

MTN Manual of Operational Procedures (MOP)

Section 22: Information Technology Services

22. Information Technology (IT) Services.....22-1

22 Information Technology (IT) Services

Each of the organizational components of the Microbicide Trials Network (MTN), including the Leadership and Operations Center (LOC) [i.e., University of Pittsburgh (Pitt) and FHI 360], the Laboratory Center (LC) and the Statistical Data Management Center (SDMC), maintain separate electronic data processing and storage systems at their facilities for daily operations. They also maintain their own organizational Standard Operating Procedures (SOPs) and Work Instructions (WIs) related to these processes and systems, as well as regulatory compliance and validation processes/procedures. In addition, several databases and data sharing platforms are provided for shared use:

- Division of AIDS (DAIDS) provides the National Institute of Allergy and Infectious Diseases (NIAID) Clinical Research Management System (NCRMS),
<https://ncrms.niaid.nih.gov/NCRMS/Main/Login.aspx>
- DAIDS provides the Laboratory Data Management System (LDMS),
<https://www.webldms.org/Account/Login/Index?ReturnUrl=%2f>
- HIV/AIDS Network Coordination (HANC) provides the Financial Disclosure Database,
<https://fd.hanc.info/>
- MTN LOC (FHI 360) provides SharePoint, <https://login.microsoftonline.com/>
- MTN LOC (FHI 360) provides DocuSign, <https://www.docusign.com/>
- MTN SDMC provides ATLAS, <https://atlas.scharp.org/>
- MTN SDMC provides Medidata Rave, www.imedidata.com

To the extent possible, each electronic system is validated prior to implementation and complies *with 21 CFR Part 11* and National Institute of Standards and Technology (NIST) standards.

The MTN LOC cooperative agreement from the National Institute of Allergy and Infectious Diseases (NIAID) is granted to Magee-Womens Research Institute and Foundation (MWRIF). As such, the MTN LOC (Pitt) relies on the Information Technology (IT) services provided by the grantee organization which is part of the University of Pittsburgh Medical Center (UPMC). The IT policies that are implemented by UPMC and MWRIF are based on guidelines from the National Institute of Standards and Technology (NIST). Changes in those guidelines or recommendations are addressed by MWRIF within a reasonable amount of time (no later than 120 days) after such changes are publicized. MWRIF manages the deployment, configuration and day-to-day maintenance of the MWRIF servers and daily backs up data to disk and tape, with replication to a disaster recovery site. Documented disaster recovery testing is performed on an annual basis.

The Fred Hutchinson Cancer Research Center (Fred Hutch) provides the MTN SDMC a computing environment that consists of a data center and network that are governed by IT security policies that follow guidelines from the National Institute of Technology Standards (NIST). The MTN SDMC is responsible for implementing and maintaining systems within the Fred Hutch computing environment that follow DAIDS policies and other regulations such as *21 CFR Part 11*, *ICH E6* and the Food and Drug Administration's (FDA) guidance for industry on Computer Systems Validation. The policies and procedures implemented by the MTN SDMC for these systems include system development life cycle, computer system validation, system change control, system access control, system maintenance, data backup and restore, disaster recovery and business continuity.

The MTN LC is comprised of three Laboratory Cores. The Site Support Core is located at MWRI and the Virology Core is located at the University of Pittsburgh in Pittsburgh, PA. The Pharmacology Core has two laboratory locations; one at Johns Hopkins University in Baltimore, MD and the other at the University of Colorado in Aurora, CO. Each Core relies on the IT services provided by their institution for daily operations. Sample inventory (tracking and shipment) are centrally managed by LDMS, which is developed, maintained and hosted by Frontier Science and Technology Research Foundation (FSTRF). The FSTRF LDMS was selected and provided by DAIDS and is compliant with the *Federal Information Security Management Act of 2002 (FISMA)* and *21 CFR Part 11*.

The MTN LOC (FHI 360) *Electronic Systems Policy* applies regulations from the *International Council for Harmonisation (ICH) E6 (R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)*, *21 CFR Part 11*, the *Health Insurance Portability Accountability Act (HIPPA)* and NIST. Any product, vendor or service provider is evaluated prior to purchase and monitored throughout implementation to ensure systems are compliant with the expected requirements. FHI 360's SOPs describe risk assessments, security controls, computer system validation and functionality testing, system maintenance and security measures, change control, data backup, recovery, contingency planning and decommissioning. Sponsor-delegated documents that FHI 360 is responsible for maintaining in the study Trial Master Files (TMF) are stored in the validated, *21 CFR Part 11* compliant TransPerfect electronic TMF system, according to the policies listed above.