

MTN-028 Study-Specific Procedures Manual
Overview of Section Contents and Identification of Current Section Versions

Section Number	Section Title	Version Number	Version Date	Updates and Comments
1	Introduction	1.0	24JUN15	
2	Documentation Requirements	1.0	24JUN15	
3	Accrual and Retention	1.0	24JUN15	
4	Study Visit Procedures	1.1	18AUG15	Version 1.1 <ul style="list-style-type: none"> • Sections 4.4.1, 4.5, 4.5.4.1, 4.5.7, 4.5.11: Updated per CM#1
5	Informed Consent	1.0	24JUN15	
6	Web Randomization	1.1	12OCT15	Version 1.1 <ul style="list-style-type: none"> • Section 6.4: Updated to clarify the meaning of the Eligibility Checklist Date listed on the Randomization confirmation notice
7	Study Product Considerations For Non-Pharmacy Staff	1.0	24JUN15	
8	Clinical Considerations and Safety Monitoring	1.2	1SEP15	Version 1.1 <ul style="list-style-type: none"> • Section 8.7: Updated per CM#1 Version 1.2 <ul style="list-style-type: none"> • Section 8.7.2: Updated to clarify documentation of pelvic findings due to biopsy
9	Laboratory Considerations	1.1	18AUG15	Version 1.1 <ul style="list-style-type: none"> • Table 9.1 and Section 9.6.7, 9.7.5: Updated per CM#1 • Table 9.3, Section 9.7.6: Updated to reflect current ring storage instructions and temperature
10	Counseling Considerations	1.0	24JUN15	
11	Data Collection	1.1	18AUG15	Version 1.1 <ul style="list-style-type: none"> • Table 1.1: Staff has been updated • Section 11.4: Name of PER CRF has been corrected
12	Data Communiqués	1.0	24JUN15	

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13	Study Reporting Plan	1.2	16NOV15	<p>Version 1.1:</p> <ul style="list-style-type: none">• MTN-028 Statistical and Data Management Center (SDMC) and DF/Net Research Staff table: Has been updated <p>Version 1.2:</p> <ul style="list-style-type: none">• Section 13.2, item 11 (Missed Visit Report) has been updated to reflect current procedures.
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