

# MTN-036/IPM 047 Study-Specific Training Agenda

## Monday, September 11, 2017

### SF Bridge Clinical Research Site (on-site)| Alabama Clinical Research Site (remote)

Time	Topic	Presenter
<b>8:00 – 8:05 am PT</b> <b>10:00 – 10:05 am CT</b> <b>11:00 – 11:05 am ET</b>	Welcome and Introductions Review of Training Agenda and Materials	Tara McClure
<b>8:05 – 8:15 am PT</b> <b>10:05 – 10:15 am CT</b> <b>11:05 – 11:15 am ET</b>	Protocol Overview <ul style="list-style-type: none"> <li><input type="checkbox"/> Background</li> <li><input type="checkbox"/> Study Objectives</li> <li><input type="checkbox"/> Study Design</li> <li><input type="checkbox"/> Accrual and Retention Targets</li> <li><input type="checkbox"/> Population and Key Eligibility Criteria</li> <li><input type="checkbox"/> Key Study Resources and Team Communication(s)</li> </ul>	Albert Lui
<b>8:15 – 8:40 am PT</b> <b>10:15 – 10:40 am CT</b> <b>11:15 – 11:40 am ET</b>	Screening and Enrollment Considerations <ul style="list-style-type: none"> <li><input type="checkbox"/> Procedures Overview/Initial Eligibility Assessment</li> <li><input type="checkbox"/> Eligibility Confirmation</li> <li><input type="checkbox"/> Tools/Worksheets</li> <li><input type="checkbox"/> Counseling Requirements</li> </ul> <i>SSP Reference: Section 5: Study Procedures; Section 4: Informed Consent; Section 11: Counseling Considerations</i>	Tara McClure Lisa Levy
<b>8:40 – 9:15 am PT</b> <b>10:40 – 11:15 am CT</b> <b>11:40 am – 12:15 pm ET</b>	Screening and Enrollment CRFs PTID Assignment Randomization Procedures <i>SSP Reference: Section 12: Data Collection</i>	Tanya Harrell Jen Berthiaume
<b>9:15 – 9:40 am PT</b> <b>11:15 – 11:40 am CT</b> <b>12:15 – 12:40 pm ET</b>	Follow Up Considerations <ul style="list-style-type: none"> <li><input type="checkbox"/> Procedures/Schedule Overview</li> <li><input type="checkbox"/> Tools/Worksheets</li> <li><input type="checkbox"/> PK specimen collection coordination</li> </ul> <i>SSP Reference: Section 5: Study Procedures; Section 10: Laboratory Considerations, and Section 12: Data Collection</i>	Tara McClure Lisa Levy
<b>9:40 – 10:05 am PT</b> <b>11:40 am – 12:05 pm CT</b> <b>12:40 – 1:05 pm ET</b>	Follow-up Visit CRFs and other tools <i>SSP Reference: Section 12: Data Collection</i>	Tanya Harrell Jen Berthiaume
<b>10:05 – 10:15 am PT</b> <b>12:05 – 12:15 pm CT</b> <b>1:05 – 1:15 pm ET</b>	Break	
<b>10:15 – 10:45 am PT</b> <b>12:15 – 12:45 pm CT</b> <b>1:15 – 1:45 pm ET</b>	Study Product Considerations (Non-Pharmacy Staff) <ul style="list-style-type: none"> <li><input type="checkbox"/> Prescription Completion</li> <li><input type="checkbox"/> Vaginal Ring Dispensation and Labeling</li> <li><input type="checkbox"/> Chain of Custody and Accountability</li> <li><input type="checkbox"/> Vaginal Ring Request Slip: Resupply, Hold, Permanent Discontinuation and Product Use Period Completed</li> <li><input type="checkbox"/> Vaginal Ring Retrievals</li> <li><input type="checkbox"/> Vaginal Ring Complaints</li> </ul> <i>SSP Reference: Section 7: Study Product Considerations for Non-Pharmacy Staff</i>	Lindsay Kramzer

<b>10:45 – 11:30 am PT</b> <b>12:45 – 1:30 pm CT</b> <b>1:45 – 2:30 pm ET</b>	<b>Clinical Management Considerations</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Physical and Pelvic Exams</li> <li><input type="checkbox"/> Medical and Menstrual History</li> <li><input type="checkbox"/> STI/RTI/UTI Management</li> <li><input type="checkbox"/> Concomitant Medications</li> <li><input type="checkbox"/> Contraceptive Requirements</li> <li><input type="checkbox"/> Prohibited Medications and Practices</li> <li><input type="checkbox"/> Product Use Management</li> <li><input type="checkbox"/> Vaginal Bleeding</li> </ul> <i>SSP Reference: Section 8: Clinical Considerations and SSP Section 9: Safety Monitoring</i>	Katie Bunge
<b>11:30 am – 12:00 pm PT</b> <b>1:30 – 2:00 pm CT</b> <b>2:30 – 3:00 pm ET</b>	<b>Overview of Laboratory Considerations</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Protocol-required laboratory tests</li> <li><input type="checkbox"/> Specimen collection and processing</li> <li><input type="checkbox"/> LDMS Tracking Sheet(s)</li> </ul> <i>SSP Reference: Section 10: Laboratory Considerations</i>	Lorna Rabe May Beamer
<b>12:00 – 12:45 pm PT</b> <b>2:00 – 2:45 pm CT</b> <b>3:00 – 3:45 pm ET</b>	Lunch	
<b>12:45 – 1:15 pm PT</b> <b>2:45 – 3:15 pm CT</b> <b>3:45 – 4:15 pm ET</b>	<b>Overview of Behavioral Assessments</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> CASI assessments</li> <li><input type="checkbox"/> IDI randomization and participation</li> <li><input type="checkbox"/> Ring Adherence CRF</li> </ul> <i>SSP Reference: Section 6: Behavioral Assessments</i>	Rachel Weinrib
<b>1:15 – 1:45 pm PT</b> <b>3:15 – 3:45 pm CT</b> <b>4:15 – 4:45 pm ET</b>	<b>Clinical Management and Laboratory-Related CRFs</b> <i>SSP Reference: Section 12: Data Collection</i>	Tanya Harrell Jen Berthiaume
<b>1:45 – 2:15 pm PT</b> <b>3:45 – 4:15 pm CT</b> <b>4:45 – 5:15 pm ET</b>	<b>Site Strategies</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Recruitment methods</li> <li><input type="checkbox"/> All-day clinic visit considerations</li> </ul>	Site IoRs, Study Coordinators
<b>2:15 – 2:45 pm PT</b> <b>4:15 – 4:45 pm CT</b> <b>5:15 – 5:45 pm ET</b>	<b>Medidata RAVE Considerations</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> User Accounts</li> <li><input type="checkbox"/> Navigation</li> <li><input type="checkbox"/> Query Management</li> <li><input type="checkbox"/> QC Processes</li> <li><input type="checkbox"/> Study Reports</li> </ul>	Tanya Harrell Jen Berthiaume <i>(targeted to those who will be entering data directly into Medidata)</i>
<b>2:45 – 3:00 pm PT</b> <b>4:45 – 5:00 pm CT</b> <b>5:45 – 6:00 pm ET</b>	<b>Wrap Up/Review of Pending Questions/Training Action Items</b> <b>Review Study Timeline, Completion of Pending Site Activation Requirements and Activation</b>	Site IoR, Study Coordinator, Management Team, as needed.
<b>3:00 – 3:30 pm PT</b> <b>5:00 – 5:30 pm CT</b> <b>6:00 – 6:30 pm ET</b>	<b>Medidata Practice (Optional)</b>	Tanya Harrell Jen Berthiaume <i>(targeted to those who will be entering data directly into Medidata)</i>
	SF Site walk-through	Tara McClure Lisa Levy SF site staff
	Adjourn	

(Next page for webinar/call-in information)

# MTN-036/IPM 047 Study-Specific Training Agenda

**Monday, September 11, 2017**

**SF Bridge Clinical Research Site (on-site) | Alabama Clinical Research Site (remote)**

For those participating/presenting remotely, please use the following information to join the training:

- Webinar link: [MTN-036 Training \(Webinar\)](#)
- Call-In Toll Free Phone Number: 866.740.1260 | Access Code: 4011527

**NOTE: You must use the webinar link to view the presentations and the phone access for audio (listen and speak).**