



HPTN 083-01

Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Males – A sub-study of HPTN 083

Study-Specific Procedures Manual (SSP)

Section Number	Section Title	Current Version	Date
1	Introduction	3.0	13 Sep 2021
2	Protocol	3.0	13 Sep 2021
3	Document Requirements	3.0	13 Sep 2021
4	Recruitment, Screening, and Enrollment	3.0	13 Sep 2021
5	Study Procedures Overview	3.0	13 Sep 2021
6	Visit Checklists	3.1	16 Nov 2021
7	Participant Retention	3.0	13 Sep 2021
8	Study Product Considerations	3.0	13 Sep 2021
9	Clinical Considerations	3.0	13 Sep 2021
10	Adverse Event Reporting and Safety Monitoring	3.0	13 Sep 2021
11	Laboratory and Specimen Management Procedures	3.0	13 Sep 2021
12	Counseling Considerations	3.0	13 Sep 2021
13	Data Management Section 13.13: Schedule of Forms	3.0	13 Sep 2021
14	CASI	3.0	13 Sep 2021
15	Reporting Plan	3.0	13 Sep 2021
16	Data Communiqués	3.0	13 Sep 2021
Appendix Ia	Record of Dispensation of Participant-Specific Study Product to Non-Pharmacy staff	3.0	13 Sep 2021
Appendix Ib	Record of Return of Participant-Specific Study Product by Non-Pharmacy Staff	3.0	13 Sep 2021
Appendix II	Participant Transfer and Receipt Process within Medidata Rave	3.0	13 Sep 2021
Appendix III	Guidance for the management of “discordant/discrepant” HIV testing results	1.2	6 March 2019
Appendix IV	Study Schema Graphic	2.0	14 May 2021