

MTN-033 CRF Schedule of Forms

Visit	Form Name
Screening	Screening Date of Visit
	Inclusion/Exclusion Criteria
	Demographics
	Baseline Medical History Summary
	Physical Exam
	Anorectal Exam
	Vital Signs
	STI Test Results
	Hematology
	Local Labs
	HIV Test Result
	Genital Exam
V2 - Enrollment Visit	Randomization
	Enrollment
	CASI Summary
	CASI Tracking
	Physical Exam
	Vital Signs
	Anorectal Exam
	Genital Exam
	HIV Test Result
	Anorectal Specimen Storage
	Specimen Storage
V3, V5 – Dosing Visits	Follow-up Visit Yes/No, Follow-up Visit Summary
	Pharmacy Dispensation (completed by and accessible by site pharmacists only)
	Dose Administration
	CASI Summary
	CASI Tracking
	Anorectal Exam
	Specimen Storage
	Timed Anorectal Specimen Storage
V4, V6 – 24 Hr OR Early Termination Visit (Completed in lieu of expected study visit within the visit window)	Follow-up Visit Yes/No, Follow-up Visit Summary
	Anorectal Exam
	Local Laboratory Results (<i>Visit 6 only</i>)
	HIV Test Result (<i>Visit 6 only</i>)
	Specimen Storage
	Anorectal Specimen Storage

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V7 – Termination, F/U contact	Follow-up Visit Yes/No, Follow-up Visit Summary
	Study Discontinuation
As needed (Additional Study Procedures/Interim Visits Procedures)	Interim Visit Summary
	Additional Study Procedures
	HIV Test Results
	HIV Confirmatory
	Local Laboratory Results
	Hematology
	Physical Exam
	Vital Signs
	Anorectal Exam
	Genital Exam
	Specimen Storage
	Anorectal Specimen Storage
	Timed Anorectal Specimen Storage
	STI Test Results
	Missed Visit
	Pharmacy Dispensation (completed by and accessible by site pharmacists only)
	Dose Administration
	Product Discontinuation
	CASI Summary
	CASI Tracking
Participant Replacement Assessment	
As needed, Ongoing Logs	Adverse Event Summary
	Adverse Event Log
	Concomitant Medications Summary
	Concomitant Medications Log
	Baseline Medical History Summary
	Baseline Medical History Log
	Protocol Deviation Summary
	Protocol Deviation Log
Pharmacy	Pharmacy Dispensation
Discontinuations	Study Discontinuation
	Product Discontinuation