

# CQMP REFERENCE MATERIAL NOT FOR SUBMISSION

## Clinical Research Site (CRS) Quality Assurance (QA) Summary Report

*Instructions: Please complete this form from QA reviews conducted for at least 3 consecutive months of protocol activities at your CRS. Use information from your chart review tool, protocol regulatory file review tool and other documents used in your QA activities*

Site Name \_\_\_\_\_

Site Number \_\_\_\_\_

Role of Person Preparing Report \_\_\_\_\_

Date of QA Report \_\_\_\_\_

Period of Review (At least 3 consecutive Months): (Date) \_\_\_\_\_ to (Date) \_\_\_\_\_

### 1. Composition of PIDs reviewed;

- a. Number of newly enrolled PIDs at CRS during the review period (=m) \_\_\_\_\_
- b. Number of newly enrolled PIDS reviewed during this period (=n) \_\_\_\_\_
- c. Percent of newly enrolled PIDs reviewed ( $=n/m * 100$ ) \_\_\_\_\_
- d. Total number of PIDs reviewed during this period (Old PIDs + Newly enrolled PIDs=x) \_\_\_\_\_
- e. Total number of PIDs with study visits occurring during this review period (y) \_\_\_\_\_
- f. Percent of total PIDS reviewed ( $=x/y * 100$ ) \_\_\_\_\_ (*Reflective of Minimum Sample Size per site's CQMP*)

*PIDs reviewed are unique PIDs*

*Newly Enrolled PIDs – PIDs enrolled at CRS during the period in which QA reviews were conducted and captured for this report*

*Old PIDs-PIDs with study visits occurring during the review period, in which QA reviews were conducted and captured for this report, enrollment occurred prior to this QA review period*

## 2. Summary of Protocols Reviewed

Complete only for protocols associated with PIDs for which chart review was conducted. All cells may not need to be completed

Protocol	First PID Enrolled (yr)	Number of Records Reviewed

## 3. List Quality Control (QC)/Quality Assurance (QA) tools used for this QA review. *E.g. Chart Review Tool etc.*

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**4. Summary of Key Indicators (KIs) and Number of Associated Findings** (Key Indicators as noted in the DAIDS CQMP Policy and site specific KIs in blank cells, if applicable)

Key Indicator(s)	Number of Findings	Not Applicable
Informed Consent Form and Process		
Assessment of Understanding		
Eligibility Criteria		
Protocol Required Tests and Procedures		
Visits/Missed Visits		
Concomitant Meds/Prohibited Meds.		
Study Product Administration/Dosing		
AEs/SAEs/EAEs		
Protocol Defined Endpoints		
Source Docs, Signatures, Initials and Dates		

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### 5. Summary of deficient Key Indicators (KIs) and associated Criteria

List one Key Indicator per line for each PID. Capture the criteria associated with the deficient KI. If there is more than 1 criteria per key indicator, capture all associated criteria in one cell. List all corrective and preventative actions associated with each different criterion in one cell. Use short and concise statements. (See example in first row)

PID #	Protocol #	Deficient Key Indicator(s)	Criteria Associated with Deficient KIs	Describe Corrective and Preventative Action Implemented
123	A1000	Informed Consent	1. Missing Participant Signature 2. Participant was not offered copy of signed ICF	1. Participant was asked to sign ICF at next visit. 2. A copy of signed ICF offered to Participant. Revise Enrollment visit checklist to include review of ICF requirements prior to Participant departure from clinic


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## Regulatory File Review

*Based on findings identified in the Clinical Quality Management Regulatory File Review Tool, complete the following questions*

1. Was a Quality Assurance Review of the Regulatory File conducted during this review period? Y \_ N \_
2. If no, provide an explanation

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3. **If yes, specify protocol and complete table below for protocol(s) reviewed.** Capture the deficient document and associated criteria. If there is more than 1 criteria, capture all associated criteria in one cell. List all corrective and preventive actions associated with each different criteria in one cell. Use short and concise statements

Protocol	Deficient Document(s)	Criteria Associated with Deficient Documents	Describe Corrective and Preventative Action Implemented
A53XX	DAIDS Approval	1. Initial DAIDS Regulatory Support Center (RSC) approval for protocol registration not on file 2. Subsequent RSC approval missing on file	1. Locate DAIDS RSC approval letter and file in regulatory binder. 2. Implement a system of filing all communication documents on a weekly basis and delegate that task to the Research assistant.

4. **CQMP Revision**

- a. Does the CQMP need revision based upon the QA findings included in this CRS QA Summary Report?

Y\_\_\_\_\_ N\_\_\_\_\_

- b. If yes, please specify areas to be revised