

DAIDS Clinical Laboratory Team (DCLOT)

The DAIDS Clinical Laboratory Team (DCLOT), made up of DAIDS laboratory staff from the vaccine, therapeutic and prevention Programs at DAIDS, is responsible for lab establishment, oversight and implementation of laboratory policies, evaluation of lab performance, and follow-up on lab-related issues. DCLOT members serve as Point of Contacts (POC) to each of the funded clinical trial Networks. Working closely with the respective DCLOT POC, each Network has a laboratory management and oversight team that also supports Network site laboratories, focusing on protocol-related laboratory issues.

DAIDS and Network Laboratory Contacts				
Network	ACTG	HPTN	HVTN	IMPAACT
DCLOT POC	Daniella Livnat dlivnat@nih.gov	Usha Sharma usharma@niaid.nih.gov	Nina Kunwar Nina.kunwar@nih.gov	Naana Cleland clelandn@niaid.nih.gov
Network Lab Center	ACTG.labcenter@fstrf.org	hptnlc-lab@jhmi.edu	vtn.site.lab.support@hvtm.org	impaact.qaqc@fstrf.org

The Network, together with DCLOT, has the final word on a laboratory’s readiness to participate in a study. Ensuring quality laboratory testing requires laboratories to perform testing in compliance with Good Clinical Laboratory Practices (GCLP) and generate reliable test results. To ensure GCLP compliance, DAIDS has developed guidelines and monitors laboratories’ compliance with GCLP through periodic visits/audits performed by NIAID DAIDS HIV Clinical Research Support Services (CRSS) contractors. Because clinical laboratories operating in the US must adhere to CLIA regulations, which are similar to GCLP and include regular inspections, annual GCLP audits are generally not performed but DAIDS may perform periodic visits or for-cause audits at US clinical labs.

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Ensuring reliable laboratory test results is accomplished through the monitoring of results obtained by laboratories on proficiency testing samples. DAIDS employs a few laboratory quality assurance contracts that work closely with DCLOT, the Networks and site laboratories to help ensure the quality of testing:

DAIDS Laboratory Quality Assurance Contracts	
Contract Name	Target Support
IQA	The Immunology Quality Assessment contract (IQA), administered by Duke University, provides proficiency testing services for CD4 testing and PBMC cryopreservation. The contract also assists US specimen processing and Endpoint laboratories resolve GCLP audit observations.
VQA	The Virology Quality Assurance contract (VQA), administered by Duke University, provides proficiency testing services for virological testing.
SMILE	Patient Safety Monitoring in International Laboratories (SMILE) provides proficiency testing services for all other testing mandated by study protocols (e.g. safety and diagnostic tests) at international laboratories. SMILE also helps laboratories resolve observations resulting from the GCLP assessments at international laboratories.

The laboratories that will be used for Network studies will be supported by one or more of the above resources. US clinical laboratories must perform proficiency testing according to CLIA regulations; therefore, proficiency testing is not provided by DAIDS for US clinical laboratories.

Each CRS will soon be contacted by DAIDS and the Network(s) to further discuss the laboratory component of future Network studies, including specimen and data management needs.

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