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.
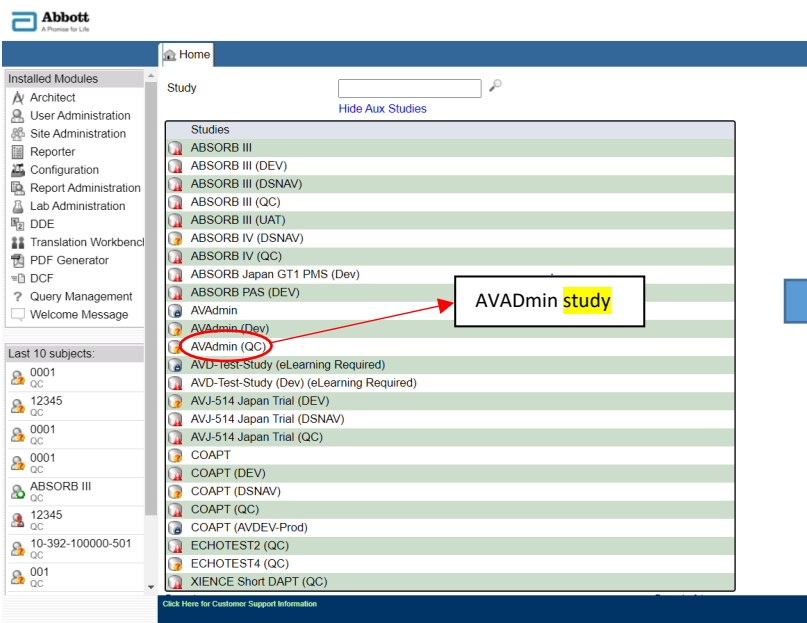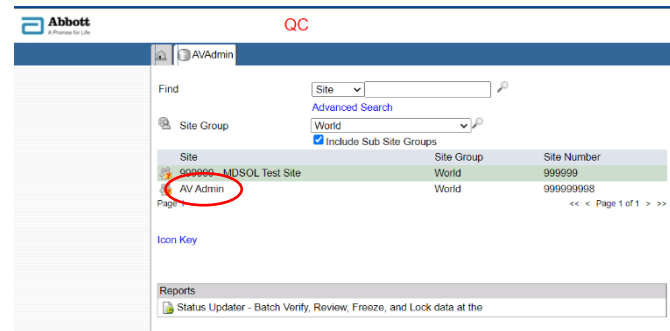

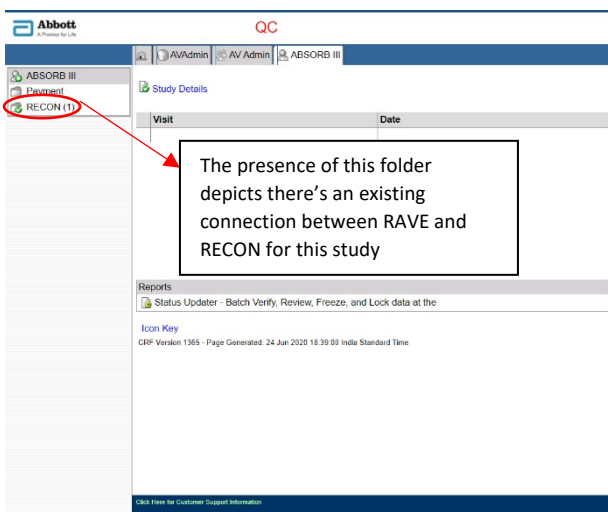*Figure 1 AVAdmin in home page*

Figure 2 The AVADmin SIte

Figure 3 AvAdmin Subject page

Figure 1 RECON configuration folder
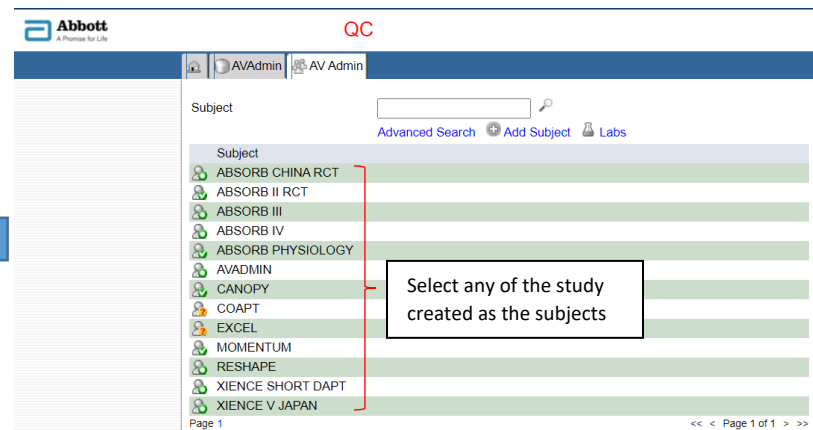
2. Metadata:

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

    a. AE Metadata

    b. DM Metadata

    c. Subject Enrollment Metadata

Figure 2 AE Metadata

Figure 3 DM Metadata

Figure 4 Subject Details Metadata

3. <u>List of fields in the subject view to understand the relation:</u>

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

a. <u>AE Metadata and AE Form and AETREAT Form relation =></u>

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		

Figure 5 AE Form and AETREAT Form fields' data that will be going to RECON

b. <u>DM Metadata from Device Deficiency Form:</u>

Occurrence Date [?]	22 JUN 2020
Study Device SN or LOT Number [?]	1234

Type of Device Deficiency or Reason for Not Implanting Device:

Packaging issue [?]	✓
Contaminated by user	
Opened in error/wrong size	
Unable to prepare device properly	
Device damaged prior to insertion in anatomy [?]	
Device dislodgement outside of body	
Device loose on balloon delivery system	
Unable to load onto guide wire	
Unable to insert device into guide catheter	
Difficulty advancing delivery system (trackability) due to resistance with: [?]	
Another device	
Anatomy	
Failure to advance delivery system due to resistance with:	
Another device	
Anatomy	
Device damaged after failure to advance [?]	
Device loose on balloon delivery system after failure to advance	
Marker visibility issues	
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:

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.