

Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual Appendix:

Guidelines for Clinical Research Site (CRS) staff on Preparing the Bi-annual Quality Assurance (QA) Summary Report

Purpose

This document provides guidance to Clinical Research Staff (CRS) staff responsible for preparing and submitting bi-annual Quality Assurance (QA) Summary Reports to the Office of Clinical Site Oversight (OCSO) Program Officers (PO).

Preparing QA Summary Reports

The QA reporting process starts with completing a review of selected participant research records and selected regulatory files spanning at least three consecutive months. The SCORE Manual includes two tools for CRS staff to complete the QA reviews:

- Appendix: [Participant Chart Review Tool](#)
- Appendix: [Protocol Regulatory File Review Tool](#)

CRSs may also use any other supplemental tools necessary to complete QA reviews. CRSs must save all completed tools in an internal folder separate from protocol regulatory files. These completed tools are not auditable by regulatory agencies but must be available for review by DAIDS and DAIDS representatives.

Once CRS staff review participant research records and/or the regulatory files for a period of at least three consecutive months and populate the corresponding review tools (*Participant Chart* and *Protocol Regulatory File Review Tools*), they can prepare the CRS QA Summary Report as part of the bi-annual submission to DAIDS. Appendix [Clinical Quality Management Plan: Clinical Research Site Quality Assurance Summary Report Template](#) is provided in this Manual.

QA Summary Report data must come from the CRS's internal QA review, not from findings or trends identified by monitors in a CRS monitoring report.

The CRS staff must complete the following sections of the *QA Summary Report*:

Title Page

Site Name: Populate the CRS 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 the *QA Summary Report*. This does not have to be the same person who conducted the QA reviews of the participant research records or the regulatory file, or even the person who submits the *QA Summary Report* to DAIDS. For example, the Data Manager may conduct the QA review of the participant research records and the Site Coordinator may conduct the regulatory file review. Then, both provide their findings to a Nurse who compiles the QA Summary Report. Alternately, the same person may complete all three tasks.

Date of QA Report: Populate the date the *QA Summary Report* is completed, not the QA review dates. The QA review dates (of participant research records and/or regulatory files) should be populated in the tools used to complete those reviews.

Period of Review: (Start Date to End date): The review period must span at least three consecutive months of protocol activities. If participant visits occurred in January and March but none in February, the period of review will still be January through March. If participant visits occurred in January, March, and April, enter either “January through March,” or “February through April.” This review period can start any day of the month, e.g., 10 January 2019 to 10 April 2019.

1. Summary of Protocols Reviewed

Populate this table with no more than five protocols. Use the data from *Participant Charts Review Tools* completed during the current QA review cycle. For example, if research records of 25 participants were reviewed from seven protocols, only populate this table with data from five protocols; do not report the other two protocols. If nine participant research records were reviewed from three protocols, report all three protocols.

If the CRS has more than five active protocols, report on only five of them each cycle. CRSs may rotate the protocols being reported in the bi-annual *QA Summary Reports* by choosing to report protocols one through five in the first cycle and six through ten in the next or any other combination chosen. Always try to prioritize reporting protocols that have high-impact findings, more findings, or more deficient Key Indicators (KIs). Please note that DAIDS may ask CRSs to include certain protocols in the *QA Summary Report*.

Protocol: Populate with the protocol numbers that are being reported on in the *QA Summary Report*.

Total Number of PIDs Enrolled: Enter the number of participants enrolled in this protocol at the CRS, from study start to the time the *QA Summary Report* is complete. This number should come from CRS protocol screening and enrollment logs.

Number of PIDs QA Reviewed: Enter the number of participant research records reviewed for the three consecutive month reporting period. This number should match the number of *Participant Chart Review Tools* completed per protocol.

Percentage of PIDs QA Reviewed: Calculate this entry using the two numbers populated in the previous columns: (Number of PIDs QA Reviewed divided by Number of PIDs enrolled) multiplied by 100.

- In the example below, the CRS had two active protocols during their QA review cycle and reviewed 28 PIDs—13 from Protocol XXXX and 15 from Protocol YYYY.

Example Table 1:

Protocol	Total Number of PIDs Enrolled <i>(as of the date this document was completed)</i>	Number of PIDs QA Reviewed <i>(during this review period)</i>	Percentage of PIDs QA Reviewed
<i>Ex: Protocol XXXX</i>	100	13	$(13/100) = 13\%$
<i>Ex: Protocol YYYY</i>	150	15	$(15/150) = 10\%$

2. List QA Review Tools Used

List the tools used to conduct the QA review, i.e., the *Participant Chart Review Tool*, the *Protocol Regulatory File Review Tool*, and any other CRS tools available. Ensure that any tools outside of the *Participant Chart Review Tool* and *Protocol Regulatory File Review Tool* are described in the CRS’s Clinical Quality Management Plan (CQMP).

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

Each CRS must report numbers for the 11 DAIDS-required KIs defined in this section of the tool. The CRS may include additional KIs in this section of the *QA Summary Report* but may not omit any DAIDS-required KIs.

Protocol Number

Populate the protocol number in the top row of the table. Only populate the protocol numbers being reported in the table in Section 1, “Summary of Protocols Reviewed.”

Number of Findings (per protocol): *This reporting is not limited to number of participants; please report all KIs for all participants reviewed from the five reporting protocols.*

- If a KI does not apply 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 been enrolled and the study is in follow-up, then the KIs for Informed Consent Form (ICF) and Process, Assessment of Understanding of ICF, and Eligibility Criteria and Process can 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) <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. In the example below for Protocol YYYY, if all visits were conducted within the visit window for the period under review, then the KI would 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 finding for a given KI, the number of findings reported for that KI will be the actual number of findings. In the example below, for Protocol XXXX, if one participant missed one visit and did not complete one visit within the visit window, the number of findings reported for the “Visits/Missed Visits” KI will be two.

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 and Associated Criteria

Provide details on the deficient KIs reported in the previous section by PID number. Make no more than 20 PID entries. All PIDs must be associated with the five protocols being reported on 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 Number

List the 20 PID numbers selected to report in this column. These PID numbers should belong to the five protocols listed in the table in Section 1 of the QA Summary Report. If more than 20 PIDs have deficiencies for the five protocols chosen, only report 20 PIDs in this section. Select high-impact PIDs and/or a variety of KI deficiencies.

Protocol Number

Enter the protocol number associated with the PID number listed in column 1 of the table.

Deficient Key Indicator(s)

List deficient KIs in this section of the table associated with the PID number in column 1. KIs should come from the “Indicator” column in the *DAIDS Participant Chart Review Tool*. List one KI per row in this table; if a PID has more than one deficient KI, use additional rows to list KIs with the same PID number in column 1 and protocol number in column 2.

Please note: more than one deficient KI per PID still counts as one PID toward the 20 PID maximum.

Criteria Associated with Deficient Key Indicators

List the criteria associated with the deficient KI. These criteria should come from the “Criteria” column in the *Participant Chart Review Tool*. If a PID has more than one deficient criterion per KI, list multiple criteria in the same cell.

- The example below shows one KI deficiency for Protocol XXXX but two findings for that KI. Report two findings for this protocol. Protocol YYYY has one KI deficiency for “ICF and Process” and one KI deficiency for “Visits/Missed Visits.” Report each of these deficiencies separately.

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

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>	2	1			
Visits/Missed Visits		1			

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

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

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

Describe Corrective Actions Implemented: Describe corrective actions that the CRS has implemented or plans to implement. Provide an implementation timeline for corrective actions that have not been implemented yet. If multiple corrective actions are implemented for one KI, describe them all briefly in the same cell.

Describe Preventative Actions Implemented: Describe preventative actions that the CRS has implemented or plans to implement. Provide an implementation timeline for preventative actions that have not been implemented yet. If multiple preventative actions are implemented for one KI, describe them all briefly in the same cell.

List “N/A” in each column if a Corrective Action and Preventive Action (CAPA) was not performed for a KI finding. Include a comment if necessary.

5. Regulatory File Review

Populate this section with the findings identified during the Regulatory File review. Use the *Protocol Regulatory File Review Tool* to conduct the regulatory file review.

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

Was a Regulatory File Review Conducted? Indicate whether the regulatory file review was conducted. If not, provide a reason in the next column as to why regulatory review was not conducted.

Document Findings: Categories should come from the *Protocol Regulatory File Review Tool*'s “Document” column. These broad categories classify the regulatory file review findings. If there is more than one document deficiency for a given protocol, list each of them in a separate row.

Criteria Associated with Deficient Findings: Criteria should come from the *Protocol Regulatory File Review Tool*'s “Criteria” column. If more than one criterion is associated with the document of a given protocol, capture all criteria in the same cell.

- The example below shows one Document finding category for Protocol YYYY but two criteria for that Document category. In this instance, report two findings for Protocol YYYY in Section 5 of the *QA Summary Report*. Since the Regulatory review was not performed for Protocol XXXX, report N/A in Section 5 of the *QA Summary Report*.

Example Table 7: Regulatory File Review (examples are from the Section 3 of the QA Summary Report Template).

Protocol	Was a Regulatory 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	Regulatory file review conducted during previous review period.	N/A	N/A	N/A	N/A
YYYY	YES	N/A	DAIDS Approvals	Initial DAIDS Protocol Registration Office (DAIDS PRO) notification not on file. Subsequent confirmation of submission not on file.	Locate DAIDS PRO approval letters and file in regulatory binder.	Implement a system to file all documents weekly. Delegate task to research assistant. <i>*This preventative action plan applies to both criteria associated with the document finding.</i>

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	Protocol	Protocol
Investigator File Review Deficiencies	N/A	2			

Describe Corrective Actions Implemented: Describe corrective actions that the CRS has implemented or plans to implement. Provide an implementation timeline for corrective actions that have not been implemented yet. If multiple corrective actions have been implemented for one type of document finding, describe them all briefly in the same cell.

Describe Preventative Actions Implemented: Describe the preventative actions that the CRS has already implemented or plans to implement. Provide an implementation timeline for preventative actions that have not been implemented yet. If multiple preventative actions have been implemented for one type of document finding, describe them all briefly in the same cell.

6. CQMP Revision

When a revision to the CQMP is needed, submit a copy of the revised CQMP to the assigned OCSO PO for review and approval. Indicate if the revision is based on findings from a QA review period and what revisions were made. Revision plans can encompass clarifications, additional processes, or a major update of the CQMP and/or CRS tools.

7. Submission instructions

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