



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	3.1	24 Feb 2022
2	Protocol	3.1	24 Feb 2022
3	Document Requirements	3.1	24 Feb 2022
4	Recruitment, Screening, and Enrollment	3.0	13 Sep 2021
5	Study Procedures Overview	3.1	24 Feb 2022
6	Visit Checklists	3.3	24 Feb 2022
7	Participant Retention	3.0	13 Sep 2021
8	Study Product Considerations	3.1	24 Feb 2022
9	Clinical Considerations	3.1	24 Sep 2022
10	Adverse Event Reporting and Safety Monitoring	3.1	24 Feb 2022
11	Laboratory and Specimen Management Procedures	3.0	13 Sep 2021
12	Counseling Considerations	3.1	24 Feb 2022
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	2.1	16 Nov 2021
Appendix IV	Study Schema Graphic	2.0	14 May 2021