

# Data Analysis Plan

## Template

Author Name

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## 1 Title: Your project title

## 2 Background & Objectives

### 2.1 Background

Brief description of the scientific or practical problem motivating the analysis, including why this analysis is being undertaken and any important constraints (e.g. observational data, fixed sample size).

### 2.2 Objectives

Clearly state the analysis objectives.

- Primary objective(s): 1, 2, 3, ...
- Secondary / exploratory objective(s): 1, 2, 3, ...

## 3 Data and Statistical Methods

### 3.1 Data sources and structure

Data source(s) and how data were generated

- Independent **unit(s) of analysis**
- Expected **effect size** and justification of **Sample size** (planned or fixed)
- **Experimental design** (if relevant), **sampling design** (e.g. groups, time, space, plots, fields, etc.)

### 3.2 Variables

Description of variables, such as Identifying:

- Dependent variable(s)
- Key predictors / exposures
- Covariates / confounders
- Grouping / random effects

### 3.3 Data handling and quality control

- Inclusion and exclusion criteria
- Missing data approach
- Outliers and data validation
- Transformations or derived variables

### 3.4 Statistical analysis strategy

Overall analytical approach, including:

- Exploratory vs confirmatory emphasis
- Modelling philosophy (explanatory, predictive, parsimonious)
- Statistical framework (e.g. frequentist, Bayesian)

### 3.5 Primary analysis

- **Statistical model(s)** to be used
- **Key predictors** and adjustments

- **Assumptions** to be assessed
- Estimands or contrasts of interest

### 3.6 Secondary and sensitivity analyses

- Alternative model specifications
- Subgroup or stratified analyses
- Robustness checks or sensitivity analyses
- Multiple testing considerations (if relevant)

## 4 Outputs, Interpretation & Reporting

### 4.1 Planned outputs

- Tables (e.g. model estimates, uncertainty)
- Figures (e.g. effect plots, diagnostics)
- Summary statistics

### 4.2 Interpretation principles

- Emphasis on effect sizes and uncertainty
- Scientific or practical relevance
- Limitations and caveats (e.g. causal interpretation)

## 5 Reproducibility & Amendments

- Software and versions
- Reproducibility approach (scripts, notebooks, version control)
- Criteria for deviations from this plan and how they will be documented

### 5.1 Optional sign-off (as required)

- Researcher:
- Statistical consultant:
- Supervisor:
- Date:

## 6 Resources

Cressman, K.A., Sharp, J.L., 2022. Crafting statistical analysis plans: A cross-discipline approach. *Stat* 11, e528.

Stevens, G., Dolley, S., Mogg, R., Connor, J.T., 2023. A template for the authoring of statistical analysis plans. *Contemp Clin Trials Commun* 34, 101100.

Yuan, I., Topjian, A.A., Kurth, C.D., Kirschen, M.P., Ward, C.G., Zhang, B., Mensinger, J.L., 2019. Guide to the statistical analysis plan. *Pediatric Anaesthesia* 29, 237–242.