DAIDS
Bethesda, MD USA

ARCHIVED APPENDIX

Sample Clinical Quality Management Plan (CQMP)

Approval Date: 26 FEB 2010
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(SAMPLE ONLY. The template below is provided for your convenience as an example of how this information may be provided. Frequency/percentage of reviews and types of tools/reports used should be selected to meet the specific needs of the clinical research site.)

Site Number_____ **Site Name_____**

Section I: Responsibility
John Smith, MD, Principal Investigator, is responsible for the Clinical Quality Management Plan at _____.

Mary Brown, RN, Study Coordinator, has been designated by Dr. Smith to be responsible for the implementation of the Clinical Quality Management Plan.

Section II: Key Quality Control (QC) Staff
Bill Thomas, Data Manager, is responsible for the day-to-day QC activities, with support from other data personnel.

Section III: Key Quality Assurance (QA) Staff
Sara Johnson, RN, is responsible for QA activities at the site.

Section IV: QM Activities and Tools

Quality Control (QC):

The following activities and tools will be utilized in the QC process:

1. Error correction reports from the data management center will be reviewed by the Data Manager, who will immediately bring any errors identified to the attention of the appropriate site staff for correction. Errors will be corrected within 2 business days of identification.

2. Data entry and transmission reports will be reviewed by the Data Manager to assure that transmitted data was successfully entered into the database. Errors will be brought to the attention of the responsible person and corrected within one business day of identification.

3. Error tracking logs will be completed by the Data Manager. This log identifies and tracks categories of Case Report Form (CRF) errors. This information will be aggregated and reported to the site staff as a whole at weekly meetings.

4. Data staff will review 100% of CRFs prior to data entry for completeness, to ensure proper dating and signing, etc.

Quality Assurance (QA):

The following activities and tools will be utilized in the QA process:

1. The Chart Review Tool is utilized for participant specific chart review. It is inclusive of all key indicators for QA review as listed in Section V below.

2. The Regulatory Review Tool is used for quarterly review of regulatory documents, including Safety Report submission, Institutional Review Board (IRB)/Ethics Committee (EC) approvals and communications, Form FDA 1572, etc.

3. Monthly Activity Reports are protocol-specific summaries of QM activities that are shared with the site staff at monthly meetings.

4. Quarterly Site Monitoring Reports from the DAIDS Contract Monitor are utilized as a QA tool, checking for any adverse trends or problems. These reports will be shared quarterly during staff meetings.

Section V: Key Indicators

These indicators are part of the chart review:

1. Informed consent forms and processes
2. Eligibility criteria
3. Missed visits, tests, and procedures
4. Concomitant/prohibited medications
5. AE/SAE/EAE identification and reporting
6. Study Product administration
7. Protocol endpoint identification

Section VI: Review Priorities

QA and QC are ongoing activities. Monthly QA reviews will consist of 10%, at a minimum, of the clinic records, alternating existing open protocols to assure review of all active protocols over the course of the year.

Priorities will be in the following order:

1. New Staff: 100%, and no less than 5, of all visits completed by new staff will receive a QA review until competency is determined.
2. New Protocols: The first 3 records for a new protocol will receive a QA review.
3. Complex Protocols: Based on recommendations of the Principal Investigator (PI) and/or Study Coordinator, complex or large protocols may be targeted for an early or more thorough review.

Section VII: Correction Process

Once a problem has been identified by analysis of the QA or QC findings, it will be discussed with the site staff at the next monthly meeting. The root cause of a recurrent problem will be identified and actions will be taken to correct the problem based on the input from the site staff. These actions may include, but are not limited to, changing a process or form, training, or reassigning a task. Any adverse trend will be re-evaluated to assess the effectiveness of the corrective action.

Section VIII: QM Results Reporting

Documentation of QM findings will include:

1. Date of review
2. Name of reviewer
3. Participant Identification (PID) Number
4. Items reviewed
5. Findings/results of review
6. Time period covered by review

Additionally, there will be a monthly report prepared by the Data Manager, which will include both the protocol-specific and site-specific summary of QM findings for the month. When monitoring reports are received, these findings will be included in the summary report. This report will be

shared with site staff at the monthly staff meeting. Overall QA and QC findings, corrective actions, and follow-up actions will be discussed at staff meetings.

Section IX: Staff Training

All new staff will have a competency-based orientation using the tools and forms from the site SOP manual. A competency checklist will be completed by both the new staff member and site-designated training mentor. Orientation to DAIDS-specific and other relevant policies and procedures will occur. Training will be documented, signed, and filed in the study Regulatory binder.

Section X: Revision/Evaluation/Reporting

There will be an annual staff meeting at which an analysis of the findings and activities of the previous year is undertaken. At this meeting it will be determined if any changes are to be made to the CQMP. Additionally, Dr. Smith will prepare an annual evaluation of the CQMP and its activities to be submitted to DAIDS, utilizing the DAIDS-specific format.

Submitted by: John Smith, MD, Principal Investigator (Example)

Signature: _____ Date: _____