

DAIDS
Bethesda, MD USA

ARCHIVED APPENDIX

Sample Clinical Quality Management Summary of Activities Tool

Approval Date: 26 FEB 2010

Effective Date: 26 MAR 2010

No.: DWD-POL-CL-009.03A4

Sample Clinical Quality Management Summary of Activities Tool

(SAMPLE ONLY. This information may be utilized (at site specified frequencies) for the summary of QA/QC activities, and includes information from completed chart review tools, regulatory files review tools, and other site-developed tools.)

Site Name _____ Site _____

Report Date _____ Person Preparing Report _____

Reporting
Period _____

A. Summary of QA/QC Activities for the Reporting Period:

1. Number of Participant Records Reviewed (List by protocol number):
2. Protocols Reviewed (List by Number):
3. Number of Regulatory Files Reviewed (List by protocol number):

B. QA/QC Problems/Trends Identified:

Protocol #	Problems Identified

C. Corrective Action Implemented: (Note planned date of completion)

Protocol #	Corrective Action and Planned Date of Completion

D. Improvement Noted: (effectiveness of corrective action implemented)

Protocol #	Improvement and Date Noted

Signature and date of Reviewer _____

Reviewed by Principal Investigator (signature and date) _____