

# Statistical Analysis Plan (SAP) Template

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## Key Information

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Title  
CRU/Department/Division/Center  
IRB Number  
Investigators  
Primary Investigator  
Collaborative Lead  
Co-authors (if known)  
Analysis Biostatistician(s)  
Biostatistics Supervisor  
Lead Biostatistician  
Subject Matter Expert  
Original Creation Date  
Version Date  
Project Folder Location  
Project Goal(s)  
Submission Deadline(s)  
Effort Estimate (optional)

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## 1 Study Overview

### *1.1 Study Aims*

### *1.2 Study Hypotheses*

#### *1.2.1 Primary Hypotheses*

#### *1.2.2 Secondary Hypotheses*

## 2 Study Population

### *2.1 Inclusion Criteria*

### *2.2 Exclusion Criteria*

### *2.3 Data Acquisition*

This is an example of the information that could be provided in this section:

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Study design  
Data source/how the data were collected  
Contact information for team member responsible for data collection/acquisition  
Date or version (if downloaded, provide date)  
Data transfer method and date  
Where dataset is stored

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## 3 Outcomes, Exposures, and Additional Variables of Interest

### 3.1 Primary Outcome(s)

You should only have 1-2 primary outcomes and the rest should be secondary. A table with the following headers could be helpful.

- Outcome
- Description
- Variables and Source
- Specifications
  - e.g., how is it coded?

### 3.2 Secondary Outcome(s)

- Outcome
- Description
- Variables and Source
- Specifications
  - e.g., how is it coded?

### 3.3 Additional Variables of Interest

This is optional but generally this would be all your covariates of interest. If there are any variables that need special calculations etc. include them here or in a data dictionary that is an appendix to this SAP which you can reference here.

- Variable
- Description
- Variables and Source
- Specifications
  - e.g., how is it coded?

## 4 Statistical Analysis Plan

### 4.1 Analysis Plans for Aim 1

### 4.2 Analysis Plans for Aim 2

## 5 Results

### 5.1 Demographic and Clinical Characteristics (“Table 1”)

### 5.2 Analysis Plans for Aim 1

### 5.3 Analysis Plans for Aim 2

## 6 Limitations

All design and analysis limitations (this will grow as you do the study and should be included in the report)

## 7 Addendum for Additional Analyses

[insert if applicable]

All post-hoc analyses should be described here. If minor changes are made to the main analysis (e.g. adding a covariate to the model), this can be changed in the main analysis section above and a note should be added to the activity log.

## **8 Appendix**

This section can be used to include table shells, example figures, or anything else that does not belong in the body of the SAP but you feel should be included.

## **9 References**

If needed, this section can include citations to statistical methods, programming software (including R packages), and/or relevant clinical literature.