

MTN 005 Study-Specific Procedures Manual

Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Current Version Number	Current Version Date	Updates and Comments
1	Introduction	1.0	25 April 2011	First final version.
2	Protocol	1.0	25 April 2011	First final version.
3	Documentation Requirements	1.0	25 April 2011	First final version.
4	Participant Accrual	1.0	25 April 2011	First final version.
5	Informed Consent	1.0	25 April 2011	First final version.
6	Participant Follow-up	1.1	05 March 2012	Updated for guidance on split enrollment visit; added scenarios for ACASI.
7	Visit Checklist	1.0	25 April 2011	First final version.
8	Participant Retention	1.0	25 April 2011	First final version.
9	Study Product Considerations for Non-Pharmacy Staff	1.0	25 April 2011	First final version.
10	Clinical Considerations	1.0	25 April 2011	First final version.
11	Adverse Event Reporting and Safety Monitoring	1.0	25 April 2011	First final version.
12	Laboratory Considerations	1.0	25 April 2011	First final version.
13	Data Collection	1.1	01 December 2011	
14	Counseling Considerations	1.0	25 April 2011	First final version.
15	Data Communiqués	1.0	25 April 2011	First final version.
16	ACASI Users' Manual	1.0	25 April 2011	First final version.
17	Study Reporting Plan	1.0	25 April 2011	First final version.