

## **DBDC Statistical Analysis Plan Template (Form D)**

**Project:** Project Title

**First Author(s):**

**Appointment(s) of First Author(s):** List only those relevant to the current study.

**Lead Statistician:**

**Co-authors (follow the PPAC guidelines):**

**Deadlines:**

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### **NOTE:**

- All comments pertaining to writing the SAP are colored **in red**. Prior to circulating the SAP, these comments should be deleted.
- **This is a living document.** This document can be changed/updated based on data availability and or primary analysis outcomes. The purpose of this document is for DCC Stats personnel to review the data requests for the proposed ancillary studies and to provide guidance to the DBDC investigators.

### **Background**

This section should be provided by the primary author and should give sufficient context to the research question.

Suggested information:

- Description of the study
- Motivation for the current study
- Previous studies/state of the field in question
- Primary objective

### **Analytic Goals:**

All analytical goals and corresponding hypotheses should be described here. These are determined by the primary author(s). The goals should clearly define the outcome and information to be used, and the hypotheses should clearly define the expected results. Make sure that descriptive aims are clearly marked as such.

- **Aim 1:** Write aim here.
  - **Hypothesis:** Write hypothesis / hypothesis generating question here
- **Aim 2:** Write aim here.
  - **Hypothesis:** Write hypothesis / hypothesis generating question here

**Population:**

Suggested information (can be bulleted) for main analysis and sensitivity analyses.

*Analysis population A*

- Inclusion criteria
- Exclusion criteria
- Timepoints

**Outcomes and Variables of Interest: Please list all of variables required for the analyses.**

Outcomes should be clearly defined and include units of measure when necessary. If outcomes are time-dependent, be sure to include the timepoints. These can be bulleted.

**Data Sources:**

If the investigator(s) have some variables of interest, it will be helpful to know where they will get the data. Will all of the data needed for analyses are from the site datasets transferred to the DCC? Or will they use some data from their own sources? If they use their own data sources, it will be important to know the data sources are in good quality and approved by the PPAC.

**Adjustment Variables**

This should be a list (preferably bulleted) of variables that are associated or prognostic of the primary /secondary endpoints

**Handling of Missing Data**

Plan for handling all missing data, e.g. exclude incomplete observations, impute missing data, etc.

**Quality Assurance Procedure**

The statement below is typically sufficient to address quality assurance concerns, but other information/proposed steps may be added if appropriate.

**Modification History:**

Date	Modification
dd/mm/yyyy	Initial draft completed
dd/mm/yyyy	