Visit Procedures & Form Completion

MTN 005
Study-Specific Training
Where are these procedures described?

- Protocol Table 4 (Screening)
- Protocol Table 5 (Enrollment)
- Protocol Table 6 (Follow-up Visits)
- Protocol Table 7 (16-Week/Study Termination Visits)
- SSP Section 7 (Checklists)
- Appendix I of the protocol
Visit Checklists

- Each site should develop visit checklists for each study visit
- Examples are provided in SSP Section 7
- Checklists may vary by cohort (IVR vs. no-IVR)
- Checklists should be designed so that procedures are listed in logical order according to visit flow
Order of Presentation

- Per visit, we will cover:
  - Visit procedures
  - Form completion
  - Relevant checklists and exam details
Screening Procedures
Complete Physical Exam
What Must Be Included?

- See Appendix III of the protocol

- Height (may be omitted after the Enrollment Visit)
- Weight (may be omitted after the Enrollment Visit)
- Vital signs
  - Temperature
  - Pulse
  - Blood pressure
- General appearance
- Abdomen
- Other components as indicated by participant symptoms
Eligibility Checklist
Screening Forms
Questions?
Enrollment Procedures

name (print)

signature
Questions?
Randomization

Pharmacy
Follow-Up Visits
Follow-Up Visit Forms
Questions?
Termination / 16-Week Visit
Termination / 16-Week Visit Forms
Questions?
Interim Visit
Questions?