 3-digit support code: AVD (2-8-3).  
Medidata Rave® 2016.4.1  
Copyright © 1999-2016 Medidata Solutions, Inc.  
Patents Pending

[Click Here for Customer Support Information](#)

*Login page view*

### 2. The Home page:

Abbott  
A Promise for Life

Home

Study  [Hide Aux Studies](#)

Studies

- ABSORB III
- ABSORB III (DEV)
- ABSORB III (DSNAV)
- ABSORB III (QC)
- ABSORB III (UAT)
- ABSORB IV (DSNAV)
- ABSORB IV (QC)
- ABSORB Japan GT1 PMS (Dev)
- ABSORB PAS (DEV)
- AVAdmin
- AVAdmin (Dev)
- AVAdmin (QC)
- AVD-Test-Study (eLearning Required)
- AVD-Test-Study (Dev) (eLearning Required)
- AVJ-514 Japan Trial (DEV)
- AVJ-514 Japan Trial (DSNAV)
- AVJ-514 Japan Trial (QC)
- COAPT
- COAPT (DEV)
- COAPT (DSNAV)

Installed Modules

- Architect
- User Administration
- Site Administration
- Reporter
- Configuration
- Report Administration
- Lab Administration
- DDE
- Translation Workbench
- PDF Generator
- DCF
- Query Management
- Welcome Message

Last 10 subjects:

- ABSORB III QC
- 10392-28247-1001 Prod
- 12345 QC
- XIENCE SHORT DAPT QC
- COAPT QC
- COAPT

*Home page view*

### 3. The Study hierarchy:

Studies → Sites → Subjects → Folders → Forms

Site	Site Group	Site Number
118334 - Royal Brisbane and Women's Hospital	World	118334
26974 - Scripps Green Hospital	World	26974
26992 - Santa Barbara Cottage Hospital	World	26992
26999 - Torrance Memorial Medical Center	World	26999
27008 - Sharp Memorial Hospital	World	27008
27024 - Franciscan St Francis Health	World	27024
27053 - Saint Joseph's Hospital of Atlanta	World	27053
27076 - Sacred Heart Hospital of Pensacola	World	27076
27101 - Saint Francis Medical Center	World	27101
27119 - Massachusetts General Hospital	World	27119
27149 - Morton Plant Hospital	World	27149
27161 - University of Alabama Birmingham	World	27161
27239 - Lennox Hill Hospital	World	27239
27276 - Washington University	World	27276
27278 - University of Massachusetts Memorial Medical Center	World	27278

Visit	Date
Procedure (1)	09 Jan 2015
1-Month Follow-Up (1)	08 Feb 2015
6-Month Follow-Up (1)	08 Jul 2015
1-Year Follow-Up (1)	09 Jan 2016
2-Year Follow-Up (1)	08 Jan 2017
3-Year Follow-Up (1)	08 Jan 2018
4-Year Follow-Up (1)	08 Jan 2019
5-Year Follow-Up (1)	08 Jan 2020

4. **Subject Enrolment page:** Creating/enrolling a subject is done from Subject list page, by clicking into the “Add Subject” button.

The screenshot shows the 'Subject Enrolment page' in the Abbott QC system. The page header includes the Abbott logo, 'QC', and user information (User: saikat saha (Power User)). The main content area is divided into two sections. On the left, there is a 'Subject' list with a search bar and an 'Add Subject' button circled in red. The list contains several subjects, including '001', '0012', '10-392-100000-501', '10392-118334-1017', '7001', 'AB-01', 'AUD1', 'AUD1REPORT1', 'DF', 'PK-118334-0004', 'PK-118334-5656', 'TEST012345', 'TEST1234', and 'TEST-RECON2'. On the right, there is a 'Task Summary: Site' section with a table of tasks and their counts. The tasks include 'NonConformant Data' (1), 'Requiring Coding' (0), 'Requiring Translation' (0), 'Open Queries' (12), 'Answered Queries' (1), 'Requiring Review' (6), 'Requiring Verification' (12), 'Overdue Data' (5), 'Ready for Entry Lock' (15), 'Ready for Data Lock' (15), and 'Cancel Queries' (6). The page footer includes a 'Page 1' indicator and a '<< < Page 1 of 1 > >>' navigation bar.

5. **Subject enrollment :** While creating a subject the subject number must be given to distinguish a particular subject.

The screenshot shows the 'Subject Enrollment form' in the Abbott QC system. The form is titled 'Subject: 10392-118334-1017' and 'Page: Rave System Screening Information'. The form contains several fields for screening information, including 'Screening Date', 'Informed Consent Date', 'Inclusion and Exclusion Criteria Met', 'Screening Number', 'Subject Number', 'CTMS Study Number', and 'Screening Date (for CDRT)'. The 'Subject Number' field is circled in red. A red arrow points to the 'Save' button. The form also includes a 'Printable Version' link, a 'View PDF' link, and an 'Icon Key' link. The footer includes a 'Click Here for Customer Support Information' link and a copyright notice for Medidata Rave® 2016 4.1.

6. **The data that is the point of interest:**

From Rave to recon only three types of data flow.

- a. Adverse Event data ( AE data).
- b. Device Malfunction data (DVD data).
- c. Demographic data (DM data).

Other than these three type of data no other form need to be filled as they would be the waste of effort cuz ultimately they wont be going into the recon system. In recon system the data received in XML format.

## 7. Types of data that flow into recon :

The screenshot shows the 'Adverse Event' form in the Medidata Rave system. The top navigation bar includes the Abbott logo, 'QC' status, and user information (saikat saha, Power User). The left sidebar contains a menu with 'AE (2)', 'Adverse Event', 'AV Clinical Safety Monitor', and 'Adverse Event Coding'. The main form area is titled 'Subject: 10392-118334-1017' and 'Page: Adverse Event - AE (2)'. The form fields include: 'Adverse Event (AE)' dropdown, 'Other Specify' text field, 'Is this a vascular complication?' radio buttons (Yes/No), 'AE Description' text field, 'Chest pain, discomfort, pressure, tightness, sensation or other chest-pain like symptoms are part of this AE' radio buttons (Yes/No), 'Adverse Cardiac Event' radio buttons (Yes/No), 'If "Yes" is selected, complete an AE Cardiac Event form.' section with 'AE Condition at Onset' radio buttons (New, Worsening of Condition Diagnosed Before Index Procedure, Worsening of Condition Diagnosed After Index Procedure), 'Start Date' date field, 'Onset of AE' radio buttons (Procedure - Before Device Entered Vasculture, Procedure - After Device Entered Vasculture, Post-Procedure, Follow-Up), and a footer with 'Click Here for Customer Support Information' and 'Medidata Rave® 2016.4.1 Copyright © 1999-2016 Medidata Solutions, Inc.'

Figure 1 Adverse event from

The screenshot shows the 'Device Deficiency' form in the Medidata Rave system. The top navigation bar includes the Abbott logo, 'QC' status, and user information (saikat saha, Power User). The left sidebar contains a menu with 'Device Deficiency (1)', 'Device Deficiency and Non-Implanted Device Information', and 'GRF History'. The main form area is titled 'Subject: 10392-118334-1017' and 'Page: Device Deficiency and Non-Implanted Device Information - Device Deficiency (1)'. The form fields include: 'Occurrence Date' date field, 'Device Implanted' radio buttons (Yes/No), 'Was this a Device Deficiency?' radio buttons (Yes/No), 'Select Device Record Number' dropdown, 'Abbott Vascular Device' dropdown, 'Specify RX versus OTW' radio buttons (RX/OTW), 'Device Diameter' dropdown, 'Other Device Diameter, specify' text field, 'Device Length' dropdown, 'Other Device Length, specify' text field, 'Study Device Reference Code' text field, 'Study Device SN or LOT Number' text field, and 'Study Device S Number' text field. The footer includes 'Click Here for Customer Support Information' and 'Medidata Rave® 2016.4.1 Copyright © 1999-2016 Medidata Solutions, Inc.'

Figure 2 Device Malfunction form

Abbott QC

Messages My Profile Help Home Logout User: saikat saha (Power User)

118334 - Royal Brisbane and Women's Hospital 10392-118334-1017 Pre-Procedure (1) **Demographics**

Pre-Procedure (1)

Subject: 10392-118334-1017  
Page: Demographics - Pre-Procedure (1)

Gender at Birth? ☐ Male ☐ Female

Age (Years)?

Day of birth?

Cultural Origin, check all that apply?

American Indian or Alaskan Native?

Asian?

Black or African American?

Hispanic or Latino?

Native Hawaiian or Pacific Islander?

White?

Does not wish to disclose?

Highest Level of Education?

Employment (including self-employment)?

Household Income?

Printable Version View PDF Icon Key  
CRF Version 1435 - Page Generated: 22 Jun 2020 22:25:37 India Standard Time

Save Cancel

Figure 3 Demographic form

## 8. Different types of forms:

There are specifically two types of forms existing in RAVE interface.

- Regular Form : Where you can enter a single set of data, and most of the forms are regular forms e.g. **AE form**.
- Log Form : Where you can enter multiple sets of data. While entering they will appear like a regular form but after saving it will appear like a list, more like a log view of different actions e.g. **DVD form**

Abbott QC

Messages My Profile Help Home Logout User: saikat saha (Power User)

118334 - Royal Brisbane and Women's Hospital 10392-118334-1017 Device Deficiency (1) Device Deficiency and Non-Implanted Device Information

Device Deficiency (1)

Subject: 10392-118334-1017  
Page: Device Deficiency and Non-Implanted Device Information - Device Deficiency (1)

#	Occurrence Date?	Device Implanted?	Was this a Device Deficiency?	Select Device Record Number?	Abbott Vascular Device?	Specify Device RX versus OTW?	Device Diameter?	Other Device Diameter, specify?	Device Length?	Other Device Length, specify?	Study Device Reference Code?	Study Device SN or LOT Number?	Study Device S Number?	Device Expiration Date?	Did the BVS TagAlert show "OK" before being implanted into subject?	Device Package Opened?	Device Inserted Into Guiding Catheter?	Device Deficiency Resulted in an Adverse Event?	Adverse Event Resulted from Device Deficiency In?	Specify Adverse Event Record Number to be Treated?	CASS # of Lesion Intended?	Type of Device Deficiency or Reason for Not Implanting Device?	Contaminated by user?
1	21 JUN 2020	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
2	22 JUN 2020	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	

Add a new Log line Inactivate

Printable Version View PDF Icon Key  
CRF Version 1435 - Page Generated: 22 Jun 2020 22:36:02 India Standard Time

You can add a new log line by clicking this option

Save Cancel

Figure 4 A typical log form

## 9. Adding Adverse Event and Device Deficiency form in to the subject :

Abbott A Promise for Life

QC

12345

Enrollment

Pre-Procedure (1)

Adverse Events (1)

Study Completion (1)

Sponsor

CRF History

12345 - Adverse Event

10-392-100000-501 - Adverse Event

001 - Device Deficiency and Non-Implanted Device Information

Visit

Date

Save System Screening Information

Add Events ☐ Disabled ☒ Enabled

Add Event ...

Adverse Event

Core Lab - Follow-up

Core Lab - Procedure

Device Deficiency and Non-Implanted Device Information

Non-Target Lesion Information

Protocol Deviation

Target Lesion

Unscheduled - Angio Follow-Up

Unscheduled Visit

Add

Select the forms and click "Add" button

Figure 5 Adding Forms dynamically

## 10. The Build phase of a Study:

In the build phase of a study it is called a **Project**. And projects can be made and modified at the architect module of the RAVE.

Abbott A Promise for Life

Home

Installed Modules

Architect

User Administration

Site Administration

Reporter

Configuration

Report Administration

Lab Administration

DDE

Translation Workbench

PDF Generator

DCF

Query Management

Welcome Message

Last 10 subjects:

001 QC

AUDITREPORT1 QC

10-392-100000-501 QC

10392-118334-1017 QC

Study

Hide Aux Studies

Studies

ABSORB III

ABSORB III (DEV)

ABSORB III (DSNAV)

ABSORB III (QC)

ABSORB III (UAT)

ABSORB IV (DSNAV)

ABSORB IV (QC)

ABSORB Japan GT1 PMS (Dev)

ABSORB PAS (DEV)

AVAdmin

AVAdmin (Dev)

AVAdmin (QC)

AVD-Test-Study (eLearning Required)

AVD-Test-Study (Dev) (eLearning Required)

AVJ-514 Japan Trial (DEV)

AVJ-514 Japan Trial (DSNAV)

AVJ-514 Japan Trial (QC)

Figure 7 The architect module

Abbott A Promise for Life

Architect

Get Draft Template

Upload Draft

Amendment Manager

Scheduler

Add New Project:

Add Project

Active Projects

ABSORB III

ABSORB IV

ABSORB Japan GT1 PMS

ABSORB PAS

AV Global Standards

AVAdmin

AVD Mock Study - Amarnath REDDY

AVD Mock Study - dsNav1

AVD Mock Study - dsNav2

AVD Mock Study - dsNav3

AVD Mock Study - Sudheer Tadi

AVD Mock Study - Venkat Sungishala

AVD-Test-Study

AVJ-514 Japan Trial

COAPT

COAPT (AVDEV-Prod)

CoderTestStudy

ECHOTEST2

ECHOTEST4

Form Testing

Medflex

new\_project

Active projects

Figure 6 Existing active projects

## 11. CRF Drafts and all the modules inside project:

Let us discuss about the Architect hierarchy here. In the **Architect** we build a **project**, inside a project we create a **draft**, inside that draft we create **forms, folders, edit checks etc whatever is needed for the Study**. After building the draft we publish the draft as a **version** and push that version into the **Study**.

The screenshot shows the 'Project Settings' for 'ABSORB III'. The 'CRFDrafts' list includes various drafts, with '4.4\_Ver 1.0\_04JUN2020' selected. A callout box with an arrow points to the 'Add New Draft' button, stating 'To create a new draft'.

Click any of the draft to enter in that draft and to see the elements in the architectural state.

Figure 9 Draft phase

The screenshot shows the 'CRF Draft Settings' for '4.4\_Ver 1.0\_04JUN2020'. The 'Library Icon' is set to 'Study'. A callout box points to the 'Elements of a study' section, which includes a text area for the study description.

Elements of a study.

Figure 8 Element building phase

## 12. A Form Building stage and different elements of a Form:

Since only form is the point of interest here as of now, so this part is just to give a brief regarding the form element and an insider to the form.

- A form consists multiple fields.
- Fields are having distinctive characteristics and separated by unique OIDs

The screenshot shows the 'Forms' page with a table of forms. A callout box points to the 'Fields' column, stating 'Click to enter into a form'.

Order	Form Name	OID	Help Text	#Fields	Active	Other	Log Direction	Save Confirm	Redirect	Signature Required	Edit	Fields
1	Rave System Screening Information	SCRN	For enrolled subj...	8	✓	□	□	□	None	□	□	□
2	Registered	REG		1	✓	□	□	□	None	□	□	□
3	Rave System Screen Failure Information	SCRNFIL	%/abbottvascula...	13	✓	□	Landscape	□	None	□	□	□
4	Rave System Randomization	RAN		7	✓	□	□	□	None	□	□	□
5	Date of Visit	DOV	This form is used...	6	✓	□	□	□	None	□	□	□
6	Informed Consent	IC		6	✓	□	□	□	None	□	□	□
7	Inclusion Exclusion Criteria	INCL_EXCL	%/abbottvascula...	11	✓	□	□	□	None	□	□	□
8	Demographics	DM		14	✓	□	□	□	None	□	□	□
9	Pregnancy Test	PREG	This form will be...	5	✓	□	□	□	None	□	□	□
10	Physical Measurement	PHYSMNT	If Height, weight...	8	✓	□	□	□	None	□	□	□
11	Baseline Laboratory Assessment	BASELAB	The baseline labo...	9	✓	□	Landscape	□	None	□	□	□
12	Cardiac Enzymes	CARDENZ	Cardiac enzyme dr...	26	✓	□	□	□	None	□	□	□
13	ECG	ECG	12-Lead ECG MUST...	8	✓	□	□	□	None	□	□	□
14	Risk Factors and Medical History	MHRISK		14	✓	□	□	□	None	□	□	□
15	Cardiac History and Status	MHCARD		33	✓	□	□	□	None	□	□	□
16	PRO Tools Questionnaire	PROTOCOL		5	✓	□	□	□	None	□	□	□
17	Blood Draw Form	BDF		2	✓	□	Landscape	□	None	□	□	□
18	Antiplatelet Medications	APLTMED	Enter protocol re...	19	✓	□	Portrait	□	None	□	□	□
19	Concomitant Medications	CM	Administration of...	15	✓	□	Portrait	□	None	□	□	□
20	Loading Doses for Antiplatelet Medications	LOADMED	Subjects selected...	40	✓	□	□	□	None	□	□	□
21	Procedure	PROC		17	✓	□	□	□	None	□	□	□



Figure 11 Field view of a Form

**Note:**

- a. Two fields can have similar Variable OIDs but will definitely have unique Field OIDs.
- b. There are 4 datatypes
  - i. Numeric datatype : Only numeric values can be entered. (Sometimes radio button fields and drop down fields are also given the numeric datatype values.)
  - ii. Alphanumeric datatypes : Both alphabets and numeric values can be entered
  - iii. Date fields : Only date values can be entered.
  - iv. Check boxes : Check marks can be entered.

**13. Publishing a draft to version and to study:**

Item	Count	Updated	Include in Download
Forms	49	22 Jun 2020	<input checked="" type="checkbox"/>
Fields	1073	22 Jun 2020	<input checked="" type="checkbox"/>
Variables	785	22 Jun 2020	<input checked="" type="checkbox"/>
Folders	29	22 Jun 2020	<input checked="" type="checkbox"/>
Edit Checks	1647	22 Jun 2020	<input checked="" type="checkbox"/>
Valid Checks	1647		
Invalid Checks	0		
Derivations	33	22 Jun 2020	<input checked="" type="checkbox"/>
Data Dictionaries	219	22 Jun 2020	<input checked="" type="checkbox"/>
Unit Dictionaries	2	22 Jun 2020	<input checked="" type="checkbox"/>
Matrices	23	22 Jun 2020	<input checked="" type="checkbox"/>

Figure 12 Creating a version and publish



