

MTN-020 Study-Specific Procedures Manual

Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Version Number(s)	Version Date(s)	Updates and Comments for Version Change (if applicable)
1	Introduction	1.0 1.1 1.2	17 July 2012 31 January 2013 31 July 2014	<ul style="list-style-type: none"> No updates
2	Protocol	1.0 1.1	17 July 2012 31 January 2014	<ul style="list-style-type: none"> No updates
3	Documentation Requirements	1.0 1.1 1.2 1.3 1.4 1.5	17 July 2012 31 January 2013 31 July 2013 31 January 2014 31 July 2014 13 February 2015	<ul style="list-style-type: none"> Section 3.6 updated to clarify that all materials that are read verbatim or provided to the participant must be translated
4	Participant Accrual, Screening and Enrollment	1.0 1.1 1.2	17 July 2012 31 January 2013 31 July 2013	<ul style="list-style-type: none"> No updates
5	Informed Consent	1.0 1.1 1.2 1.3	17 July 2012 31 January 2013 31 July 2013 31 January 2014	<ul style="list-style-type: none"> No updates
6	Participant Follow-Up	1.0 1.1 1.2 1.3 1.4 1.5	17 July 2012 31 January 2013 31 July 2013 31 January 2014 31 July 2014 13 February 2015	<ul style="list-style-type: none"> Edits made throughout to specify ‘study exit’ versus ‘termination’ Completion of Study Exit Worksheet and Permission for Future Contact log added to Section 6.9 Form completion guidance for the Termination CRF added to Section 6.9 Sample PUEV scheduling text removed from Section 6.10 and operational guidance referenced instead Section 6.10.4 updated to clarify that a final contact is not required for all participants Appendices 6-2 and 6-3 updated with current versions.

7	Visit Checklists	1.0 1.1 1.2 1.3 1.4	17 July 2012 31 January 2013 31 January 2014 31 July 2014 13 February 2015	<ul style="list-style-type: none"> Section 7.1 updated to include final participant contacts as an example when chart notes are required Section 7.2 updated to replace the Male Partner CRF with the Baseline Family Planning CRF
8	Participant Retention	1.0 1.1 1.2 1.3	17 July 2012 31 January 2013 31 July 2013 31 January 2014	<ul style="list-style-type: none"> No updates
9	Study Product Considerations For Non-Pharmacy Staff	1.0 1.1 1.2 1.3 1.4 1.5	17 July 2012 31 January 2013 31 July 2013 31 January 2014 31 July 2014 13 February 2015	<ul style="list-style-type: none"> Section 9.4 updated to specify that IoR approval/acknowledgement must be documented when 2 rings are dispensed to a participant Section 9.7 updated to clarify ring retrieval guidance at the end of the study
10	Clinical Considerations	1.0 1.1 1.2 1.3 1.4 1.5	17 July 2012 31 January 2013 05 August 2013 31 January 2014 31 July 2014 13 February 2015	<ul style="list-style-type: none"> Section 10.4.5 updated to remove cervical ectopy from the list of pelvic findings considered normal and cervical ectopy text per DC #13 added Section 10.6.1 updated to include guidance on recurrent bleeding due to contraceptive change from DC #12 Section 10.6.2 updated to include infrequent bleeding AE guidance from DC#13
11	Adverse Event Reporting and Safety Monitoring	1.0 1.1 1.2 1.3 1.4 1.5	17 July 2012 31 January 2013 31 July 2013 31 January 2014 31 July 2014 13 February 2015	<ul style="list-style-type: none"> Section 11.4 updated to include guidance from DC #13 re: grading a genitourinary AE that is treated with system antimicrobials Section 11.6 updated to include guidance from DC #13 re: resolution dates for any AE requiring treatment Section 11.7 updated to remove classification of Grade 3 or Grade 4 AEs present at termination as those requiring re-assessment Section 11.7 has clarified guidance on AE follow up post termination
12	Counseling Considerations	1.0 1.1 1.2 1.3 1.4 1.5	17 July 2012 31 January 2013 31 July 2013 31 January 2014 31 July 2014 13 February 2015	<ul style="list-style-type: none"> Section 12.2.1 updated to clarify that contraceptive counseling is required until PUEV. It is 'if indicated' or 'per local standard of care' at PUEV and SEV.

13	Laboratory Considerations	1.0 1.1 1.2 1.3 1.4	17 July 2012 31 January 2013 31 July 2013 31 January 2014 31 July 2014	<ul style="list-style-type: none"> No updates
14	Data Collection	1.0 1.1 1.2 1.3 1.4 1.5	17 July 2012 31 January 2013 31 July 2013 31 January 2014 31 July 2014 13 February 2015	<ul style="list-style-type: none"> Updates made to SDMC Staff list Section 14.3.2 updated to reflect that there might be up to 37 follow up visits for a participant Section 14.4.1 updated to include DC#12-#14
15	Data Communiqués	N/A	DC#1: 18 Sep 2012 DC#2: 24 Sep 2012 DC#3: 29 Oct 2012 DC#4: 20 Nov 2012 DC#5: 21 Dec 2012 DC#6: 22 Feb 2013 DC#7: 12 Mar 2013 DC#8: 10 May 2013 DC#9: 05 Aug 2013 DC#10: 25 Oct 2013 DC#11: 12 Mar 2014 DC#12: 08 Aug 2014 DC#13: 18 Nov 2014 DC#14: 04 Feb 2015	<ul style="list-style-type: none"> DC#12-#14 should now be filed with this section
16	ACASI User Manual	1.0 1.1 1.2 1.3 1.4 1.5	17 July 2012 31 January 2013 31 July 2013 31 January 2014 31 July 2014 13 February 2015	<ul style="list-style-type: none"> Contact list updated in Section 16.3

17	Study Reporting Plan	1.0 1.1 1.2 1.3 1.4	31 January 2013 31 July 2013 31 January 2014 31 July 2014 13 February 2015	<ul style="list-style-type: none"> • Updates made to SDMC staff roster
18	Qualitative Component	1.0 1.1 1.2 1.3 1.4	11 December 2012 31 July 2013 31 January 2014 31 July 2014 13 February 2015	<ul style="list-style-type: none"> • Section 18.2.2 updated to further clarify visit checklist processes • Section 18.3.1 updated to clarify who is responsible for emailing the QMT with purposeful selection participants • The 'FGD Participant Worksheet' updated to 'FGD Group Participant Checklist' throughout. Further information on this checklist provided in Section 18.5.4 • Section 18.6 corrected location of qualitative documents on ASPIRE website • Section 18.8.1 updated documentation procedures and added reference to individual FGD checklist • Appendix 18-2 updated