



National Institute of Allergy and Infectious Diseases

DAIDS Laboratory Oversight Activities

2014 MTN Annual Meeting:

ASPIRE Protocol Team Meeting

Sunday, February 23rd

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DAIDS



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



Presentation Outline

- **What are DAIDS Expectations for Clinical Laboratory Testing Activities?**
- **DAIDS Clinical Laboratory Oversight Team (DCLOT): Who, What and Why?**
- **DAIDS Laboratory Oversight Resources**
- **DAIDS 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.





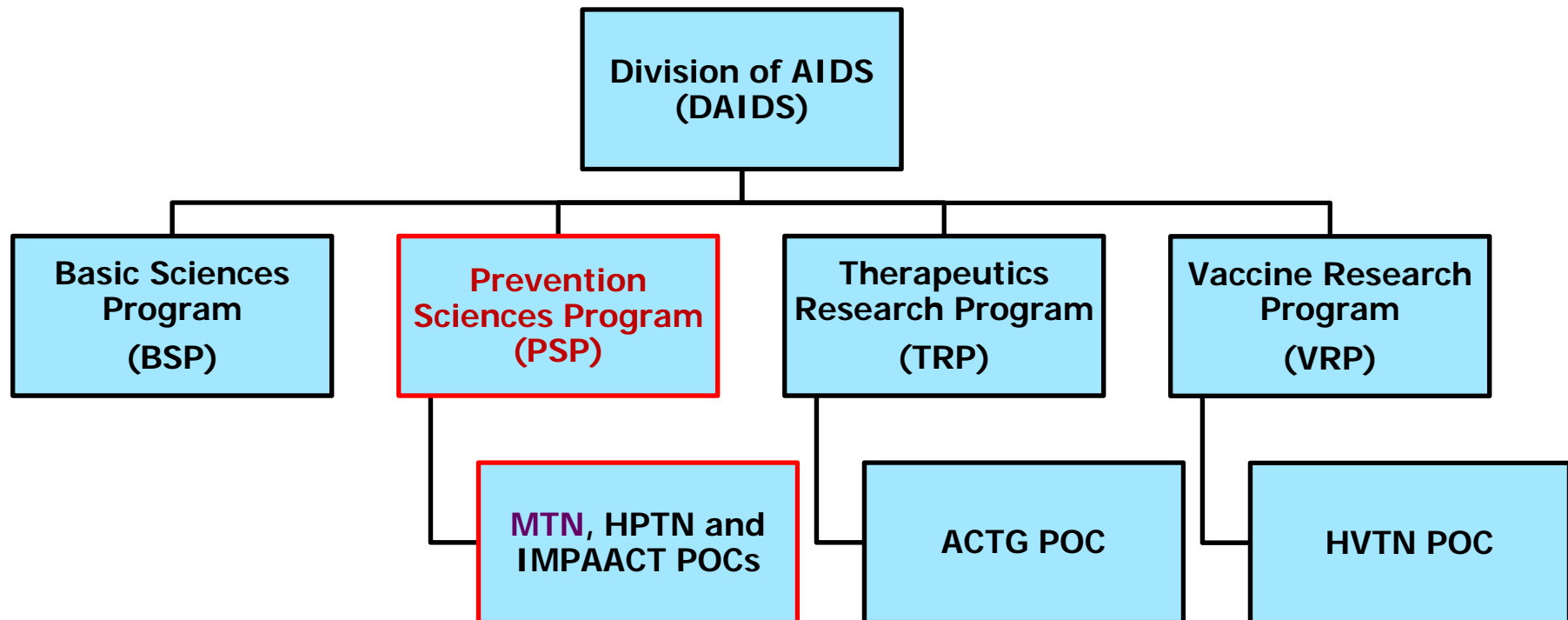
DAIDS Clinical Laboratory Oversight Team (DCLOT)

- 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-supported and/or -sponsored clinical studies.
- Why:** To communicate, coordinate, discuss, and resolve problems among the various lab components.



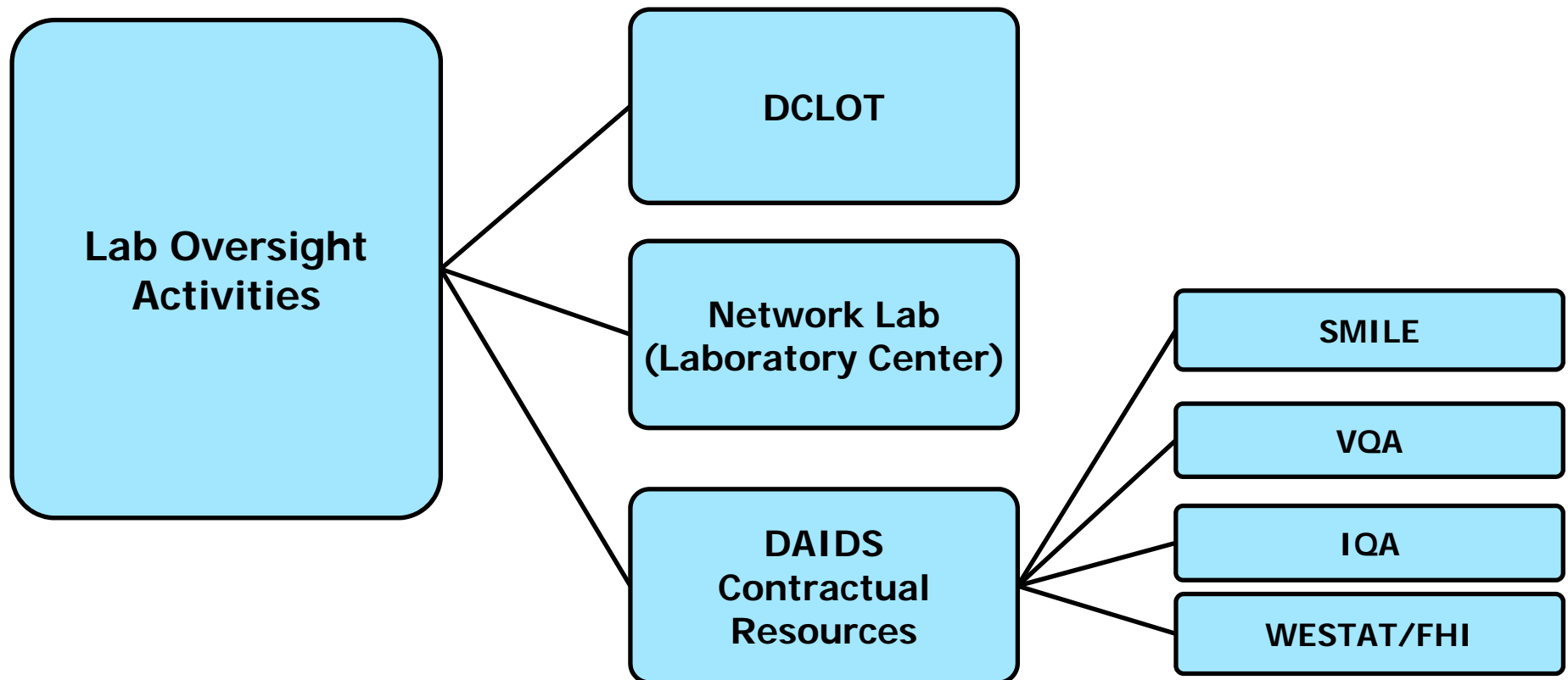


Designated DCLOT Network POCs





DAIDS Laboratory Oversight Resources



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





DAIDS-Sponsored Laboratory Audit

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)

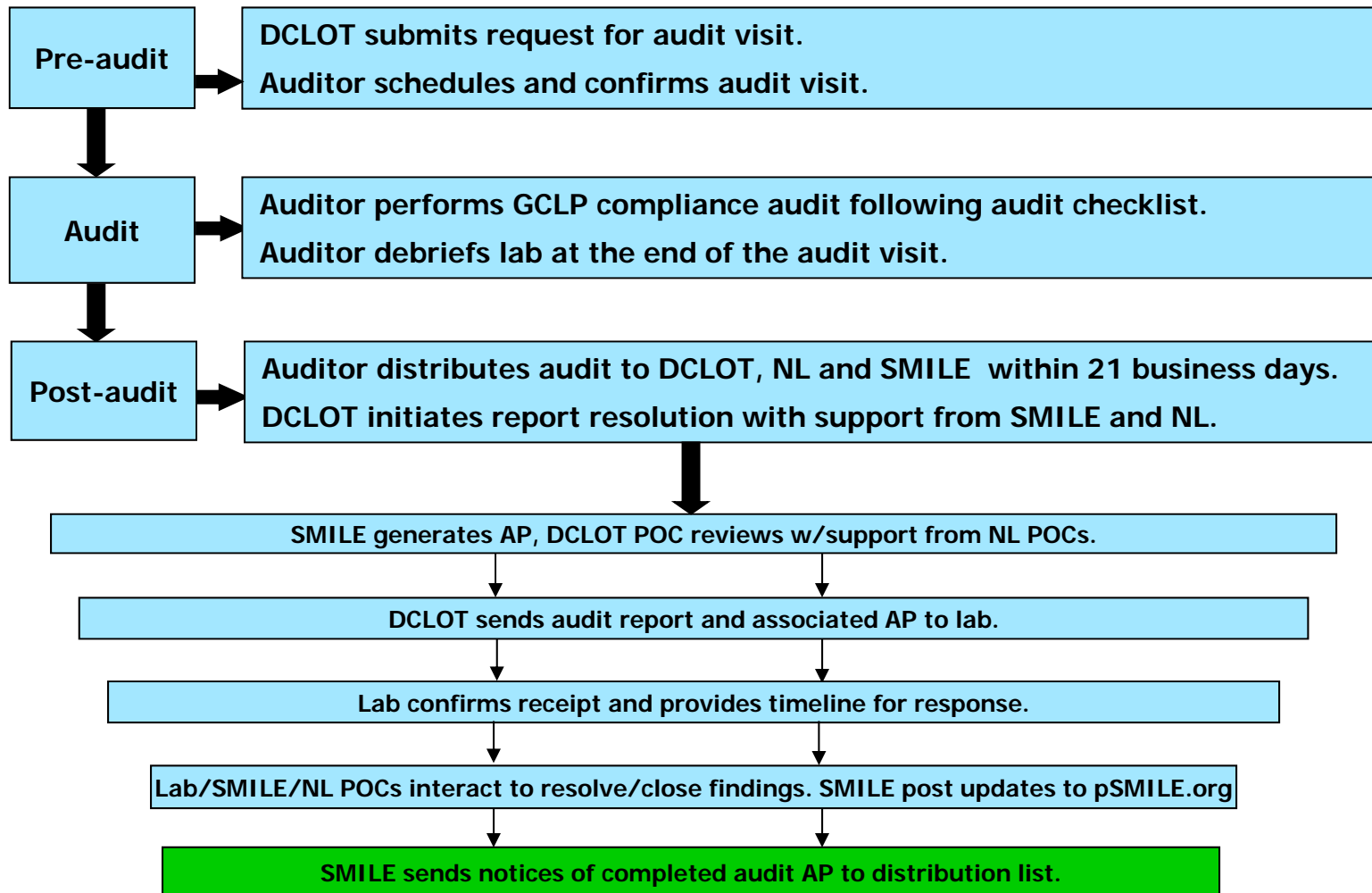
Which labs are audited?

- Main lab and clinic point-of-care testing areas/rooms





Audit Logistics & Report Resolution Process



Action Plan: AP Network Lab: NL





References & Resources

- **DAIDS Lab Policy and associated appendices:**
 - <http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Laboratories.aspx>

- **SMILE website:**
 - <http://psmile.org/>

- **VQA website:**
 - <https://www.hanc.info/labs/labresources/vqaResources/Pages/default.aspx>

- **IQA website:**
 - <http://iqa.center.duke.edu/proficiency-testing/cd4>

- **GCLP Training:**
 - GCLP eLearning Modules: <https://daidslms.plateau.com/learning/user/login.jsp>
 - DAIDS-Sponsored Face-to-Face GCLP Training Workshop:
https://www.daidscrss.com/Training/DRTEs/Pages/DAIDS_Regional_Training_Events.aspx





Acknowledgements

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





DAIDS Clinical Laboratory Oversight

Questions?



Thank you!

