**[*Insert Clinical Research* *Site (CRS) Name and CRS number*]**

# Clinical Quality Management Plan (CQMP) Template

**CQMP Version:**  *[insert version]*

**Effective Date:** *[insert date]*

*[SAMPLE ONLY. The template below is provided as an example of how a CQMP may be developed and the information within organized. Wording, frequency/percentage of reviews and types of tools/reports used in addition to those which DAIDS requires, should be selected to meet the specific needs of the clinical research site (CRS)]*

## 1.0 PURPOSE

*The purpose of this CQMP is to outline the roles and responsibilities, various activities, and procedures that will be undertaken at [insert CRS name] to implement Quality Management (QM).*

## 2.0 SCOPE

*This CQMP applies to all CRS staff, and the procedures used to conduct clinical trials at [insert CRS name]. It outlines the steps followed by the CRS staff to conduct Quality Management activities.*

## 3.0 DEFINITIONS

*Include a list of terms including but not limited to, Quality Assurance (QA), Quality Control (QC), Quality Management (QM) and acronyms that are helpful for the proper understanding of the Plan. Include additional items to this list as appropriate. Consider country, state, local, or institutional terms and acronyms that may be specific to your CRS.*

## 4.0 ROLES AND RESPONSIBILITIES

The Clinical Research Site (CRS) Leader is responsible for the development, implementation, and evaluation of the CQMP and may delegate QM activities to other clinical research personnel qualified by documented training and experience.

*Clearly indicate the role(s) responsible for each action. Please note:*

* *Job titles/roles should be used in this Plan instead of specific staff members’ names to limit revisions due to staff turnover.*

*For example:*

*Quality Assurance Manager: Will be responsible for determining the sample for the bi-annual Quality Assurance review.*

*Study Coordinator and/or Regulatory Specialist: Will be responsible for Regulatory File Reviews.*

*Study Nurse and/or Data manager: Will be responsible for conducting Participant Chart reviews.*

*Quality Assurance Manager and/or Research Manager: Will be responsible for generating the QA Summary Report.*

*Quality Assurance Manager and/or Study Coordinator: Will be responsible for submitting the QA Summary Report to Office of Clinical Site Oversight (OCSO) Program Officer (PO) bi-annually.*

***Note:*** *The titles provided above are examples, can be replaced by the titles of other CRS staff.*

### 5.0 PROCEDURES

*Describe the specific actions to be completed to implement QM activities. Use simple language and be clear and concise.*

### 5.1 Quality Control (QC)

*Describe the quality control activities at the CRS.*

*For example:*

* *100% of Completed Informed Consent Forms (ICF) will be reviewed for participant signatures and dates by a 2nd study staff member at each ICF visit before the participant leaves the CRS.*
* *100% of Visit Documentation will be reviewed by a 2nd study staff member for the first 5 visits conducted by a new study staff member before the participant leaves the CRS.*
* *100% of the eligibility checklists will be reviewed by Principal Investigator (PI)I/Investigator of Record (IoR) before administration of first dose of the study product.*
* *100% of the prescriptions will be reviewed by a 2nd Pharmacist for completion before study drug dispensation (if clinic and Pharmacy will have the same Quality Management Plan).*
* *100% of Visit Documentation will be reviewed by a 2nd study staff member for all study drug administration/Infusion visits.*
* *100% of the Institutional Review Board (IRB)/Ethics Committee (EC)approvals will be reviewed by the study coordinator and/or regulatory affairs specialist for accuracy of dates, versions and titles of the approved documents.*
* *100% of Serious Adverse Events (SAEs) documentation will be reviewed by PI/IoR/Clinician within 48 hours of CRS becoming aware of the event.*

### 5.2 Quality Assurance (QA)

*Describe the quality assurance activities at the CRS.*

*For example:*

* *10% or at least two participant charts**, whichever is higher, will be reviewed bi-annually for each active protocol at the CRS by [add role, for example: QA specialist].*
* *Regulatory Files will be reviewed for completeness and accuracy for 25% or at least one, whichever is higher, active protocols at the CRS bi-annually by [Regulatory Specialist].*
* *20% or at least two of the re-consents, whichever is higher, administered at the CRS will be reviewed bi-annually for completeness and timeliness by [add role, for example: Data Manager].*
* *20% or at least two of completed initial ICFs, whichever is higher, administered at the CRS will be reviewed bi-annually for completeness, accuracy and timeliness by [add role, for example: Study Coordinator].*
* *20% or at least two of the initial AND re-consent ICF process documentation, whichever is higher, completed at the CRS will be reviewed bi-annually for completeness and timeliness by [add role, for example: Study Nurse].*
* *10% or at least two eligibility checklists, whichever is higher, (for x number of protocols) will be reviewed bi-annually for completeness and accuracy by [add role, for example: Study Coordinator].*
* *100% of the all reported SAEs will be reviewed bi-annually for completeness and accuracy of initial as well updates documentation by [add role, for example: Study Coordinator].*

CRSs should consider a risk-based approach in determining the frequency and the sample of the QA review. For fast and high enrolling trials a higher frequency of QA reviews may be needed.

If the CRS does not perform any or all of the QA activities required by their CQMP for a clinical trial for a review cycle, the *[Quality Assurance manager]* will document in the QM binder the reasons for not conducting the bi-annual QA review for that clinical trial.

### 5.3 Key Indicators (KIs)

The following KIs (as applicable) will be included in the bi-annual QA review:

* Informed Consent Form and Process
* Assessment of Understanding of ICF as applicable
* Eligibility Criteria and Process
* Protocol Required Tests and Procedures
* Visits/Missed Visits
* Concomitant/Prohibited Medications
* Study Product Administration/Dosing
* Adverse Events (AE), SAE and DAIDS Expedited Adverse Events (EAE) identification and reporting
* Protocol Defined Endpoint identification and reporting as applicable
* Source Documents, signatures, initials, dates
* Investigator File review deficiencies
* *Any other CRS-specific KIs, for example:*
	+ *Participant recruitment*
	+ *Participant retention*
	+ *Study staff retention*

### 5.4 QC/QA Review Tools

*Describe the tools used by the CRS staff to conduct the QA/QC activities*

* DAIDS CQMP Participant CHART Review Tool
* DAIDS Protocol Regulatory File Review Tool
* *Visit reminder checklists*
* *Data management query reports*
* *Site monitoring reports*
* *Eligibility checklists*
* *Other tools developed by the CRS*

### **5.5 Evaluation of the findings**

*Describe how and who will be responsible for evaluation of the findings, who will determine what the corrective and preventive actions will be, who will implement the corrective and preventive actions, timeline for who will review and assess the completed corrective and preventive actions for effectiveness.*

*For example:*

* *The CRS staff will meet and discuss all the findings, collect input towards corrective and preventive actions; meeting minutes will be shared for those unable to attend these meetings.*
* *[QA Manager] will draft corrective and preventive actions as applicable for each finding.*
* *[CRS leader/PI/IoR] will review the draft corrective and preventive actions as applicable for each finding and agree or ask to revise the actions.*
* *[Study Coordinator] will implement the corrective and preventive actions (CAPA) as applicable for each finding.*
* *[Study Coordinator] will conduct the effectiveness check of the implemented corrective and preventive actions.*
* *[CRS Leader] will review the effectiveness check results and the CAPA tracker annually.*

### 5.6 Documentation of the QM activities

Documentation of all QM activities must include the following:

* Name and role of reviewer
* Date of the review
* Participant identification (PID) numbers reviewed
* Specific indicators that were reviewed
* Protocol regulatory documents reviewed
* Time period covered by the review
* Findings/results of review
* Root Cause analysis, if applicable
* Corrective actions
* Preventive actions

### 5.7 Preparation of the DAIDS CRS QA Summary Report

*[QA manager or designee]* will use the CRS Quality Assurance QA Summary Report template to summarize the QA findings and submit to OCSO PO bi-annually.

For guidance and instructions on preparation of the QA Summary Report please consult Guidelines for Preparation of the Bi-annual Quality Assurance (QA) Summary Report in the DAIDS SCORE Manual.

### 5.8 Retention of QM Documents

Completed CRS QA Summary Reports, Participant Chart Review Tools and Protocol Regulatory File Review Tools will be kept on file (separately from the Investigator Site File) and be accessible to DAIDS and their representatives upon request.

## 6.0 APPENDICES

*List forms, templates, examples, or samples referenced in the body of this CQMP.*

*Appendix 1 -* Participant Chart Review Tool

*Appendix 2 -* Protocol Regulatory File Review Tool

*Appendix 3 - Any other CRS-specific tools*

## 7.0 CHANGE HISTORY

List previously approved versions of the CQMP and a brief description of the change(s), with the most recent version of the CQMP listed at the top. DD/MM/YYYY date format is encouraged.

|  |  |  |  |
| --- | --- | --- | --- |
| **Date:**  | **Version Number:** | **Pages:** | **Description of Change:** |
| blank |  |  |  |

## 8.0 CQMP APPROVAL

Each updated version of the CQMP should be approved by the *[PI/IoR/CRS Leader].*

|  |  |  |
| --- | --- | --- |
| **Printed Name:** | **Signature:** | **Date:** |
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