



HPTN 084
A Phase 3 Double Blind Safety and Efficacy Study of Long- Acting
Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-
Exposure Prophylaxis in HIV-Uninfected Women

Study-Specific Procedures Manual (SSP)

Section Number	Section Title	Current Version	Version Date
1	Introduction	3.0	04Jan2022
2	Protocol	3.1	26Apr2022
3	Document Requirements	3.0	04Jan2022
4	Recruitment, Screening, and Enrollment	3.1	26Apr2022
5	Study Procedures Overview	3.0	04Jan2022
6	Visit Checklists	3.1	26Apr2022
7	Participant Retention	3.0	04Jan2022
8	Study Product Considerations	3.0	04Jan2022
9	Clinical Considerations	3.1	26Apr2022
10	Adverse Event Reporting and Safety Monitoring	3.2	03Jun2022
11	Lab and Specimen Management Procedures	3.1	26Apr2022
12	Counseling Considerations	3.1	26Apr2022
13	Data Management	3.1	06Apr2022
14	CASI	3.0	04Jan2022
15	Reporting Plan	3.0	04Jan2022
16	Data Communiqués	3.0	04Jan2022
17	COVID-19 Measures	3.0	04Jan2022
Appendix I	Guidance for the management of “discordant/discrepant” HIV testing results HPTN 083 and 084	2.1	16Nov2021