

**MTN-011 Study-Specific Procedures Manual**  
**Overview of Section Contents and Identification of Current Section Versions**

| <b>Section Number</b> | <b>Section Title</b>                                | <b>Current Version Number</b> | <b>Current Version Date</b> | <b>Updates and Comments</b> |
|-----------------------|---|-------------------------------|-----------------------------|-----------------------------|
| 1                     | Introduction  | 2.0                           | 13 November 2013            |                             |
| 2                     | Protocol  | 2.0                           | 13 November 2013            |                             |
| 3                     | Documentation Requirements                          | 2.0                           | 13 November 2013            |                             |
| 4                     | Participant Accrual and Enrollment                  | 2.0                           | 13 November 2013            |                             |
| 5                     | Participant Follow-Up                               | 2.0                           | 13 November 2013            |                             |
| 6                     | Participant Retention                               | 2.0                           | 13 November 2013            |                             |
| 7                     | Study Product Considerations For Non-Pharmacy Staff | 2.0                           | 13 November 2013            |                             |
| 8                     | Clinical Considerations and Safety Monitoring       | 2.0                           | 13 November 2013            |                             |
| 9                     | Laboratory Considerations                           | 2.0                           | 13 November 2013            |                             |
| 10                    | Data Collection                                     | 2.0                           | 13 November 2013            |                             |
| 11                    | Data Communiqués                                    | 2.0                           | 13 November 2013            |                             |
| 12                    | CASI Users Manual                                   | 2.0                           | 13 November 2013            |                             |
| 13                    | Counseling Considerations                           | 2.0                           | 13 November 2013            |                             |
| 14                    | Study Reporting Plan                                | 2.0                           | 13 November 2013            |                             |