**Outline of a Data Analysis Plan**

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**09 Feb 2015**

1. Introduction
   * Purpose
   * Objectives/Aims
   * Background
   * Investigative team members and role
   * Target audience for final report
2. Hypotheses to test/Questions to answer
   * Primary
   * Secondary
   * Check that question(s) have
     1. a defined population or group,
     2. a stated effect (the cause of interest)
     3. a comparison effect, and
     4. an outcome
3. Data Description
   * State the source of the data
     1. How data was received
     2. When it was received
     3. From whom it was received
     4. File name and format
   * How was the data collected
     1. Any potential sources of bias
   * Inclusion & Exclusion criteria
   * Define cases and controls
   * Define the outcome of interest
     1. How collected
     2. How verified
   * Variables used in the analysis
     1. Definitions
     2. Time point of measurement
     3. Unit of measure
     4. Derivation formula
   * Variable distributions
     1. Outliers
     2. missing
     3. QQ plots (Transformations defined)
     4. Truncated distributions
4. Data tables
   * Identify outliers
   * Sources of variation
5. General approach (applies to all analyses)
   * type I error
   * One-sided or two-sided hypotheses tests
   * Sample size/power analysis/events needed analysis
   * Adjustment for multiple outcomes
   * Covariate adjustment if applies to all models
   * How are missing values handled
   * Correlated data
     1. How to test
     2. How to control
   * How results will be presented
     1. Estimates with 95% confidence intervals
     2. Sensitivity analysis
   * Timeline for completing analysis
6. Hypothesis/Question
   * Primary and Secondary questions
   * Do this section for each question
   * State model to test
   * Covariates
   * Collinearity tests
   * Assumptions
     + How assumptions will be tested
     + Assessment of model fit
   * Adjustment of type I error for multiple comparisons
   * Pre-specified subgroup analysis
   * Table shell(s)
7. State potential conclusions
   * Inference
8. List weaknesses