DSMB REPORT OUTLINE

Title page
- Study name, date of report, author of report (e.g., Statistical Data Center, not specific names)

Table of contents
- Open-session and closed-session sections separated
- All pages should be numbered

List of tables and figures
- Note: each table and figure should show date of data cut-off for inclusion. Totals, denominators should match where appropriate.

Introductory material
- Summary of protocol and procedures, including treatment arms; outcomes; screening, enrollment and follow-up procedures; flow of data
- Overview of report, including list of abbreviations, sources of data, conventions used in the report.

Main sections
- Accrual
  - By month
  - Cumulative overall and by treatment
  - Cumulative compared with projected
  - By center and treatment
  - Gender and ethnicity data

- Data availability
  - Completeness of reporting of baseline and follow-up data
  - Timeliness of receipt of data
  - Protocol deviations/violations
  - Quality of data

- Baseline characteristics
  - Distributions of demographic and key clinical features by treatment group

- Adverse events
  - Distributions of adverse events by treatment group, grouped by type of event, if applicable.
  - Premature withdrawals

- Primary outcome analysis*
  - Number of events overall and by treatment group; completeness of reporting.
  - Events by time and treatment group; subgrouped by age or other key characteristics.
  - Interim monitoring boundary.

- Other outcomes*
  - Overall and by treatment

- Summary narratives for each section (interpretation and implications of reported data)

*NOTE: All outcome analyses should be presented in a separate, *closed-session*, section