



## **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	1.2	15 Feb 2021
2	Protocol	1.1	4 Feb 2021
3	Document Requirements	1.1	4 Feb 2021
4	Recruitment, Screening, and Enrollment	1.1	4 Feb 2021
5	Study Procedures Overview	1.1	4 Feb 2021

6	Visit Checklists	1.1	4 Feb 2021
7	Participant Retention	1.1	4 Feb 2021
8	Study Product Considerations	1.1	4 Feb 2021
9	Clinical Considerations	1.1	4 Feb 2021
10	Adverse Event Reporting and Safety Monitoring	1.1	4 Feb 2021
11	Laboratory and Specimen Management Procedures	1.2	4 Feb 2021
12	Counseling Considerations	1.1	4 Feb 2021
13	Data Management Section 13.13: Schedule of Forms	1.1	4 Feb 2021
14	CASI	1.1	4 Feb 2021
15	Reporting Plan	1.1	4 Feb 2021

16	Data Communiqués	1.1	4 Feb 2021
17	Qualitative	1.0	21 Oct 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	1.2	6 March 2019
Appendix IV	Study Schema Graphic	1.0	12 August 2019