

POLICY
Requirements for Clinical Quality Management Plans

Approval Date: 17 MAR 2015
Effective Date: 17 APR 2015

No.: DWD-POL-CL-009.04

CHANGE SUMMARY: This policy and associated appendices have been reviewed for accuracy and updated to meet 508 compliance guidelines. Key changes to the policy require all sites to submit a bi-annual Clinical Research Site (CRS) Quality Assurance (QA) Summary Report. Additionally, the role of DAIDS in the review of the CRS QA Summary Report is outlined. This version supersedes version 3.0 dated 26 February 2010.

1.0 PURPOSE

The purpose of the policy is to describe the minimum requirements for the development, implementation, and evaluation of a Clinical Quality Management Plan (CQMP) at National Institute of Allergy and Infectious Disease (NIAID) Division of AIDS (DAIDS)-supported and/or -sponsored CRSs to ensure that the rights and safety of participants are protected and that data collected are valid, accurate and complete.

2.0 SCOPE

This policy applies to all CRSs conducting or participating in NIAID (DAIDS)-supported and/or -sponsored clinical research which includes all clinical and regulatory activities at the CRS.

3.0 BACKGROUND

Quality Management (QM) is part of a system of oversight required for the conduct of NIAID (DAIDS) - supported and/or -sponsored clinical research. QM activities will allow planning for effective protocol implementation, assure compliance with sponsor and applicable regulatory requirements, identify areas in need of corrective action, verify data accuracy, and assure a constant state of readiness for an external audit or monitoring visit. Since extensive external monitoring by DAIDS is not feasible, DAIDS has instituted a requirement for each CRS to develop, implement and evaluate a CQMP.

The CQMP is a “living document” that will be updated as site procedures are streamlined and new areas of focus are identified.

A QM system is a sites’ management system that is used to direct, control and manage quality in clinical trials. QM system includes defined quality requirements and includes site procedures, forms and templates, quality control (QC) and quality assurance (QA) processes, corrective and preventative action (CAPA) processes and continuous quality improvement activities that support data completeness and data integrity.

POLICY
Requirements for Clinical Quality Management Plans

Approval Date: 17 MAR 2015

No.: DWD-POL-CL-009.04

Effective Date: 17 APR 2015

QC is routine site operations, techniques and activities taken to verify the trial requirements are executed correctly, at the time the work is being performed with real time corrections.

QA is a retrospective, objective, systematic, and periodic review of trial-related activities to ensure that the trial is conducted and the data are generated, documented and reported in compliance with Good Clinical Practice (GCP) and any applicable regulatory requirements.

4.0 DEFINITIONS

For definitions, see [DAIDS glossary](#).

5.0 RESPONSIBILITIES

The Clinical Trial Unit (CTU) will fulfill the requirement of the CQMP policy by developing a SOP that clearly describes how its CRS components plans to implement the CQMP policy.

The requirement for the CQMP policy at a Non-Network site should be discussed with the assigned DAIDS Program Officer.

The Principal Investigator (PI) is ultimately responsible for the development, implementation, and evaluation of a CQMP. The PI may delegate QM activities to the CRS Leader and other clinical research personnel qualified by training and experience.

6.0 POLICY

All DAIDS -supported and/or -sponsored sites conducting clinical research will develop, implement, and evaluate a CQMP.

6.1 DAIDS requires that the CQMP include the following:

6.1.1 Description of roles and responsibilities of key personnel involved in the development, implementation, and evaluation of the CQMP.

6.1.2 At a minimum, inclusion of the following key indicators (as applicable) for QA/QC review:

1. Informed Consent Form and Process
2. Assessment of Understanding as applicable
3. Eligibility Criteria

POLICY
Requirements for Clinical Quality Management Plans

Approval Date: 17 MAR 2015
Effective Date: 17 APR 2015

No.: DWD-POL-CL-009.04

4. Protocol Required Tests and Procedures
5. Visits/Missed Visits
6. Concomitant/Prohibited Medications
7. Study Product Administration/Dosing
8. Adverse Events (AE), Serious Adverse Events (SAE) and DAIDS Expedited Adverse Events (EAE) identification and reporting
9. Protocol Defined Endpoint Identification
10. Source Documents, Signatures, Initials, Dates
(See Appendix 1, Clinical Quality Management Plan: Sample QA Chart Review Tool)

6.1.3 Description of Quality Management (QM) Activities

6.1.3.1 Quality Control (QC)

QC activities function to support and ensure that the staff performing the work are doing so correctly per the designated instructions and requirements, while the work is being performed in real-time. QC activities also support GCP compliance, human subject protection (HSP), adherence to protocol requirements and site procedures.

Examples include:

1. At the end of a participant visit, double check and verify that all required tests and procedures on the Study Visit Checklist have been completed prior to the participant departure from the clinic.
2. Re-review Informed Consent documents to ensure that all required dates, entries and signatures are recorded prior to participant departure from the clinic.

6.1.3.2 Quality Assurance (QA)

QA audit activities are conducted periodically in a systematic manner on a defined subset of the sites' clinical trial related activities and documents. The QA audits are conducted after the work has been completed and functions as an independent examination for adherence to GCP, HSP, protocol and all other requirements.

POLICY
Requirements for Clinical Quality Management Plans

Approval Date: 17 MAR 2015
Effective Date: 17 APR 2015

No.: DWD-POL-CL-009.04

Examples include:

1. Weekly evaluations to determine agreement between key elements of source documentation when compared to completed CRFs.
2. Monthly assessment of regulatory file documents to ensure that contents are current and complete. (See Appendix 2, Clinical Quality Management Plan: Sample QA Protocol Regulatory File Review Tool)

6.1.3.3 Description of tools to be used in the QA and QC processes

Examples may include, but are not limited to the following: visit reminder checklists, data entry, query reports from the Data Management Center, Clinical Site Monitoring Reports and Chart and Protocol Regulatory Review Tools.

6.1.4 QA Audit Sample Size

6.1.4.1 QA Audit sample size determination

1. Designation of a minimum percent of records for QA audit based on, but not limited to: high risk protocols, higher accruing protocols, initial enrollments in new protocols, and protocol visits conducted by new or less experienced staff members.
2. DAIDS may set a minimum required percent of participant records for QA audit for a particular trial or a CRS at DAIDS discretion.

6.1.5 Description of QA activities to be performed in order to ensure that the contents of the protocol regulatory files are complete and current

6.1.6 Documentation of QM activities to include the following:

1. Name of reviewer
2. Date of the review
3. Participant identification (PID) numbers reviewed
4. Specific indicators that were reviewed
5. Protocol regulatory documents reviewed
6. Time period covered by the review
7. Findings/results of review
8. Corrective actions

POLICY
Requirements for Clinical Quality Management Plans

Approval Date: 17 MAR 2015
Effective Date: 17 APR 2015

No.: DWD-POL-CL-009.04

- 6.1.7 Description of CQMP Evaluation Process
 - 6.1.7.1 The CQMP will describe how the findings from QC and periodic QA activities will be analyzed and evaluated.
 - 6.1.7.2 The CQMP will describe process for communication of findings to appropriate staff.
 - 6.1.7.3 The CQMP will describe process for corrective action and continuous improvement that may require changes to site practices and the CQMP.
- 6.2 Quality Assurance Reporting Requirements
 - 6.2.1 QA findings will be reported to DAIDS bi-annually using the CRS QA Summary Report template. (See Appendix 3, CRS Quality Assurance Summary Report.) At DAIDS discretion, QA reporting may be required more frequently based on site performance. The CRS will evaluate the CQMP after each QA review.
 - 6.2.2 The CRS QA Summary Report will include identification of problems, identification of possible causes, and any corrective actions taken.
 - 6.2.3 If an unreported SAE is identified during the QM activities, the event must be reported per protocol, DAIDS EAE policy and institutional requirements.
- 6.3 DAIDS review of the CQMP and CRS QA Summary Report
 - 6.3.1 DAIDS will review the CQMP prior to its implementation. The CRS will submit any subsequent non-administrative changes of the CQMP to DAIDS.
 - 6.3.2 DAIDS will review the CRS QA Summary Report using a DAIDS-defined process and communicate any recommendations to the CRS.
- 6.4 Retention of QM documents
 - 6.4.1 The CQMP will be signed and dated by the PI and or the CRS Leader and kept on file.

DAIDS
Bethesda, MD USA

POLICY
Requirements for Clinical Quality Management Plans

Approval Date: 17 MAR 2015

No.: DWD-POL-CL-009.04

Effective Date: 17 APR 2015

6.4.2 Completed CRS QA Summary Reports, Chart Review Tools and Protocol Regulatory File Review Tools will be kept on file and accessible upon DAIDS request.

7.0 REFERENCES

[International Conference on Harmonization, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidance](#)

8.0 INQUIRIES

Questions and comments regarding this SOP may be directed to the [OPCRO Policy Group](#).

9.0 AVAILABILITY

This policy is available electronically on the [Division of AIDS \(DAIDS\) Clinical Research Policies and Standard Procedures](#) webpage.

10.0 APPENDICES

Appendix 1- Clinical Quality Management Plan (CQMP): Sample QA Participant CHART Review Tool DWD-POL-CL-009.04A2

Appendix 2- Clinical Quality Management Plan (CQMP): Sample QA Protocol Regulatory File Review Tool DWD-POL-CL009.04A3

Appendix 3- Clinical Research Site (CRS) Quality Assurance (QA) Summary Report OMB Control #: 0925-0668

11.0 APPROVAL

Carol J. Worrell, M.D.

Director, Office for Policy in Clinical Research Operations (OPCRO)