

# **DAIDS Laboratory Oversight Activities**

**2016 MTN Regional Meeting:**  
*Laboratory Session*  
*28 September, 2016*

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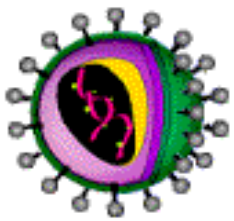
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DAIDS



# 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.





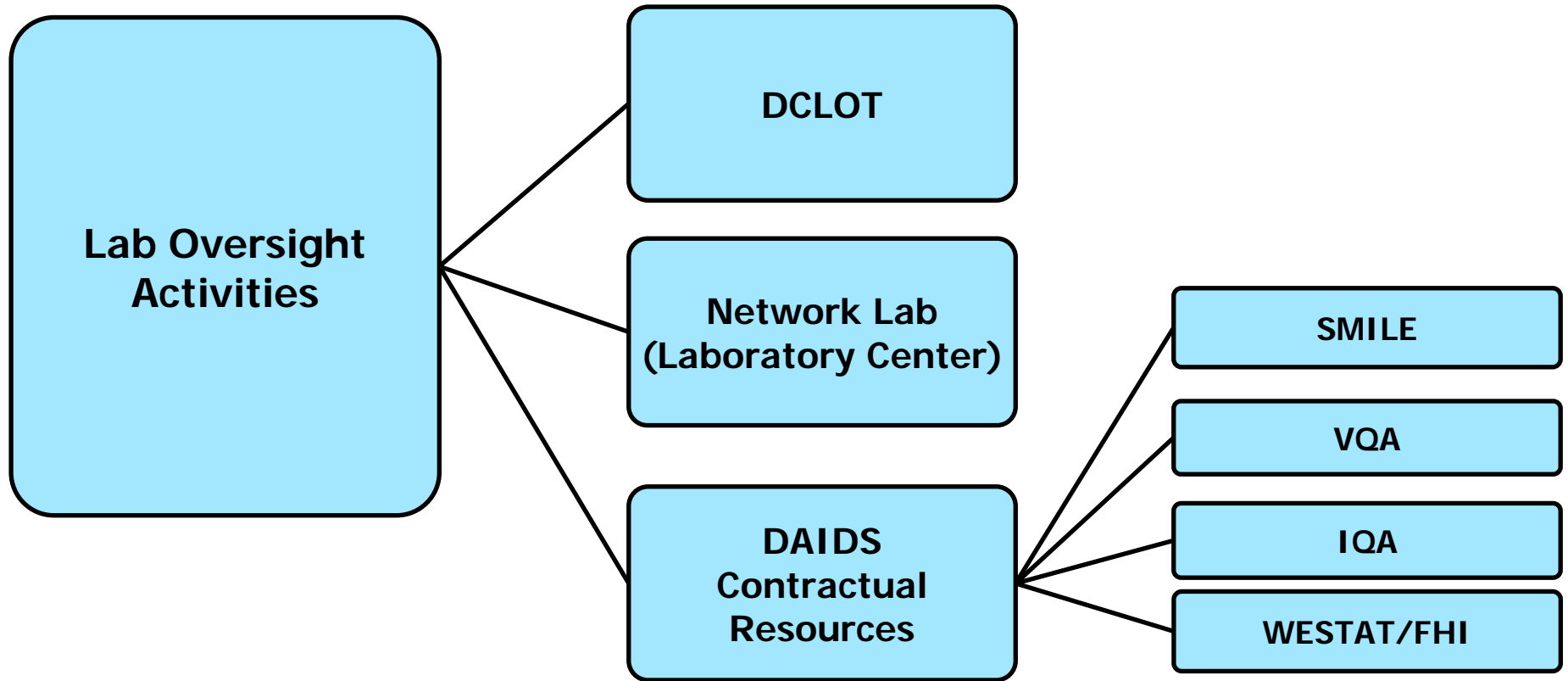
# DAIDS Clinical Laboratory Oversight Team (DCLOT)

- 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.





# DAIDS Laboratory Support Teams

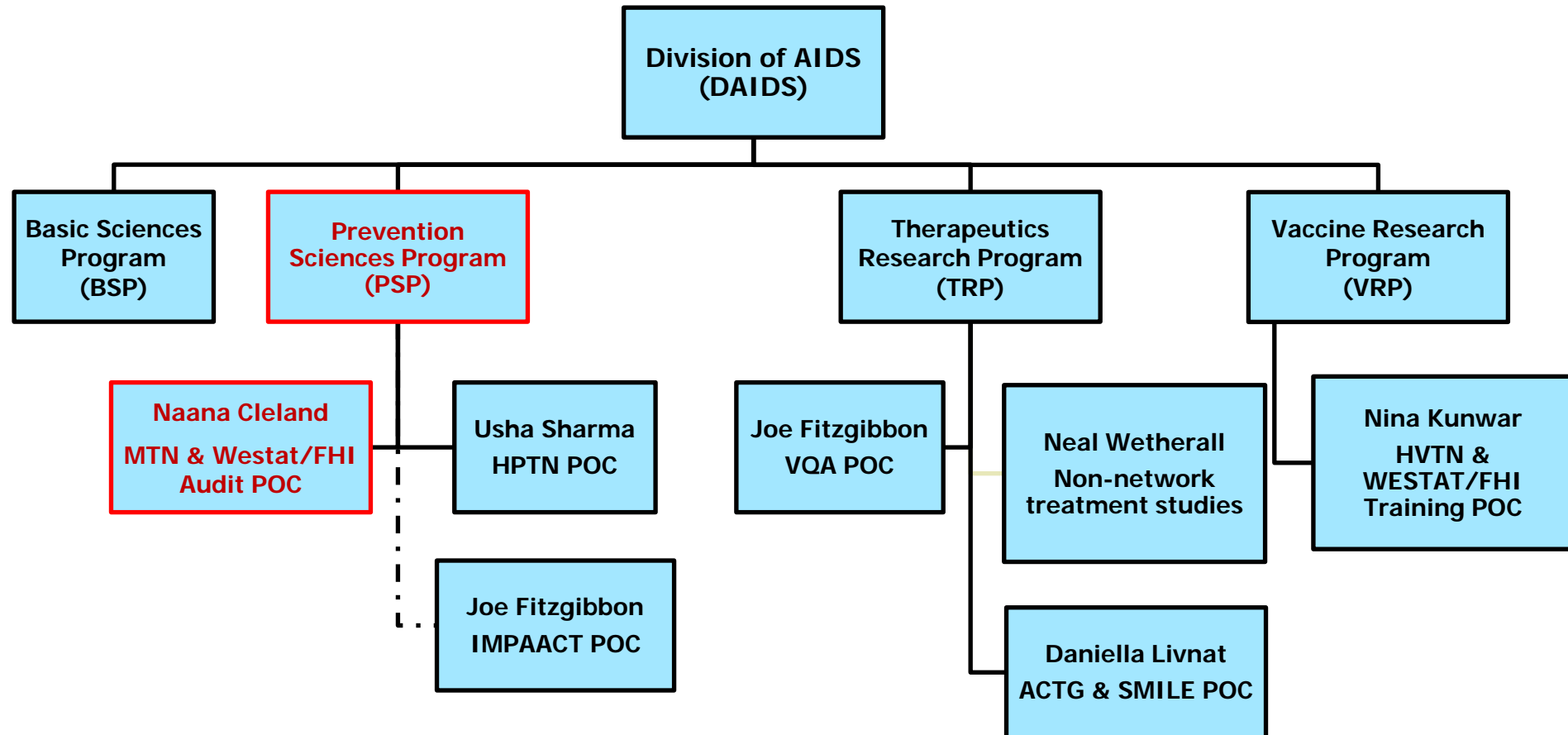


SMILE: Patient Safety Monitoring in International Laboratories  
VQA: Virology Quality Assurance  
IQA: Immunology Quality Assurance  
WESTAT/FHI: HIV Clinical Research Support Services Contract (CRSS)





# DCLOT POC Assignments





# References & Resources

- **DAIDS Lab Policy and associated appendices:**
  - <http://www.niaid.nih.gov/research/daids-clinical-research-laboratory-specimens-management>
- **SMILE website:**
  - <http://psmile.org/>
- **VQA website:**
  - <https://www.hanc.info/labs/labresources/vqaResources/Pages/default.aspx>
- **IQA website:**
  - <https://iqa.center.duke.edu/>
- **GCLP Training:**
  - GCLP eLearning Modules: <https://www.daidslearningportal.com/>





# Acknowledgements

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







# DAIDS Clinical Laboratory Oversight

Questions?



**Thank you!**

