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":

SCHARP	UAT				👔 iMedidata 🖂 Messages 🔯 My Profile 😨 Help 🏩 Home 🕅 Logout User: Leslie Cottle (Clinical Research Coordinator)			
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A 001163750	i 🛯	Participant Identifier			Grid View			
V2.0 - Day 0/Enrollmer								
V3.0 - Week 2 (1)		Visit	Date	V Task Summary: Subject	Pages			
V4.0 - Week 4 (1)		V2.0 - Day 0/Enrollment		Para Para Para Para Para Para Para Para	4 🖓			
V5.0 - Week 5 (1)	1	V29.0 - Week 97 (1)	29 Feb 2	016 🕞 🔔 NonConformant Data	107			
V6.0 - Week 6 (1)	-			V 🥐 Open Queries	3 🗗			
V7.0 - Week 9 (1)				V2.0 - Day 0/Enrollment-Enrollment				
(3 V2 0 - Week 10 (1)				Interim Visit 29.1-Interim Visit Summary				

- 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".

Participant Identifier							Calendar View
Sign and Save	991945481	Pre- Screening	V1 - Screening (1)	V2 - Enrollment (1)	V3 - Month 1 (1)	✓ Ongoing Logs (1)	All
Participant Identifier							Participant Identifier
Pre-Screening Outcome		2					Pre-Screening Outcome
Date of Visit					3		Date of Visit
Participant Date of Visit			3	6			Participant Date of Visit
Eligibility Criteria			3				Eligibility Criteria
Demographics			0				Demographics
Baseline Medical History Y/N			0				Baseline Medical History Y/N
Pelvic Exam			0				Pelvic Exam
Physical Exam			0				Physical Exam
Vital Signs			0				Vital Signs
Enrolment				3			Enrolment
Adverse Experience Y/N						3	Adverse Experience Y/N
Adverse Experience						2	Adverse Experience
Concomitant Medications Y/N			3	0		2	Concomitant Medications Y/N
Concomitant Medications						3	Concomitant Medications
STI Test Results			0				STI Test Results
Clinical Product Hold/Discontinuation Y/N						0	Clinical Product Hold/Discontinuation Y/N

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

	×					
l certify that I have ensured Melissa Peda	the accuracy and completeness of the data reported in the Case Report Forms. 24 Sep 2016 13:27:18 Pacific Daylight Time					
	::: medidata					
	Username					
	Password					
	eSign					

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.