Data Analysis Plan

Template

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1 Title of Project

1.1 1. Background & Objectives

1.1.1 1.1 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).

1.1.2 1.2 Objectives

Clearly state the analysis objectives.

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

1.2 2. Data and Statistical Methods

1.2.1 2.1 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.)

1.2.2 2.2 Variables

Description of variables, such as Identifying:

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

1.2.3 2.3 Data handling and quality control

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

1.2.4 2.4 Statistical analysis strategy

Overall analytical approach, including:

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

1.2.5 2.5 Primary analysis

For each primary objective:

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

- Estimands or contrasts of interest

1.2.6 2.6 Secondary and sensitivity analyses

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

1.3 3. Outputs, Interpretation & Reporting

1.3.1 3.1 Planned outputs

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

1.3.2 3.2 Interpretation principles

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

1.4 4. Reproducibility & Amendments

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

1.4.1 Optional sign-off (as required)

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

1.5 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.