

Guidelines for Clinical Research Site (CRS) staff on Preparation of the Bi-annual Quality Assurance (QA) Summary Report required per DAIDS Clinical Quality Management Plan (CQMP) Policy

Purpose

This document provides guidance to the CRS staff that are responsible for the preparation and submission of the bi-annual Quality Assurance (QA) Summary Reports to the Office of Clinical Site Oversight (OCSO) Program Officers (PO) per “Requirements for Clinical Quality Management Plans (CQMP) Policy” POL-A28-OCS-001.00.

QA Summary Reports Preparation

The process will start with completing the review of selected participant charts and selected regulatory files for a period of at least three (3) consecutive months. POL-A28-OCS-001.00 provides two (2) appendices that should be used as tools to complete these reviews:

- Appendix I: Participant Chart Review Tool; APP-A28-OCS-001.00
- Appendix II: Protocol Regulatory File Review Tool; APP-A28-OCS-002.00

CRS staff should use these tools to complete your QA reviews. In addition, sites can use any other supplemental tools they feel necessary to complete these QA reviews. Please save all the completed tools in a folder separate from the Regulatory Files of the protocols. These completed tools are not auditable by the Regulatory Agencies, only by the sponsors and sponsor representatives.

Once you have completed review of participant charts and/or the regulatory file for at least a 3-month consecutive period and populated the participant chart review tools (one per selected chart) and/or protocol regulatory file review tool, you should be ready to prepare the CRS QA Summary Report APP-A28-OCS-003.00 (Appendix III to the DAIDS CQMP Policy) for bi-annual submission to DAIDS.

Title Page

Site Name: Populate the site name in this section, do not use abbreviations, write the full name and abbreviation (if applicable) in parentheses. For example: Site A Clinical Research Unit (Site A-CRU)

Site Number: Populate the CRS number in the section. For example: CRS 1234

Role and name of Person Preparing the Report: Populate the name of the person who is preparing this report. This does not have to be the same person who conducted the QA reviews of the participant charts or the regulatory file, or even the person who submits the QA Summary Report to DAIDS. This is simply the person who is preparing the QA Summary Report.

Depending upon the organizational structure of the clinical site, the person conducting the QA reviews of the participant charts and/or regulatory file can be different or the same as the person preparing the QA Summary Report. For example: The Data Manager may conduct the QA review of the participant charts. The Site Coordinator may conduct the regulatory file review. Both then provide their findings to a Nurse who then compiles the QA Summary Report. Alternatively, all three (3) tasks may be completed by the same person.

Date of QA Report: Populate the date of the completion of the QA Summary Report. This date is not to be confused with the date(s) of the actual QA reviews of participant charts and/or regulatory file. Those dates should be populated in the tools used to complete those reviews.

Period of Review: The period of review should be at-least three (3) consecutive months of protocol activities. If you had participant visits in January and March but none in February, the period of review will still be January through March. If you had participant visits in January, March and April, then you can choose the period to be January through March, or February through April, or March through May. This period of review can start from any particular date in the month, for example 10 Feb 2019 to 10 May 2019.

Start Date to End date: These are the dates of the participant chart review period and is not to be confused with the period of preparation of the QA Summary Report. If it took you two (2) or three (3) days to prepare the QA Summary Report that does not go here. Only the start date of the 3-month consecutive period that the site chose and the end date of that 3-month consecutive period.

1. Summary of Protocols Reviewed

Populate this table with no more than five (5) protocols, with data from the participant charts you have reviewed to populate the participant chart review tool. For example, if you reviewed 25 participant charts and they came from seven (7) protocols, then only populate this table with five (5) protocols, leave the other two (2) protocols from reporting. If you reviewed nine (9) participant charts from three (3) protocols, then report all three (3) protocols.

If your site has more than five (5) active protocols, try to rotate the protocols that you are reporting in the bi-annual QA Summary Reports. You can choose Protocols 1 to 5 in the first report and Protocols 6 to 10 in the next report or you can choose odd numbers in the first report and even in the next report, etc. Prioritize the reporting of protocols that have high impact findings, greater number of findings or higher number of deficient Key Indicators. Additionally, at DAIDS discretion, certain protocols can be requested for inclusion in the QA Summary Report.

Protocol: Populate the protocol numbers that you are reporting in the QA Summary Report.

Total Number of PIDs Enrolled: This is the number of participants that have been enrolled in this protocol at your site, from beginning of the study to the time of completion of the QA Summary Report. This number should come from the screening and enrollment logs of the protocol at your site.

Number of PIDs QA Reviewed: This is the number of participant charts you have reviewed for the 3-month consecutive period for this reporting period. It should be the same number as the participant chart review tools completed per protocol.

Percent of PIDs QA Reviewed: This will be a calculation from the two (2) numbers populated in the previous columns. (Number of PIDs QA Reviewed/Number of PIDs enrolled)*100.

- In the example below the site selected participants from two (2) protocols only for this review period and a total of 28 PIDs were reviewed, 13 from Protocol XXXX and 15 from Protocol YYYY.

Example Table 1:

Protocol	Total Number of PIDs Enrolled <i>(at the time of completion of this document)</i>	Number of PIDs QA Reviewed <i>(during this review period)</i>	Percent of PIDs QA Reviewed
<i>Example: Protocol XXXX</i>	<i>100</i>	<i>13</i>	<i>(13/100) = 13%</i>
<i>Example: Protocol YYYY</i>	<i>150</i>	<i>15</i>	<i>(15/150) = 10%</i>

2. List tools used for this QA review

In this section list the tools that were used to conduct the QA review. You should use the DAIDS CQMP Chart Review Tool, Appendix I and the DAIDS CQMP Regulatory File Review Tool Appendix II; additionally, you can use other tools that your site may have in place. Any tools used in addition to the Chart Review Tool and Regulatory File Review Tool should be described in your CQMP.

3. Summary of Key Indicators (KIs) and Number of Associated Findings

DAIDS CQMP Policy requires the clinical sites to report numbers for 11 Key Indicators (KIs) that are defined in the CQMP Policy. The site may add additional KIs to this section of the QA Summary Report, but the site may not omit any of the DAIDS CQMP Policy required KIs.

Protocol Number

Populate the protocol number in the top row of the table. Only populate the protocol numbers that you are reporting in the table in Section 1, “Summary of Protocols Reviewed.”

Number of Findings (per protocol): *Not limited to number of participants, please report all KIs for all participants reviewed from the five (5) protocols you are reporting.*

- If a KI is not applicable to a protocol or the time-period of review, report “N/A” for that KI. For example, for Protocol YYYY below, if all participants have already been enrolled and the study is in the follow-up phase, then the KIs Informed Consent Form (ICF) and Process, Assessment of Understanding of ICF, and Eligibility Criteria and Process should be marked as “N/A”

Example Table 2:

Key Indicator(s)	Number of Findings (per protocol)				
	Protocol XXXX	Protocol YYYY	Protocol	Protocol	Protocol
Informed Consent Form (ICF) and Process <i>(initial or subsequent)</i>		N/A			
Assessment of Understanding of ICF as applicable		N/A			
Eligibility Criteria and Process <i>(as stated in the protocol)</i>		N/A			

- If there are no findings for a certain KI for a given protocol, report “0” for that KI. Per the example below, in Protocol YYYY below, if all visits were conducted within the visit window during the review period, then the KI should be reported as “0”.

Example Table 3:

Key Indicator(s)	Number of Findings (per protocol)				
	Protocol XXXX	Protocol YYYY	Protocol	Protocol	Protocol
Visits/Missed Visits		0			

- If there is more than one (1) finding for a given KI, then the number of findings reported for that KI will be the actual number of findings. In the example below, for Protocol XXXX, if you have one (1) participant that missed one (1) visit, as well as did not complete one (1) visit within the visit window, then you will report two (2) under Visit/Missed Visits KI.

Example Table 4:

Key Indicator(s)	Number of Findings (per protocol)				
	Protocol XXXX	Protocol YYYY	Protocol	Protocol	Protocol
Visits/Missed Visits	2				

4. Summary of Deficient Key Indicators (KIs) and associated Criteria

In this section you will provide details on the deficient KIs reported in the previous section by PID number. Make no more than 20 PID entries in this section. All these PIDs should be associated with the five (5) protocols that you have chosen to report in this review period (listed in the table in section 1 of the QA Summary Report). When choosing which PIDs to report, focus on choosing as many different identified deficient KIs as possible.

PID #

List the 20 PID #s you have selected to report in this column. These PID #s should belong to the five (5) protocols that you have listed in the table in Section 1 of the QA Summary Report. You may have more than 20 PIDs with deficiencies to report for the five (5) protocols that you have chosen, but you will still only report 20 PIDs in this section. Please select PIDs with higher impact deficiencies and PIDs that have different KI deficiencies.

Protocol #

Enter the protocol # associated with the PID # listed in Column 1 of the table.

Deficient Key Indicator(s)

List the deficient KI in this section of the table associated with the PID # in Column 1. The KIs should come from the column titled “Indicator” in the DAIDS CQMP Participant Chart Review Tool. List one (1) KI per row in this table; if there is more than one (1) deficient KI for a PID, then use additional rows of the table to list those KIs with the same PID # and protocol # in Column 1 and 2 of the table.

Please note that if there is more than one (1) deficient KI per PID, this will still count as one (1) PID toward the 20 PID maximum.

Criteria Associated with Deficient KIs

List the criteria associated with the deficient KI in this section. These criteria should come from the column titled “Criteria” in the DAIDS CQMP Participant Chart Review Tool, Appendix I. If a PID has more than one (1) deficient criterion per KI, then list the multiple criteria in the same cell.

- In the example below, you have one (1) KI deficiency for protocol XXXX but two (2) findings for the KI deficiency, so you will report two (2) findings for this protocol. For protocol YYYY, you have one KI deficiency for “Informed Consent Form (ICF) and Process” and one (1) KI deficiency for “Visits/Missed Visits,” so you will report each deficiency separately.

Example Table 5: Summary of Key Indicators and Number of Associated Findings (Section 3 of the QA Summary Report template)

Key Indicator(s)	Number of Findings (per protocol)			
	Protocol XXXX	Protocol YYYY	Protocol	Protoco
Informed Consent Form (ICF) and Process <i>(initial or subsequent)</i>	2	1		
Visits/Missed Visits		1		

2 findings

1 finding

1 finding

These would be elaborated in the Summary of Deficient Key Indicators and Associated Criteria

Example Table 6: Summary of Deficient Key Indicators and Associated Criteria (Section 4 of the QA Summary Report template)

Since protocol XXXX has two (2) associated criteria for the KI “Informed Consent (ICF) and Process,” they are listed in the same row as indicated below. Alternatively, if you have a PID with more than one (1) deficient KI, each KI is listed in separate rows, as indicated in protocol YYYY (PID 78910) below.

PID # (list only 1 PID per line)	Protocol #	Deficient Key Indicator(s)	Criteria Associated with Deficient KIs	Describe Corrective Actions Implemented	Describe Preventative Actions Implemented
123456	XXXX	Informed Consent Form (ICF) and Process (initial or subsequent)	<p>1. Informed consent process not documented in source</p> <p>2. Participant was not offered copy of signed ICF</p>	<p>1. Note to File documented by appropriate site staff added in chart</p> <p>2. Participant was called, asked to return to clinic, and offered a copy.</p>	<p>Revise informed consent (IC) checklist to include review of IC requirements including proper documentation prior to participant departure from clinic.</p> <p>*This preventative action plan applies to both criteria associated with the deficient KI.</p>
78910	YYYY	Visits/Missed Visits	Participant missed visit 15/Month 4.	Note to File documented by appropriate site staff added in chart.	Participants will be called to remind them of their study visits 3 days before the visit day.
78910	YYYY	Informed Consent and Process	Participant was provided the wrong version of the ICF.	Participant was asked to return to clinic and sign the correct version.	Site will add a QC step of ensuring correct version of ICF on the ICF checklist

Example shows 1 KI with 2 associated criteria

Examples show PID with 2 different KIs – listed in separate rows

Describe Corrective Actions Implemented: Describe the corrective actions that the site has already implemented or plans to implement. For the corrective actions that have not been implemented yet, please provide a timeline for implementation. If you have multiple corrective actions for one (1) KI, describe them briefly all in the same cell.

Describe Preventative Actions Implemented: Describe the preventative actions that the site has already implemented or plans to implement. For the preventative actions that have not been implemented yet, please provide a timeline for implementation. If you have multiple preventative actions for one (1) KI, describe them briefly all in the same cell.

List “N/A” in each column if a CAPA was not performed for a KI finding. Include a comment if necessary.

5. Regulatory File Review

This section should be populated with the findings identified during the Regulatory File review. You should use the DAIDS CQMP Protocol Regulatory File Review Tool, Appendix II, to conduct the regulatory file review.

Protocol: Identify the protocols that were reviewed during this period of review. These will be the same protocols you reported in section 1 and 3 of the QA Summary Report.

Was a Reg File Review Conducted: Indicate if the regulatory file review was conducted or not. If not, provide a reason in the next column as to why no regulatory review was conducted.

Document Findings: These categories should come from the first column titled “Document” of the Protocol Regulatory File Review Tool, Appendix II. These are broad categories to classify the regulatory file review findings. If there is more than one (1) document deficiency for a given protocol, list them in separate rows.

Criteria Associated with Deficient Findings: These criteria should come from the second column titled “Criteria” of the Protocol Regulatory File Review Tool, Appendix II. If there is more than one (1) criterion associated with the document of a given protocol, then capture all criteria in the same cell.

- In the example below, you have one (1) category of Document finding for protocol YYYY but two (2) criteria for that category of Document, so you will report two (2) findings for protocol YYYY in section 5 of the QA Summary Report. For Protocol XXXX, since the Regulatory review was not performed you should report N/A in section 5 of the QA Summary Report.

Example Table 7: Regulatory File Review

Protocol	Was a Reg. File review conducted?	If no review was done, provide an explanation:	Document findings	Criteria associated with deficient documents	Describe corrective actions implemented	Describe preventative actions implemented
XXXX	NO	reg file review conducted during previous review period.	N/A	N/A	N/A	N/A
YYYY	YES	N/A	DAIDS Approvals	<ol style="list-style-type: none"> 1. Initial DAIDS Protocol Registration Office (DAIDS PRO) notification not on file. 2. Subsequent confirmation of submission not on file. 	Locate DAIDS PRO approval letters and file in regulatory binder.	Implement a filing system for all documents on a weekly basis. Delegate task to research assistant *This preventative action plan applies to both criteria associated with the document finding.

Example Table 8: Summary of Key Indicators and Number of Associated Findings Table (Section 3 of the QA Summary Report template)

Key Indicator(s)	Number of Findings (per protocol)			
	Protocol XXXX	Protocol YYYY	Protocol	1
Investigator File Review Deficiencies	N/A	2		

Please note that the information in Example Table 7 above, comes from the information in the table in Section 3 of the QA Summary Report.

Describe Corrective Actions Implemented: Describe the corrective actions that the site has already implemented or plans to implement. For the corrective actions that have not been implemented yet, please provide a timeline for implementation. If you have multiple corrective actions for one (1) type of document finding, describe them briefly all in the same cell.

Describe Preventative Actions Implemented: Describe the preventative actions that the site has already implemented or plans to implement. For the preventative actions that have not been implemented yet, please provide a timeline for implementation. If you have multiple preventative actions for one (1) type of document finding, describe them briefly all in the same cell.

CQMP Revision

Indicate if based on the QA review of this period, a revision to your site’s CQMP is needed, and if so, what revisions need to be made. Revised plans can encompass clarifications, additional processes or a major update of the CQMP and/or site tools.

Submission instructions

Please submit the completed QA Summary Report to your OCSO PO and copy the CRS leader on this communication.