

Clinical Study Tracking Template

*This template is provided as a guide for investigators in developing their **internal** tracking/reporting methods. Please note that all items in this template may not apply to all studies. This template is provided to assist investigators in developing study-specific documents and should be used as appropriate. Investigators are not required to use this template.*

The actual structure and content of what is tracked should be adjusted to the type of study that is being performed. For example, multi-center studies should report data for the study as a whole, as well as by site. The following is an outline of the type of information that should be tracked. It is meant to guide and assist investigators and it is not required that this format be followed.

- I. Table of Contents
- II. Narrative/ Study Summary
 - A. Summary of Main Findings
 - B. Discussion of Issues or Problems
 - C. Report Preparation Procedures
- III. Study Description
 - A. Project Organizational Chart, Personnel
 - B. Brief Statement of Purpose of Study
 - C. Projected Timetable and Schedule
 - D. List of any Resource Centers
- IV. Study Administration
 - A. Recruitment Status
 - 1. Enrollment by Year or Month
 - 2. Comparison of Targeted to Actual Enrollment
 - B. Retention Status
 - 1. Overall Subject Status
 - 2. Individual Subject Status
 - C. Adherence to protocol
 - 1. Visit completion
 - 2. Data/outcomes collection (including quality and completeness)
 - 3. Participant adherence to medication/other intervention components
- V. List of suggested tables/figures
 - Table 1. Enrollment by Month of Study
 - Figure 1. Comparison of Target to Actual Enrollment by Month
 - Table 2. Race/Ethnic Characteristics
 - Table 3. Demographic and Key Baseline Characteristics by Group
 - Table 4. Subject Status
 - Table 5. Visit completion
 - Table 6. Outcomes completion
 - Table 7. Medication adherence
 - Table 8. Treatment Duration for All Subjects
 - Table 9. Treatment Duration for Subjects Who Discontinued Therapy
 - Table 10. Adverse Events
 - Table 11. Serious Adverse Events

Table 12. Deaths

Table 13. Observed Adverse Events by Body System