

DAIDS	Appendix 1	No.: DWD-POL-SR-01.00A1
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Guidance on Study Monitoring Reports

1. Periodic Study Progress and Safety Monitoring Reports for the Study Team

These reports include administrative, study progress, and aggregated adverse event frequencies and are reviewed by the study team at a frequency specified in the Study Progress and Safety Monitoring Plan (SPSMP). These reports do not include any efficacy data or data sorted by treatment arm.

2. Interim Reports for Study Review by Monitoring Committees

The major components of the reports for scheduled interim reviews are specified in the SPSMP. These reports are must be sufficiently detailed to give all the necessary information for review by the committee to assess study progress, feasibility, futility, quality, safety, and efficacy as appropriate. The overall interim monitoring plan and a template for this monitoring report should be discussed with the monitoring committee before the first scheduled study review, and preferably before study initiation.

For suggested formats for this type of safety monitoring report, go to [\[www.niams.nih.gov/rtac/clinical/dsmb3.html\]](http://www.niams.nih.gov/rtac/clinical/dsmb3.html)

3. Periodic Progress and Safety Reports for Designated Study Safety Monitors

For some comparative Phase II-IV studies, DAIDS may require review of additional study progress and safety monitoring reports by designated study safety monitors (for example, by a member of the Safety Monitoring Committee (SMC) or Data and Safety Monitoring Board (DSMB) designated to serve as an ISM and/or by the DAIDS Medical Officer/Medical Monitor) as part of the SPSMP. These reports are often generated approximately mid-way between the scheduled SMC or DSMB reviews. The plan for these additional reviews must be specifically approved by the study SMC or DSMB.

These reports will include administrative, study progress, and adverse event data. Frequencies of adverse events are grouped by study arm in these reports. Efficacy endpoint data is not included. These reports are not distributed to the study team, but only to the designated reviewers. The information in these reports is highly confidential and will not be shared. Treatment arms should be generically identified, i.e., A, B, C, or 1, 2, 3, etc. in order for the study to remain partially masked to the reviewers.