

RAVE KT SESSION 2

⇒ This entire session is all about the RAVE to RECON configuration

1. The place to find the configuration:

The configuration lies in the “AVAdmin” study in the home page within which each study is specified as a single subject and within that subject there will be a folder named RECON. This folder carries the configuration mapping regarding the fields for which the data will be going from RAVE to RECON.

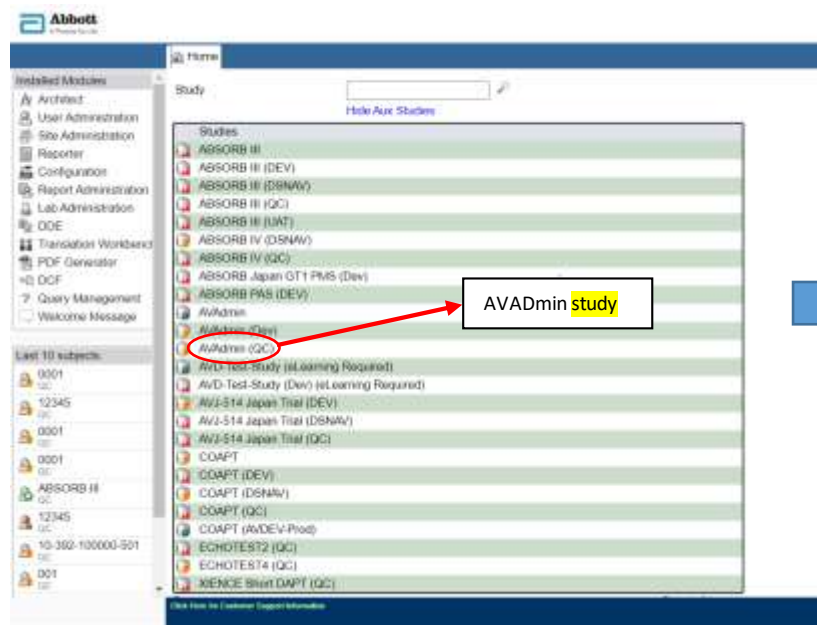


Figure 1 AVAdmin in home page



Figure 2 The AVAdmin Site

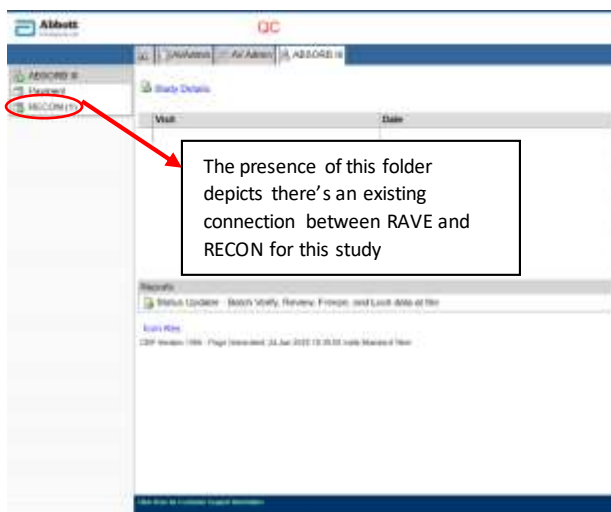


Figure 1 RECON configuration folder

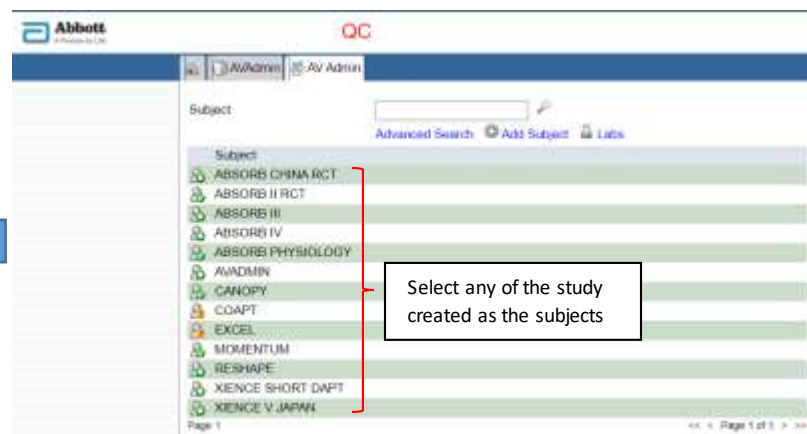


Figure 3 AvAdmin Subject page

2. Metadata:

There are 3 types Metadata are available in Rave that are configured to flow into the Recon.

- AE Metadata
- DM Metadata
- Subject Enrollment Metadata

The screenshot displays the CDISC SDTM Browser interface, specifically the 'AE Metadata' tab. The top navigation bar includes tabs for 'Admin', 'AS Admin', 'ASBOMB', 'RECON (1)', and 'AE Metadata' (highlighted with a red circle). Below the tabs, the 'Subject: ABSORB 81' and 'Page: AE Metadata - RECON (1)' are shown. The main content area features a table of AE metadata fields with columns for field names, data types, and various flags. The fields listed are: 'Generate Date', 'No. of days to fetch data', 'Form ID', 'Primary Form Type', 'AE Start Date', 'AE Event', 'Event Description', 'AE Domain', 'Treatment Given', 'AE Treatment', 'Related To Device', 'Outcome', and 'Action Taken'. Each field has a corresponding data type and a series of checkboxes for flags.

Figure 2 AE Metadata

QC

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

Subject: **ABSORB II**
 Page: **DM Metadata - RECON (1)**

Generate Data

No. of days to fetch data

[Enter '0' for all data.]

Form CID

Primary Form Type

DM Start Date

Event Description

Outcome

Action Taken

Serial Number

Lot Number

Reference Number

Recent Inclusion Criteria

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Metadata Export: 28 Feb 2021
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Figure 3 DM Metadata

QC

Messages My Profile Help Home Logout
(User: sakut.arya (Power User))

Buildman Admin ABSORB III RECON **Subject Details Metadata**

Subject: ABSORB III
Page: Subject Details Metadata - RECON (1)

General Data

Weight: PHYSNTH_WGT

Date of Birth: DMPL_AGE*

Gender: DMID_SEX

Procedure Date: INOCID_INOCSTDT

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Save Cancel

Click Here for Customized Support Information

Metadata Record 2023 (1)
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Figure 4 Subject Details Metadata

3. List of fields in the subject view to understand the relation:

Below are the list of fields that are available in Subject level which are configured in RECON details.

a. AE Metadata and AE Form and AETREAT Form relation =>

Subject: 0001

Page: Adverse Event - AE 01-MI ?

Adverse Event (AE) ?

Other Specify

AE Description ? ASDFG

Start Date ? 22 JUN 2021

AE Related to Study Indirect Procedure ? Not Related

AE Related to Device Deficiency of Sponsor Study Device ? Not Related

Serious Adverse Event (SAE) Occurred ? No

Death ?

Life Threatening ?

Requires or Prolongs Hospitalization ?

Intervention to Prevent Permanent Impairment/Damage ?

Persistent or Significant Disability/Incapacity ?

Congenital Anomaly ?

Other Medical Events Deemed Serious by Medical Judgment ?

Date Study Personnel Became Aware of SAE ?

Action Taken or Treatment for AE

If "Yes" Complete AE Treatment Form ? No

Outcome of AE?	Unknown*
If Outcome of AE is 'Death', complete the Study Completion eCRF:	
Stop Date?	
Death Date?	-
Primary Cause of Death?	
Autopsy Performed?	
AE Condition at Onset?	
New*	

Subject: 0001
Page: Adverse Event Treatments - AE 01-MI

Action/Treatment?	Medication
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Figure 5 AE Form and AETREAT Form fields' data that will be going to RECON

b. DM Metadata from Device Deficiency Form:

Occurrence Date?	22 JUN 2020
Study Device SN or LOT Number?	1234*
Type of Device Deficiency or Reason for Not Implanting Device:	
Packaging issue?	<input checked="" type="checkbox"/>
Contaminated by user	<input type="checkbox"/>
Opened in error/wrong size	<input type="checkbox"/>
Unable to prepare device properly	<input type="checkbox"/>
Device damaged prior to insertion in anatomy?	<input type="checkbox"/>
Device dislodgement outside of body	<input type="checkbox"/>
Device loose on balloon delivery system	<input type="checkbox"/>
Unable to load into guide wire	<input type="checkbox"/>
Unable to insert device into guide catheter	<input type="checkbox"/>
Difficulty advancing delivery system (trackability) due to resistance with ?	<input type="checkbox"/>
Another device	<input type="checkbox"/>
Anatomy	<input type="checkbox"/>
Failure to advance delivery system due to resistance with:	<input type="checkbox"/>
Another device	<input type="checkbox"/>
Anatomy	<input type="checkbox"/>
Device damaged after failure to advance?	<input type="checkbox"/>
Device loose on balloon delivery system after failure to advance	<input type="checkbox"/>
Marker visibility issues	<input type="checkbox"/>
Treatment(s) Related to Device Deficiency or Malfunction?	None*

Figure 6 DM Form fields that will be going to RECON

c. Subject Details Metadata from Demographics and Physical Measurement Form:

Subject: 0001

Page: **Demographics - Pre-Procedure (1)**

Gender at Birth: Male

Age (Years): 24

Subject: 0001

Type: Physical Measurement - Pre-Procedure (1)

Weight: 60 kg

Figure 7 Subject Details Fields that will be going to RECON

- ⇒ The provided data in the above mentioned fields in those forms are eligible only to go to the RECON system.
- ⇒ The data received on the RECON system updates on everyday 5.30pm IST / 12 pm GMT.
- ⇒ The data that is created on a particular day, will be reflected on the very next day after that specified time above.