

MTN-009 Study-Specific Procedures Manual

Table of Contents

Section 1. Introduction

1.1	Sources of Procedural Information.....	1-1
1.2	Investigator Responsibilities	1-1
1.3	Study Activation Process.....	1-2

Section 2. Protocol

Section 3. Documentation Requirements

3.1	Essential Documents	3-1
3.2	Participant Case History Documentation	3-2
3.2.1	Case History Contents	3-2
3.2.2	Concept of Source Data and Source Documentation	3-3
3.2.3	Document Organization	3-5
3.3	Record Retention Requirements.....	3-6

Section 4. Participant Accrual

4.1	Study Accrual Plan.....	4-1
4.2	Screening and Enrollment: Definition and Procedures	4-1
4.2.1	Screening and Enrollment HIV Testing	4-5
4.3	Screening and Enrollment Logs	4-6
4.4	Informed Consent.....	4-7
4.5	Obtaining Locator Information	4-10

Section 5. Participant Follow-up

5.1	Overview of Study Follow-up Plan.....	5-1
5.2	Types of Follow-up Visits.....	5-1
5.3	Follow-up Visit Location	5-1
5.4	Follow-up Visit Scheduling.....	5-2
5.4.1	Target Visit Windows	5-2
5.4.2	Allowable Visit Windows	5-2
5.4.3	Missed Visits	5-3
5.5	Follow-up Visit Procedures.....	5-3
5.6	Updating Locator Information.....	5-3
5.7	Reporting of Social Harm.....	5-3

Section 6. Counseling Considerations

6.1	General Counseling Information	6-1
6.2	HIV Counseling.....	6-3
6.2.1	CD4-positive T cell and Viral Load Results	6-6
6.2.2	Resistance Test Results	6-6
6.3	Helpful Hints for Promoting Care and Support Options	6-7
6.4	Documentation	6-7

Section 7. Visit Checklists

7.1	Visit Checklists	7-1
7.2	Sequence of Procedures.....	7-2

Section 8. Laboratory Considerations

8.1	Overview and General Guidance.....	8-1
8.2	Specimen Labeling	8-2
8.3	Use of LDMS	8-3
8.4	Blood Collection, Processing, Testing, and Storage	8-4
8.4.1	Specimen Collection and Initial Processing	8-4
8.4.2	HIV-1 RNA Viral Load.....	8-4
8.4.3	HIV-1 Genotypic Resistance.....	8-5
8.4.4	Recent/Chronic Infection	8-5
8.4.5	CD4+ T Cell Count	8-6
8.4.6	Plasma Archive	8-6
8.4.7	Rapid HIV and Western Blot Testing	8-6

Section 9. Data Collection

9.1	DataFax Overview.....	9-1
9.2	DataFax Form Completion.....	9-2
9.2.1	General Guidelines	9-2
9.2.2	How to Mark Response Boxes	9-3
9.2.3	How to Record Numbers.....	9-3
9.2.4	How to Record Dates	9-4
9.2.5	How to Record Time	9-4
9.2.6	Data Corrections and Additions	9-5
9.2.7	How to Handle Missing and Unknown Data.....	9-6
9.3	MTN-009 Study-Specific Data Collection Information.....	9-7
9.3.1	Participant ID numbers (PTIDs).....	9-7
9.3.2	Study Visit Timing	9-7
9.3.3	Visit Codes and Split Visits.....	9-8
9.3.4	Staff Initials/Date	9-8
9.3.5	Site Review of DataFax Forms	9-8
9.3.6	Faxing DataFax Forms	9-9
9.4	Form Supply and Storage.....	9-9
9.4.1	Form and Specimen Label Supply	9-9
9.4.2	Form Storage	9-10
9.5	Form Completion Instructions.....	9-10
9.6	Case Report Forms	9-11

Section 10. Data Communiqués

Section 11. Study Reporting Plan

11.1	Purpose of Reporting Plan.....	11-1
11.2	Study Reports	11-1
11.2.1	Data Quality Control (QC) Report	11-3
11.2.2	Specimen Monitoring Report	11-3
11.2.3	Enrollment Report	11-3

11.2.4	Visit Procedure Completion Report	11-3
11.2.5	Site Data Management Quality Report	11-3
11.2.6	Study Monitoring Committee (SMC) Report.....	11-4
11.2.7	Network Lab Assay Results Report	11-4

Section 12. ACASI Users Manual