



## **HPTN 084-01**

# **Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Females – A sub-study of HPTN 084**

## **Study-Specific Procedures Manual (SSP)**

<b>Section Number</b>	<b>Section Title</b>	<b>Current Version</b>	<b>Date</b>
1	Introduction	1.3	20 Apr 2022
2	Protocol	1.2	20 Apr 2022
3	Document Requirements	1.2	20 Apr 2022
4	Recruitment, Screening, and Enrollment	1.1	4 Feb 2021
5	Study Procedures Overview	1.2	20 Apr 2022
6	Visit Checklists	1.2	20 Apr 2022

7	Participant Retention	1.1	4 Feb 2021
8	Study Product Considerations	1.2	29 Apr 2022
9	Clinical Considerations	1.2	20 Apr 2022
10	Adverse Event Reporting and Safety Monitoring	1.2	20 Apr 2022
11	Laboratory and Specimen Management Procedures	1.3	20 Apr 2022
12	Counseling Considerations	1.2	20 Apr 2022
13	Data Management Section 13.13: Schedule of Forms	1.2	29 Apr 2022
14	CASI	1.1	4 Feb 2021
15	Reporting Plan	1.1	4 Feb 2021
16	Data Communiqués	1.1	4 Feb 2021
Appendix Ia	Record of Dispensation of Participant-Specific Study Product to Non-Pharmacy staff	1.1	4 Feb 2021

Appendix Ib	Record of Return of Participant-Specific Study Product by Non-Pharmacy Staff	1.1	4 Feb 2021
Appendix II	Participant Transfer and Receipt Process within Medidata Rave	1.1	4 Feb 2021
Appendix III	Guidance for the management of “discordant/discrepant” HIV testing results	2.1	16 Nov 2021
Appendix IV	Study Schema Graphic	1.0	12 Aug 2019