

**Virology Quality Assurance Advisory Board (VQAAB):  
Guidelines for EQA Monitoring, Data and Communication Flow**

**Abbreviations and Acronyms**

- The DAIDS Virology Quality Assurance (VQA) program refers to the contract partner which conducts the VQA program, based at Rush University Medical Center
- Statistical Analysis Group (SAG)
- Data Management Group (DMG)
- New England Research Institute (NERI)
- Frontier Science and Technology Research Foundation (FSTRF)
- National Institutes of Health (NIH)
- Division of Acquired Immunodeficiency Syndrome (DAIDS)
- DAIDS Clinical Laboratory Oversight Team (DCLOT)
- Cross-Network Laboratory Focus Group (LFG)
- Network members include:
  - HIV Prevention Trials Network (HPTN)
  - HIV Vaccine Trials Network (HVTN)
  - AIDS Clinical Trials Group (ACTG)
  - International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT)
  - Microbial Trials Network (MTN)
  - International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)
- Total Quality Management (TQM) Program
- Network Site-Affiliated Laboratory (NSAL)
- HIV Clinical Trials Network Laboratories (NL)
- Primary Network Laboratory (PNL)

**Introduction**

The validity of diagnostic and monitoring tests is entirely dependent on the quality of the measures employed before, during, and after each assay. The consistent production of valid results will more likely occur when an overall program that includes Quality Assurance (QA) and Quality Control (QC) is utilized. To this end, the HIV Clinical Trials Network Laboratories (NL), which oversee the activities of all Network Site-Affiliated Laboratories (NSAL), endeavor to improve the quality and efficiency of protocol-related testing under a Total Quality Management (TQM) Program. Oversight of the TQM Program is provided by the Cross-Network Laboratory PI/Manager Committee and the Cross-Network Laboratory Focus Group (LFG). The Lab PI/Manager Committee will guide the working groups and participants responsible for the implementation of the TQM Program, and is comprised of representatives from DCLOT, each of the Networks, and EQA contractors. The Laboratory Focus Group represents a subset of the Lab PI/Manager Committee and is comprised of key Network Laboratory (NL) and/or Operations personnel of each Network. These Network Laboratory and Operations personnel serve as network contacts and are responsible for monitoring EQA results for each Network. Each international laboratory is assigned a single Primary Network Laboratory (PNL) that is responsible for coordinating feedback from all affiliated network contacts to the laboratory during a proficiency testing failure. Detailed information about the role of the PNL is included in Appendix A: PNL Communication Procedures for VQA Proficiency Testing.

Other groups that utilize the VQA program include WIHS, MACS, CHAVI, CIPRA, R01 and other DAIDS programs.

The Virology Quality Assurance Advisory Board (VQAAB) is comprised of representatives from the VQA program, DAIDS, Statistical & Data Analysis Center, the VQA Data Management Group (DMG) at Frontier Science and Technology Research Foundation (FSTRF), the VQA Statistical Analysis Group (SAG) at the New England Research Institute (NERI), the Laboratory Technologist Committee (LTC) and each of the respective networks. The function of the VQAAB includes:

1. Reviewing and approving proposed scoring from virology assay proficiency testing analyses.
2. Establishing monitoring standards, which differentiate between missing data, transcriptional or computational errors, and technical problems.
3. Reviewing and approving proposed changes in policies or procedures to promote quality assurance in virology assay testing.
4. Reviewing and approving proposed implementation of external quality control standards for use in virology assay testing.

Decisions regarding the consequences of unacceptable performance are made by the networks and protocol teams and should take each of these types of problems into consideration. Networks and protocol teams should apply these standards to:

- a. Protocol start up
- b. Protocol continuation
- c. Cessation of testing if established criteria are not met
- d. Resumption of testing – determine what must be accomplished prior to sites being able to resume testing after testing has been suspended.

An individual network or protocol team may discontinue or place a protocol on hold if they perceive standards are not being met; in which case the network or protocol team will be responsible for a clear line of communication to the relevant quality assurance.

### **Overview of Responsibilities and Data and Communication Flow**

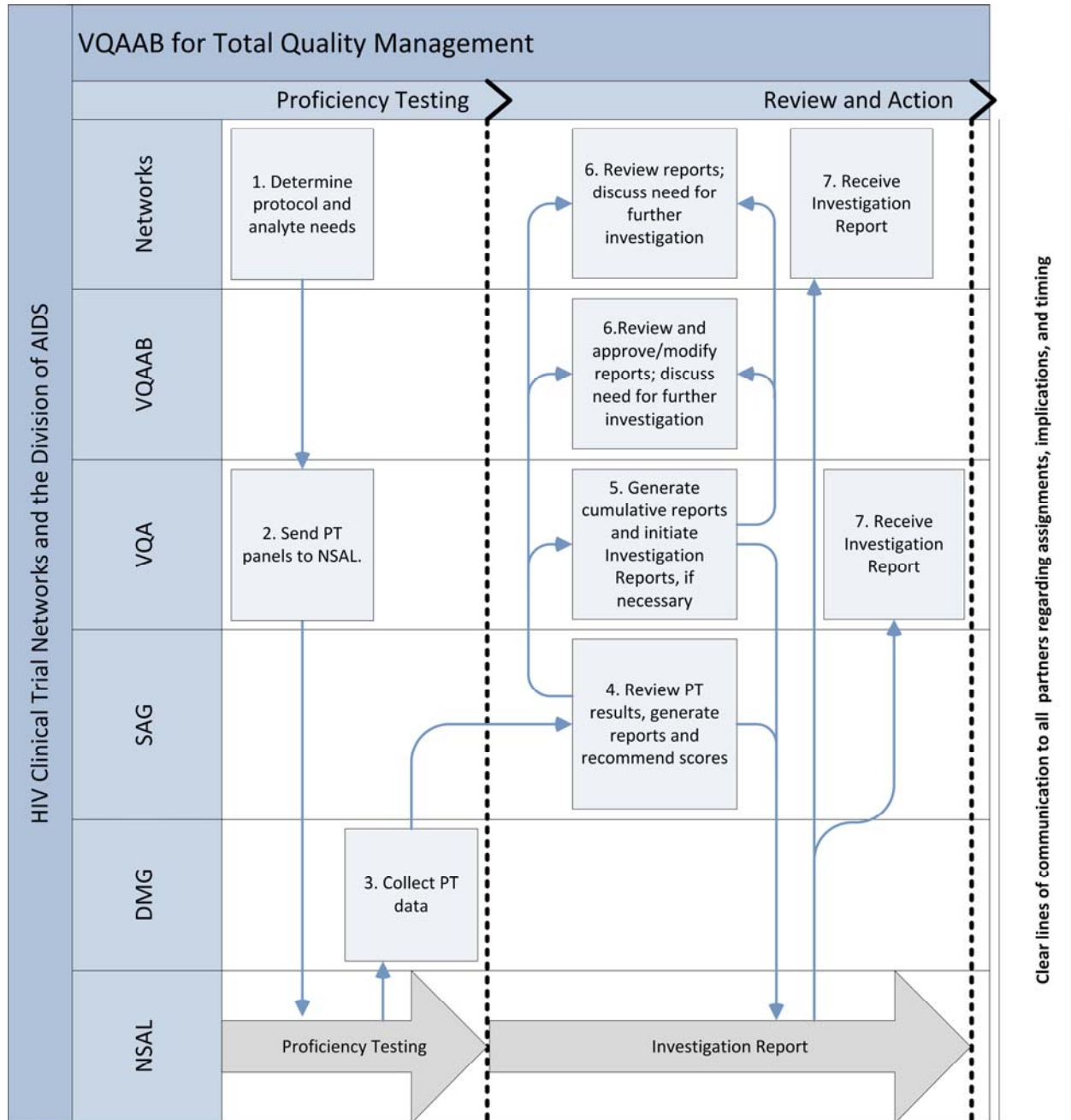
The delineation of roles and responsibilities between members of the VQAAB follows the VQAAB flow diagram of general roles and responsibilities in Figure 1 of this document.

The following are the steps in the iterative process for data and communication flow:

1. The networks will notify the VQA of specific NSAL EQA needs.
  - a. The networks will provide the VQA with a list of protocol and protocol analytes for each new NSAL.
  - b. For current NSALs, the networks will notify the VQA of new protocol and protocol analytes that are added or changes to current protocols. Additions should be communicated early so adequate EQA coverage can be purchased and performance documented prior to study initiation.
2. The VQA will ship proficiency testing panels to the NSAL on the given shipping date.
  - a. The VQA currently provides a proficiency testing program for:
    - i. Qualitative HIV-1 DNA Testing,
    - ii. Genotypic HIV -1 Drug Resistance Testing,
    - iii. Qualitative HIV-1 Macro/Microculture Performance; and
    - iv. Quantitative HIV-1 RNA Testing.

- b. The VQA will maintain a Survey Schedule on the HANC Public Website (<http://www.hanc.info/labs/Pages/VQAProficiencyTestingProgram.aspx>). Proficiency testing panels are sent to participating laboratories as outlined in the schedule.
3. The NSAL will submit proficiency testing results to the VQA DMG at FSTRF. The VQA program will:
  - a. Provide support to the NSAL to help ensure proficiency testing panel results are correctly submitted on time; this support consists of facilitating electronic data submissions.
  - b. Coordinate with the NSAL to allow delayed submittal of results via web-based exception request programs.
4. The VQA SAG will download the proficiency testing data.
  - a. The SAG will perform the analysis and will generate proficiency panel reports that contain recommended scores.
  - b. Every round, the SAG will send to each NSAL:
    - i. A report that contains the results from the proficiency testing analysis as well as the resultant score for that panel
    - ii. A report that summarizes the status of each NSAL
5. The VQA program will generate cumulative reports of NSAL status:
  - a. Cumulative reports will contain information about kits, platforms, scores, status and comments regarding follow-up
  - b. Cumulative reports of blinded data and blinded change in NSAL status will be distributed to the VQAAB
  - c. If necessary, the VQA will initiate an Investigation Report and send it to the NSAL for root cause analysis of the deficiency noted in proficiency testing
  - d. The VQA program will include all applicable NL and/or operations center personnel on reports as requested via email lists maintained by the VQA program. Email, VQA website access, and telephone calls are all possible means of communication with network personnel.
6. The VQAAB will review and approve and/or modify Proficiency Panel Reports and cumulative reports
  - a. HANC will post VQAAB Reports and proficiency testing information on the HANC public website at <http://www.hanc.info/labs/Pages/VQAAB.aspx>. This will include:
    - i. VQAAB Roster, including all VQAAB members and their contact information
    - ii. Proficiency Panel Reports dating back one year
    - iii. VQAAB Conference Call Minutes dating back one year
  - b. HANC will post blinded cumulative reports on the VQAAB team site on the HANC Portal.
  - c. HANC will post unblinded cumulative reports on the LFG team site on the HANC Portal.
  - d. Members of the VQAAB, the VQA program, and other relevant people (NL and operations center personnel) will participate in phone discussions directly as necessary.
  - e. Specific questions or issues should be addressed to the VQA site representative via email.
  - f. The VQA program will communicate with the NSAL regarding VQA evaluations.
7. Within four weeks of receiving notice that investigation is required, the NSAL will complete and submit an investigation report to the VQA program and to the appropriate NL and/or operations center.
  - a. Email and telephone will be used to decide if further investigation is required, what action should be taken, who will be assisting, etc. This will allow for all interested parties to be part of the discussion about shared sites NSAL.
  - b. Any problems or exceptions can be brought to the VQAAB for discussion and recommendations for actions to be taken

Figure 1. VQAAB EQA Monitoring, Data and Communication Flowchart



DMG = Data Management Group  
 NSAL = Network Site-Affiliated Laboratory  
 PT = Proficiency Testing  
 SAG = Statistical Analysis Group  
 VQA = Virology Quality Assurance (program)  
 VQAAB = Virology Quality Assurance Advisory Board