DAIDS Laboratory Oversight Activities

2016 MTN Regional Meeting:
Laboratory Session
28 September, 2016

Naana Cleland, MHCA
Health Specialist, Clinical Microbicide Research Branch (CMRB)
Prevention Sciences Program (PSP), Division of AIDS (DAIDS)
Presentation Outline

- What are DAIDS Expectations for Clinical Laboratory Testing Activities?
- Who are the DAIDS Laboratory Support Teams?
  - DAIDS Clinical Laboratory Oversight Team (DCLOT)
  - Network Laboratory Center (LC)
  - Contractual Resources
- Q & A
DAIDS Expectations For Clinical Laboratory Testing Activities

Overall goal:

Protect the integrity of clinical trial data and the safety of lab staff and trial participants.

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

- Laboratories performing testing in support of clinical trials funded and/or sponsored by NIAID/DAIDS should follow the DAIDS laboratory guidance documents for DAIDS-funded and/or -sponsored clinical trials.
  - 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 (if applicable) and successfully resolve subsequent audit reports.
DAIDS Clinical Laboratory Oversight Team (DCLOT)

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-funded and/or -sponsored clinical studies.

Why: To communicate, coordinate, discuss, and resolve problems among the various lab components.
DAI DS Laboratory Support Teams

Lab Oversight Activities

DCLOT

Network Lab (Laboratory Center)

DAI DS 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)
References & Resources

- **DAIDS Lab Policy and associated appendices:**

- **SMILE 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:**
  - [https://iqa.center.duke.edu/](https://iqa.center.duke.edu/)

- **GCLP Training:**
  - **GCLP eLearning Modules:** [https://www.daidslearningportal.com/](https://www.daidslearningportal.com/)
Acknowledgements

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

Thank you!