

Appendix I
DAIDS Clinical Quality Management Plan (CQMP): Participant CHART Review Tool

Effective Date: 07/05/19

Document No.: APP-A28-OCS-001.00

Instructions: Participant Quality Assurance (QA) chart review is conducted to verify adherence to protocol, GCP, HSP, site procedures, regulatory and sponsor's requirements.

- 1. Complete one (1) Chart Review Tool (CRT) per participant record audited for the review period.**
- 2. Check the appropriate boxes for each question listed in the criteria section**
- 3. Use the comments section for clarification and action and for any “no” entries checked**
- 4. Record the date range of the review using the “Reviewed from (Visit #/Date) _____ through (Visit #/Date) _____”**

Source documentation should be compared to Case Report Form (CRF) and protocol for agreement.

Note: Please refer to [DAIDS webpage](#) for DAIDS policies

Participant Identification (PID) # _____

Protocol # _____

Reviewed from (Visit #/Date) _____ through (Visit #/Date) _____

Name and Role of Reviewer _____

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Indicator	Criteria	Yes	No	N/A	Comments
1. Informed Consent Form (ICF) and Process	Did the participant sign and date the most current, IRB/IEC approved version of the Consent/Assent Form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are all required signatures present? (Parent signature, PI, witness etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are previous applicable versions of Informed Consent /Assent in the participant record signed and dated appropriately?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Was the Informed Consent/Assent process, including participant education, documented in the participant record?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Did the participant sign/date (in ink) consent/assent, prior to study-specific procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there documented evidence that the participant was provided a copy of the signed/dated Informed Consent/Assent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Assessment of Understanding of ICF as applicable	Was assessment of understanding related to the Informed Consent Form conducted and documented in the source notes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Eligibility Criteria and Process	Are all inclusion and exclusion criteria met and documented in source notes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there source documentation to address each pertinent negative?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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4. Protocol Required Tests/ Procedures	Were all protocol required tests/ procedures completed and documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are all lab or other diagnostic reports signed, dated, QC'ed, and on file in the participant record?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are any missed tests documented, with rationale provided?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are actual specimen collection times accurately reflected on lab reports?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Were all samples collected, processed and stored correctly as per protocol?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Visit /Missed Visits	Has the participant missed any visits? If yes, are missed visits documented adequately?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are all visits conducted within protocol defined windows? If no, are reasons for out of window visits documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	6. Concomitant Meds (Con. Med.)/ Prohibited Meds	Is participant Con. Med. CRF consistent with source documentation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is participant taking any protocol-defined prohibited meds?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If yes, have the prohibited meds been documented appropriately?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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7. Study Product Administration/ Dosing (When study product is administered in the clinic)	Study product administered per protocol and documented in the source notes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there documentation that the clinic staff checked the study product label against the PID # prior to administration?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there documentation that the clinic staff addressed any potential safety concerns prior to administration of study product? (E.g. Abnormal labs, suspected illness etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. AE/SAE/EAE Identification and Reporting	Are adverse events (AE) recorded and reported per protocol requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are all abnormal protocol required labs graded and documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are there any missed (unreported) AEs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are there any missed (unreported) SAEs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are there any missed (unreported) EAEs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are all identified SAE's/EAE's reported to IRB/IEC/other regulatory entities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Have all identified SAE's/EAE's been reported to the Sponsor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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9. Protocol Defined Endpoint Identification	Did the participant reach any protocol-defined endpoints?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	If yes, are all specific details (Labs, diagnosis) documented per protocol requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are protocol defined endpoints CRFs completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10. Source Documents, signatures, initials, dates	Are all source documents present in attributable, legible, contemporaneous, original and accurate (ALCOAC) format?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are all entries signed, initialed and dated including credentials as applicable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Is there a document on file listing each CRF designated to be used as source document?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Are all error corrections properly executed per DAIDS Source Documentation Requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	For each CRF reviewed are all entries verifiable in the source notes, unless the CRF has been designated as source?"	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11. Site to add any additional chosen site-specific key indicators	<i>Example: KI - HIV Prevention Counseling: Was counseling provided per protocol, and documented at each required visit?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Findings/Results of Review, Description of issues noted in this review. If additional rows needed copy page:

PID # _____

Indicator	Specific Issue(s)	Visit #/Date	Corrected by/date

Signature and role of Reviewer: _____

Date: _____

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REVISION HISTORY

APP-A28-OCS-001.00 is the initial version of the Appendix I DAIDS Clinical Quality Management Plan (CQMP): Participant CHART Review Tool 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 has been revised to include added criteria to key indicator # 4, Protocol Required Tests/Procedures and an added example of a site chosen key indicator.

Archived