

Participant Transfer and Receipt Process within Medidata Rave

Transferring site:

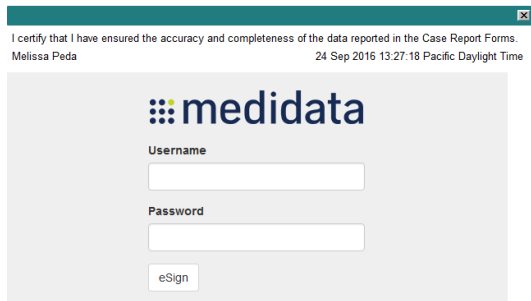
1. Mark 'Participant Transfer' under the Additional Forms section on the appropriate Date of Visit CRF; The Transfer form now appears in that visit folder.
2. Complete and save the Transfer form.
3. Ensure all data queries placed within the Rave database for the participant are resolved and all required eCRFs have been completed;
4. Investigator of Record or designee must verify that the data is complete and accurate by signing off on the participant's eCRFs as follows:
 - IoR (or designee) logs into Medidata and selects transferring PTID. On the Participant page, select "Grid View":

The screenshot shows the Medidata Rave interface. The top navigation bar includes the SCHARP logo, UAT, and user information: "You have 3 'Rave Modules' invitations in iMedidata. User: Julie Ngo (Clinical Research Coordinator)". The main content area displays a table of visits for participant 990244801. The table has columns for Visit, Date, Task Summary, and Subject. The tasks listed are: Requiring Signature (4 pages), NonConformant Data (0 pages), Open Queries (2 pages), and Overdue Data (0 pages). A red circle highlights the "Grid View" button in the top right corner.

- Grid View lists all forms completed and expected for a participant.
- To sign off on all completed forms for the PTID, select "All" forms while in Grid View and then click "Sign and Save".

The screenshot shows the Medidata Rave interface in Grid View. The top navigation bar includes the SCHARP logo, UAT, and user information: "You have 3 'Rave Modules' invitations in iMedidata. User: Julie Ngo (Clinical Research Coordinator)". The main content area displays a table of forms for participant 991945481. The table has columns for Participant Identifier, Pre-Screening, V1 - Screening, V2 - Enrollment, V3 - Month 1, and Ongoing Logs. The forms listed are: Participant Identifier, Pre-Screening Outcome, Date of Visit, Participant Date of Visit, Eligibility Criteria, Demographics, Baseline Medical History Y/N, Pelvic Exam, Physical Exam, Vital Signs, Enrollment, Adverse Experience Y/N, Adverse Experience, Concomitant Medications Y/N, Concomitant Medications, STI Test Results, and Clinical Product Hold/Discontinuation Y/N. A red circle highlights the "Sign and Save" button in the top left corner.

- A signature prompt will display alongside a user ID and password text box. This serves as your electronic signature:



Note: The time that it takes for Medidata Rave to apply the IoR signature to all completed eCRFs will depend on the number of completed CRFs within the participant's casebook. If there are large number of completed eCRFs, the application of eSignatures may take up several minutes.

Receiving Site:

1. Prior to the participant's first scheduled visit at your site, confirm that the participant's casebook is accessible within the Medidata Rave database from your site homepage. Note that the participant retains their original PTID.
2. When participant arrives for the first visit at your site, navigate to the participant's Medidata casebook.
3. Mark 'Participant Receipt' under the Additional Forms section on the appropriate Date of Visit CRF; The Receipt form now appears in that visit folder.
4. Complete and save the Transfer form.