

**MTN-007 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	2.0	20 August 2010	<ul style="list-style-type: none"> <li>No Changes</li> </ul>
2	Protocol	2.0	20 August 2010	<ul style="list-style-type: none"> <li>No Changes</li> </ul>
3	Documentation Requirements	2.1	13 September 2010	<ul style="list-style-type: none"> <li>Updated to include new case report form (Enrollment Visit Eligibility)</li> </ul>
4	Participant Accrual	2.1	17 December 2010	<ul style="list-style-type: none"> <li>Updated Section 4.2.4 to clarify participants may be rescreened if otherwise eligible but the 36 day screening and enrollment timeframe has passed due to unforeseen circumstances</li> </ul>
5	Informed Consent	2.0	20 August 2010	<ul style="list-style-type: none"> <li>No Changes</li> </ul>
6	Participant Follow-Up	2.1	17 December 2010	<ul style="list-style-type: none"> <li>Updated Section 6.10.3 to clarify study product completion procedures for participants randomized to receive gel</li> </ul>
7	Visit Checklists	2.2	07 March 2011	<ul style="list-style-type: none"> <li>Updated the Screening, Enrollment, Treatment 1 and Treatment 2 Visits checklists to clarify that contraceptive counseling is applicable to <u>all</u> study participants; not only females of child bearing potential</li> </ul>
8	Participant Retention	2.0	20 August 2010	<ul style="list-style-type: none"> <li>No Changes</li> </ul>
9	Study Product Considerations for Non-Pharmacy Staff	2.1	07 January 2011	<ul style="list-style-type: none"> <li>Updated Section 9.6 to clarify allowable timeframe in which study product should be retrieved from a study participant following the Final Clinic Visit</li> </ul>
10	Clinical Considerations	2.2	01 November 2010	<ul style="list-style-type: none"> <li>Updated Section 10.3 to clarify the Pre-existing Conditions CRF is to be completed at the Screening Visit and reviewed/updated at the Enrollment Visit</li> </ul>
11	AE Reporting and Safety Monitoring	2.2	07 January 2011	<ul style="list-style-type: none"> <li>Updated Section 11.11.2 to include the Protocol Co-Chair as a member of the PSRT</li> <li>Updated Section Appendices I and II to correct hyperlinks to the DAIDS Grading Tables</li> <li>Updated Section Appendix III to include the revised PSRT Query Form</li> <li>Updated Section 11.11.4 to update instructions for viewing and discussing PSRT queries via the PSRT Query Message Board on SCHARP/ATLAS</li> </ul>
12	Laboratory Considerations	2.3	15 November 2010	<ul style="list-style-type: none"> <li>Updated Section 12.7.5 to revise processing procedures for the lavage for Epithelial Sloughing</li> </ul>
13	Data Collection	2.1	13 September 2010	<ul style="list-style-type: none"> <li>Updated to include revised DataFax case report forms (AE Log and Pregnancy Outcome); revised (non-DataFax) case report forms (Medical Eligibility and Screening Visit Eligibility); and a new (non-DataFax) case report form (Enrollment Visit Eligibility)</li> </ul>

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14	Data Communiqués	2.0	20 August 2010	<ul style="list-style-type: none"> <li>• Includes Data Communiqué #1 dated 03 September 2010; Data Communiqué #2 dated 13 September 2010; Data Communiqué #3 dated 23 September 2010 and Data Communiqué #4 dated 10 November 2010</li> </ul>
15	Study Reporting Plan	2.0	20 August 2010	<ul style="list-style-type: none"> <li>• No Changes</li> </ul>
16	Behavioral Measures: Web-Based Questionnaires and Phone Reporting System	2.1	03 December 2010	<ul style="list-style-type: none"> <li>• Section 6.2.2 was updated to clarify that participants must report any medical problems they are having to site staff rather than using the PRS to submit such concerns.</li> <li>• Updated to include new Section 16.2.3 which describes how to determine compensation owed to participants for calling into the PRS (prior to Final Clinic Visit).</li> <li>• Updated to include new Section 16.4 to clarify procedures for completing behavioral measures for participants who have permanently discontinued study product use.</li> </ul>