

## **HSR&D Data and Safety Monitoring Board (DSMB) Data Analysis Plan (DAP) Instructions**

The Data Analysis Plan (DAP) describes the plan to monitor and track serious adverse events and summarizes the statistical analyses for the primary and important secondary data proposed by the research questions.

The DAP must cover the following content areas:

1. Rationale for the study sample size
2. Specific description of how data will be collected
3. Method of randomization (*describe any stratification and blocking techniques*)
4. Plans for and specification of the purpose of any interim analysis of the data (*with regard to stopping rules for superiority, futility, or sample size re-estimation*)
5. Methods for handling missing data points and subject dropouts
6. Definitions of covariates to be included in adjustment models
7. Methods for dealing with data transformations
8. Definitions of analytical sets (*i.e. intent-to-treat, per protocol, and any other analytical subsets*)
9. List of adverse and serious adverse events to be monitored, how they will be defined, and a plan for prospectively tracking them

### **Formatting**

Each the nine content areas should be clearly designated in the document. For sections not applicable to your study, write “n/a”.

The DAP must be 3-7 pages, using appendices when necessary. Include a table of contents and footer on each page with the page number, PI name, and date.

Name the document: *PI Last name\_XXX ##-###\_DAP.pdf* (e.g., Doe\_IIR 00-000\_DAP.pdf)

### **Supporting documentation**

Create a single document with the abstract, research plan, and summary budget table. Do not include additional sections or the entire proposal.

Name the document: *PI Last name\_XXX ##-###\_DAPSupportingDocuments.pdf* (e.g., Doe\_IIR 00-000\_DAPSupportingDocuments.pdf)

### **Submission**

Email directly to [Liza.Catucci@va.gov](mailto:Liza.Catucci@va.gov) within 60 days of the Intent to Fund notification email.