

DAIDS  
Bethesda, MD USA

ARCHIVED APPENDIX

Sample Clinical Quality Management Chart Review Tool

Approval Date: 26 FEB 2010

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No.: DWD-POL-CL-009.03A2

## Sample Clinical Quality Management Chart Review Tool

(SAMPLE ONLY. The template below is provided for your convenience as an example of how this information may be provided. You may modify this as appropriate.) **Note: Source documentation should be compared to CRF and protocol for consistency**

Participant Identification # \_\_\_\_\_ Reviewed from (Visit #) \_\_\_\_\_ Through (Visit #) \_\_\_\_\_

Name of Reviewer \_\_\_\_\_ Date of Review \_\_\_\_\_

Protocol # \_\_\_ version: \_\_\_\_\_

<i>Indicator</i>	<i>Criteria</i>	YES	NO	N/A
<b>1. Consent</b>	Current, IRB/EC approved version of consent signed?			
	Participant signed and dated (in ink) consent, prior to study-specific procedures?			
<b>2. Participant Education</b>	Education provided per protocol?			
<b>3. Test of Understanding</b>	Provided per protocol and documented. (If applicable)			
<b>4. Eligibility</b>	All eligibility criteria met and documented?			
<b>5. HIV Prevention Counseling</b>	Counseling provided per protocol, and documented?			
<b>6. Lab Tests and Procedures</b>	All required tests/ procedures performed and documented?			
	Any missed tests documented, with reason provided?			
<b>7. Concomitant Meds</b>	Source documentation and CRF consistent?			
	Is participant taking any prohibited meds?			
<b>8. Study Product Administration</b>	Study product administered per protocol and documented? (If applicable)			
	Reactogenicity recorded at appropriate timeframes with appropriate follow-up? (If applicable)			

<b>9. AE/SAE/EAE Reporting</b>	Adverse events recorded and reported properly?			
	Are there any missed (unreported) AEs?			
	Are there any missed (unreported) SAEs?			
	Are there any missed (unreported) EAEs?			
<b>10. Endpoints</b>	Has the participant reached any protocol-defined endpoints?			
	If yes, are they documented properly and protocol followed?			
<i><b>Indicator</b></i>	<i><b>Criteria</b></i>	<b>YES</b>	<b>NO</b>	<b>N/A</b>
<b>11. Missed Visits</b>	Has the participant missed any visits?			
	If yes, are they documented?			
<b>12. Signatures, initials, dates</b>	Are all entries signed and dated?			
	Are all error corrections properly executed?			

Signature of Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

Correction of error/problem noted in this review:

<b>Findings</b>	<b>Visit #/Date</b>	<b>Corrected by/date</b>