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## 18 STUDY CLOSE-OUT

The term *close-out* refers to procedures undertaken to fulfill administrative, regulatory, data, laboratory, pharmacy and human subjects requirements after participant follow-up in a Microbicide Trials Network (MTN) study has been completed. Responsibilities and procedures for study close-out are described below.

### 18.1 Study Close-Out Responsibilities

The general responsibilities of MTN network partners for close-out of MTN studies are as follows:

- MTN protocol teams are responsible for defining study-specific, close-out milestones and requirements and developing a study-specific closeout checklist.
- MTN Clinical Trials Units (CTU) and affiliated clinical research sites (CRS) are responsible for completing required study close-out procedures at each site. Ultimate responsibility for meeting all site requirements rests with the study-specific Investigator of Record (IoR).
- The U.S. National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS), the MTN Leadership and Operations Center (LOC [FHI 360] and University of Pittsburgh [Pitt]), the Statistical and Data Management Center (SDMC) and the Laboratory Center (LC) are responsible for helping study sites complete required study close-out procedures.
- The SDMC is responsible for ensuring collection and verification (if applicable) of all available study endpoint data; cleaning and locking the study database (Case Report Form [CRF] data) and study datasets (such as lab assay results and Audio/Computer Assisted Self Interviews [A/CASI]); conducting study analyses; producing a Final Study Report (FSR); and providing tables, listings, and figures (TLFs) for a Clinical Study Report (CSR), as needed.

### 18.2 Study Close-Out Procedures

To facilitate planning for study close-out, the SDMC will provide protocol teams with information on the projected date for the final participant follow-up visit for each participating study site and for the study overall. Initial timeline projections will be made upon completion of accrual into the study. Thereafter, projections will be updated as needed based on the study design and planned duration of participant follow-up.

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