DAIDS
Bethesda, MD USA

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Requirements for Clinical Quality Management Plans

Approval Date: 26 FEB 2010
Effective Date: 26 MAR 2010 No.: DWD-POL-CL-009.03

NOTE: This policy and associated appendices have been reviewed for accuracy and updated to meet 508 compliance guidelines. DAIDS has clearly stated the minimum requirements for the CQMP and provided examples as appropriate. Key changes include the clarification of Principal Investigator, Investigator of Record, and Clinical Site Leader responsibilities. Updates also include the role of DAIDS in CQMP review as described in section 6.1.10. This version supersedes version 2.0 dated 20 DEC 06.

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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 clinical research sites to ensure that the rights and safety of participants are protected and that data collected are accurate and complete.

2.0 SCOPE

This policy applies to all clinical research sites conducting or participating in NIAID (DAIDS)-supported and/or -sponsored clinical research. This policy refers to CQMPs that address clinical and regulatory activities at the clinical research site.

Note: Refer to DAIDS guidance and policies for quality management requirements for laboratory and/or pharmacy activities.

3.0 BACKGROUND

The CQMP is a "living document" that should be updated/changed as procedures are streamlined and new areas of focus are identified. Quality Management (QM) is part of a system of oversight required for the conduct of NIAID (DAIDS)-supported and/or -sponsored clinical research. Since extensive external monitoring by DAIDS is not feasible, DAIDS has instituted a requirement for each clinical research site to develop, implement and evaluate a CQMP. 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.

A QM system includes both Quality Control (QC) and Quality Assurance (QA). QC is the real time, on-going (day-to-day) operational techniques and activities that are undertaken to verify the requirements for quality trial-related activities. QA is a

retrospective, objective, systematic, and periodic review of trial-related activities to ensure that the trial is performed 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:
http://www3.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Glossary

5.0 RESPONSIBILITIES

Principal Investigator (PI), Investigator of Record (IoR), Clinical Research Site(CRS) Leader, and/or designee

The *PI, IoR, CRS Leader and/or designee* is responsible for the development, implementation, and evaluation of a CQMP.

6.0 POLICY

All DAIDS clinical research sites conducting clinical trials will develop, implement, and evaluate a CQMP.

6.1 DAIDS recommends that the CQMP include the following:

6.1.1 Description of the person(s) responsible for 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. Eligibility criteria
3. Scheduled tests and procedures
4. Missed visits, tests, or procedures

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5. Concomitant/prohibited medications

6. Study product administration/dosing

7. Clinical endpoint identification

8. Identification and reporting of Serious Adverse Events (SAE), DAIDS Expedited Adverse Events (EAE) and Adverse Events (AE)

6.1.3 Description of Quality Management (QM) activities

6.1.3.1 Quality Control (QC)

Description of QC activities, including the scope (number and type) of QC activities. QC is typically performed on 100% of Case Report Forms (CRFs) prior to entry into the database and on other trial related forms. For example: Verification that all headers, required fields, and dates are completed correctly on case report forms (CRFs).

6.1.3.2 Quality Assurance (QA)

A description of the frequency of review for each type of research record during a defined period of time. For example, staff may evaluate key elements of source documentation and compare them to completed CRFs for agreement weekly.

6.1.4 Designation of a minimum percent of records for QA review in the CQMP 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. DAIDS may set a minimum required percent of records for QA review for a particular study or clinical research site.

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6.1.5 Description of QA and QC activities to be performed in order to ensure that the contents of regulatory files are complete and up-to-date.

6.1.6 Description of tools or checklists 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 and error reports from the data management center; clinical site monitoring reports; chart review tools

6.1.7 Documentation of QM activities

6.1.7.1 Documentation of QM activities should include the following:

1. Name of the reviewer
2. Date of the review
3. Participant identification numbers of items reviewed where indicated
4. Specific items that were reviewed
5. Time period covered by the review
6. Findings/results of review

6.1.8 Description of CQMP Evaluation

6.1.8.1 Description of frequency and types of QC and QA activities that will be evaluated and how they will be communicated to appropriate staff.

6.1.8.2 A Summary of Activities Tool should include identification of problems, identification of possible causes, and any corrective actions taken.

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6.1.8.3 The CQMP should describe how the findings from annual CQMP review, or more frequently as needed, are evaluated and communicated to appropriate staff. Annual Summary Review Reports should include identification of problems, identification of possible causes, and any corrective actions taken.

6.1.8.4 DAIDS may evaluate implementation of the CQMP through site monitoring visits.

6.1.9 Description of Reporting Requirements

6.1.9.1 QM findings must be reported to DAIDS per established DAIDS and protocol requirements. For example: If an unreported serious adverse event is uncovered during QM activities, report the event per protocol, DAIDS, and site or institutional requirements.

6.1.9.2 On an annual basis, clinical research sites must prepare an evaluation of the CQMP and related activities to be submitted to DAIDS utilizing the DAIDS specified format, e.g. Type 5 grant progress report.

6.1.10 DAIDS review of the CQMP

At DAIDS' discretion, the CQMP may be reviewed prior to its implementation. The clinical research site may be required to submit revisions of the CQMP to DAIDS.

7.0 REFERENCES

International Conference on Harmonization, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guideline
http://www.fda.gov/oc/gcp/guidance.html

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8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at: NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:

http://www3.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/PDF/QMPPolicy.htm

10.0 CHANGE SUMMARY

This policy replaces version 2.0 dated 06 Dec 2006.

11.0 APPENDICES

Appendix 1 - Sample Clinical Quality Management Plan (CQMP) [CL.205]

Appendix 2 - Sample Clinical Quality Management Chart Review Tool [CL.206]

Appendix 3 - Sample Clinical Quality Management Regulatory File Review Tool [CL.207]

Appendix 4 - Sample Clinical Quality Management Summary of Activities Tool [CL.208]

Appendix 5 - Sample Clinical Quality Management Plan Annual Summary Report [CL.209]

12.0 APPROVAL

/Dr. Richard Hafner, MD/
Richard Hafner

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