# 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 | 4.0 | 02Mar2023 |
| 2 | Protocol | 4.0 | 02Mar2023 |
| 3 | Document Requirements | 4.0 | 02Mar2023 |
| 4 | Continuation in Protocol Version 4.0 (OLE) | 4.1 | 02Mar2023 |
| 5 | Study Procedures Overview | 4.0 | 02Mar2023 |
| 6 | Visit Checklists | 4.0 | 02Mar2023 |
| 7 | Participant Retention | 4.0 | 02Mar2023 |
| 8 | Study Product Considerations | 4.0 | 02Mar2023 |
| 9 | Clinical Considerations | 4.0 | 02Mar2023 |
| 10 | Adverse Event Reporting and Safety Monitoring | 4.0 | 02Mar2023 |
| 11 | Lab and Specimen Management Procedures | 4.0 | 02Mar2023 |
| 12 | Counseling Considerations | 4.0 | 02Mar2023 |
| 13 | Data Management | 4.0 | 02Mar2023 |
| 14 | CASI | 4.0 | 02Mar2023 |
| 15 | Reporting Plan | 4.0 | 02Mar2023 |
| 16 | Data Communiqués | 4.0 | 02Mar2023 |
| 17 | COVID-19 Measures | 4.0 | 02Mar2023 |
| Appendix I | Guidance for the management of “discordant/discrepant” HIV testing results HPTN 083 and 084 | 2.2 | 07Feb2023 |