

Appendix III
DAIDS Clinical Quality Management Plan (CQMP) Clinical Research Site (CRS) Quality Assurance (QA) Summary Report

Effective Date: 04/02/20

Document No.: **APP-A28-OCS-003.01**

*Instructions: Please complete this form using QA reviews of protocol activities (i.e. protocol visit documents, regulatory documents) conducted for **at least a 3-month consecutive period**. 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 and name of Person Preparing Report _____

Date of QA Report _____

Period of Review (At least 3 consecutive months of protocol activities):

(Start Date) _____ **to (End Date)** _____

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1. Summary of Protocols Reviewed

Complete only for protocols associated with PIDs for which chart review was conducted during this review period. Please report no more than five (5) protocols, even though your QA review may have included more.

If your site has more than five (5) protocols, please choose only five (5) to report at this time. You will be able to rotate protocols reviewed with each submission to account for all the protocols at the site.

If your site has less than five (5) protocols, then please include all the protocols that you are conducting.

For additional guidance, please refer to the CQMP CRS QA Report Preparation Guidelines document.

At DAIDS discretion, certain protocols can be requested for inclusion in submission of QA Summary reports.

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>

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2. List tools used for this QA review.

E.g. Eligibility Checklist, Chart Review Tool

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

These are the Key Indicators (KI) required in the DAIDS CQMP Policy to be used for QA review. You may add additional site-chosen KIs in the blank cells, if applicable.

Please note that if there was a review of a KI that yielded no findings, a zero (0) should be placed in that cell. However, if a KI was not applicable during this review period, an "N/A" should be placed in that cell. *For example: If there were informed consents conducted during this review period resulting in no findings, then a "0" should be noted. However, if there were no informed consents conducted during this review period, then "N/A" should be noted.*

For determining the number of findings, please note that one KI deficiency may have more than one (1) associated criteria applicable to a PID. Each criterion should then be counted as one (1) finding. *For example: A PID has an ICF with 2 errors (no signature from PI and version used was obsolete), this will count as 2 findings for that protocol in the ICF Key Indicator (KI) row.*

Please list the protocol number in the line provided under "protocol."

Insert rows for additional site-chosen KIs as needed.

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

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Key Indicator(s)	Number of Findings (per protocol)				
	Protocol _____	Protocol _____	Protocol _____	Protocol _____	Protocol _____
Protocol Required Tests and Procedures					
Visits/Missed Visits					
Concomitant Meds/Prohibited Meds.					
Study Product Administration/Dosing					
AEs/SAEs/EAEs identification and reporting					
Protocol Defined Endpoint identification and reporting as applicable					
Source Docs, Signatures, Initials and Dates					
Investigator File Review Deficiencies					

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

Please elaborate on the deficient key indicators from the previous section (Section 3) . Please report Key Indicator findings from the previously listed protocols, and report on 20 PIDs with findings associated with those protocols. When choosing which PIDs to report, focus on choosing PIDs with as many different identified deficient KI's as possible. If your QA review had less than 20 PIDs with findings, then please include them all.

List one Key Indicator Finding per line for each PID. Capture the criteria associated with the deficient KI. Use short and concise statements.

- If there are more than 1 criteria per key indicator, capture all associated criteria in one cell. For examples of some criteria, refer to the chart review tool.
- If a PID has more than one deficient KI, please list each KI on separate rows. Please note that if there are more than one KI per PID, this will still count as one PID towards the 20 PID maximum requirement.
- List all corrective and preventative actions (CAPA's) associated with each different criterion. If a CAPA was not performed for a KI finding, list "N/A" under the Corrective Actions column and provide a comment if necessary. Use short and concise statements. (See example in first row).

For additional guidance and examples, please refer to the CQMP CRS QA Report Preparation Guidelines document.

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	A1000	Informed Consent	<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>

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5. Regulatory File Review

Based on findings identified in the Appendix II DAIDS Clinical Quality Management Plan (CQMP) Protocol Regulatory File Review Tool(s), complete the following:

- a. Complete the table below the previously listed protocols for which a QA review was conducted during this review period.
- b. Specify the protocol and the document finding(s) and the associated criteria. Use short and concise statements
 - If there are more than 1 criteria, capture all associated criteria in one cell. For examples of some criteria, refer to the Appendix II. List all corrective and preventative actions associated with each different criterion in one cell.
 - If there are more than one document findings for the same protocol, please list them in separate rows.
- c. If a QA Regulatory File Review was not conducted for any of the protocols listed in Section 1 "Summary of Protocols Reviewed" during this review period, please provide an explanation. (See example in table below).

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
A1000	NO	reg file review conducted during previous review period.	n/a	n/a	n/a	n/a
A1500	YES	n/a	DAIDS Approvals	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.

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6. CQMP Revision

- a. Does the CQMP need revision based upon site review of the QA findings included in this CRS QA Summary Report? Y ____ N ____
- b. If Yes, please specify areas of your CQMP to be revised in the box below:

E. g. QC tools for informed consent revised
E. g. New process implemented for Reg. File Review

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7. Revision History

APP-A28-OCS-003.00 is the initial version of Appendix III DAIDS Clinical Quality Management Plan (CQMP) Clinical Research Site (CRS) Quality Assurance (QA) Summary Report submitted to the DAIDS QMS. There were three previous versions of this appendix published on the DAIDS Clinical Research Policies webpage prior to the implementation of the DAIDS QMS in 2018.

This version includes the following changes:

- Instructions with examples have been added throughout the template
- Requirements of protocol related documents and PID reporting requirements have been added.
- Role and name of Reviewer has been added.

APP-A28-OCS-003.01 was revised on 02/20/2020 to update the instructions in Section 1 and 4 for clarity

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