**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