DAIDS Laboratory Oversight Activities

2014 MTN Annual Meeting:
ASPIRE Protocol Team Meeting
Sunday, February 23rd

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Presentation Outline

- What are DAI DS Expectations for Clinical Laboratory Testing Activities?
- DAI DS Clinical Laboratory Oversight Team (DCLOT): Who, What and Why?
- DAI DS Laboratory Oversight Resources
- DAI DS Laboratory Audit and Report Resolution
- Q & A
DAIDS Expectations For Clinical Laboratory Testing Activities

Overall goal:
Protect the integrity of clinical trial data and the safety of our trial participants.

Expectations for laboratories participating in DAIDS-supported and/ or -sponsored studies:

- Laboratories performing testing in support of clinical trials supported and/ or sponsored by NIAID/DAIDS should follow the DAIDS laboratory guidance documents.
  - DAIDS Lab Policy and associated appendices
    - Appendix 1: DAIDS Requirements for U.S. Laboratories
    - Appendix 2: DAIDS Requirements for Non-U.S. Laboratories
    - Appendix 3: DAIDS Good Clinical Laboratory Practices (GCLP) Standards Guidelines

- Follow network protocol requirements.

- Participate in DAIDS-sponsored audits and successfully resolve subsequent audit reports.
Who: DAIDS staff involved in clinical lab monitoring (Prevention, Vaccine, Therapeutics). Each clinical trial network has a designated DCLOT POC.

What: To develop, evaluate, coordinate, communicate, and oversee the implementation of harmonized DAIDS clinical lab-related guidelines, standards, and requirements for determining the readiness and ongoing ability of clinical labs to participate in DAIDS-supported and/or -sponsored clinical studies.

Why: To communicate, coordinate, discuss, and resolve problems among the various lab components.
Designated DCLOT Network POCs

Division of AIDS (DAIDS)

- Basic Sciences Program (BSP)
  - Prevention Sciences Program (PSP)
    - MTN, HPTN and IMPAACT POCs
- Therapeutics Research Program (TRP)
  - ACTG POC
- Vaccine Research Program (VRP)
  - HVTN POC
DAIDS Laboratory Oversight Resources

Lab Oversight Activities

DCLOT

Network Lab (Laboratory Center)

DAIDS Contractual Resources

SMILE

VQA

IQA

WESTAT/FHI

SMILE: Patient Safety Monitoring in International Laboratories
VQA: Virology Quality Assurance
IQA: Immunology Quality Assurance
WESTAT/FHI: HIV Clinical Research Support Services Contract (CRSS)
Why audit labs?

- To assess general ability to conduct lab operations in accordance with GCLP guidelines/standards and other applicable requirements. *DAIDS has determined that GCLP are the minimal requirements that clinical research laboratories should follow.*
- To provide guidance to ensure laboratory meets all applicable requirements.
- To monitor ongoing laboratory performance.

Who performs the audits?

- DAIDS Audit Contractor (currently Westat/ FHI)

Which labs are audited?

- Main lab and clinic point-of-care testing areas/rooms
Audit Logistics & Report Resolution Process

Pre-audit
- DCLOT submits request for audit visit.
- Auditor schedules and confirms audit visit.

Audit
- Auditor performs GCLP compliance audit following audit checklist.
- Auditor debriefs lab at the end of the audit visit.

Post-audit
- Auditor distributes audit to DCLOT, NL and SMI LE within 21 business days.
- DCLOT initiates report resolution with support from SMI LE and NL.

SMI LE generates AP, DCLOT POC reviews w/support from NL POCs.

DCLOT sends audit report and associated AP to lab.

Lab confirms receipt and provides timeline for response.

Lab/SMI LE/NL POCs interact to resolve/close findings. SMI LE post updates to pSMI LE.org

SMI LE sends notices of completed audit AP to distribution list.

Action Plan: AP
Network Lab: NL

DHHS/NIH/NIAID/DAIDS
February 2014
References & Resources

- **DAI DS Lab Policy and associated appendices:**
  - [http://www.niaid.nih.gov/LabsAndResources/resources/DAI_DSClinRsrch/Pages/Laboratories.aspx](http://www.niaid.nih.gov/LabsAndResources/resources/DAI_DSClinRsrch/Pages/Laboratories.aspx)

- **SMI LE website:**
  - [http://psmile.org/](http://psmile.org/)

- **VQA website:**
  - [https://www.hanc.info/labs/labresources/vqaResources/Pages/default.aspx](https://www.hanc.info/labs/labresources/vqaResources/Pages/default.aspx)

- **IQA website:**
  - [http://iqa.center.duke.edu/proficiency-testing/cd4](http://iqa.center.duke.edu/proficiency-testing/cd4)

- **GCLP Training:**
  - GCLP eLearning Modules: [https://daidslms.plateau.com/learning/user/login.jsp](https://daidslms.plateau.com/learning/user/login.jsp)
  - DAI DS-Sponsored Face-to-Face GCLP Training Workshop: [https://www.daidscrss.com/Training/DRTEs/Pages/DAI_DS_Regional_Training_Events.aspx](https://www.daidscrss.com/Training/DRTEs/Pages/DAI_DS_Regional_Training_Events.aspx)
Acknowledgements

- DCLOT
- DAIDS Contractual Resources
- MTN Lab Center (LC)
- Site Clinic and Lab Staff
Questions?

Thank you!