CIDA CONSULTING CENTER: EXPLORATORY REPORT

Project title:  
Submitted to: Client names, department, school or organization  
Report prepared by: Biostatistician’s names, CIDA information  
Date:

# Introduction

Provides concise description of the key elements of the objectives, design, methods and analysis

* Scientific background to help understand rationale for the analysis and address any knowledge gaps
* General objectives – overall study
* Specific objectives – explore and describe data, estimates, hypothesis, or other specified purpose
* State the hypotheses (should be in the SOW)

# Study Design

The following overarching items should be documented:

* Type of design of the experiment/study/survey (e.g. factorial, cohort, case-control, cross-sectional, longitudinal, stratified, clustered)
* Interventions by treatment level and administration route (if applicable)
* Primary and secondary endpoints along with auxiliary and confounding factors (if applicable) and their expected biological, chemical and/or physical relevant effect (if applicable)
* Stopping rules (if applicable)
* Ethical approval (if applicable, in case it is not requested).
* Randomization and blinding
  + method to generate the random allocation sequence
* Sampling strategy, including definition of sampling unit, sample size required to meet objectives and sampling design used to get sample from target population

# Data Sources and Quality

Describe any data sources that were used (e.g. existing data, databases, experimental studies, literature review), and provide rationale for using these sources. If multiple data sets used, explain how they were combined.

* Existing sources of data
  + Description - nature of data, institution in charge of data, methodology used to collect data, date/period of data collection, confidentiality issues
  + Procedural conditions – inclusion/exclusion criteria applied to select sub-sets of data
* Direct data collection – if the study included collecting data, the method of data collection should be documented as part of planned study design
* Data quality –elements of data collection and pre-processing that could influence data quality
  + Data collection quality assurance - actions put in place in order to minimize bias and maximize precision at level of data collection should be described
  + Data quality checking methods (looking for outliers, illogical results, etc.)
  + If missing data were imputed, then methods used and actions taken to ensure that bias was not introduced and that variance was not compromised should be described
  + Description of methods which have been adopted to minimize the amount of missing data

# Methods of Analysis

Describe the analysis as it was conducted (may include pre-defined plan for processing and analysis of data and any additions, deviations, or adjustments made with justification).

* Data processing – all methods used for processing of data should be reported and justified – transformations, processing for creation of descriptive summaries or graphs, methods used for selection and/or weighting of data, etc.
* Statistical analysis
  + Unit that was considered for each statistical analysis
  + Hypotheses tested
  + Description and justification of any methods used to handle multiple comparisons or interval estimation (if applicable)
  + Identification and justification of any relevant data points that are excluded from the model
* Software - identify any software package used for analysis (including version and operating system)

# Results

* Descriptive statistics
  + Tables (provide a summary of all variables used in the analysis to allow for the investigator(s) to confirm the validity of their data)
  + Graphs
* Results of statistical analysis - should be consistent with the objectives of the study
* Graphical summaries
* Interpretation of the results
* Report uncertainty (e.g., limitations)

# Appendix

Information for the investigator to be able to reference for their own understanding. This might include extra figures, graphics, or tables, especially if there are copious amounts of output/results. If it ends up going in the paper, it should probably be moved to the sections above.