

Statistical Analysis Plan Template

John M. Kribelson, PhD

1. Review of statistical design

Insert relevant summary from the trial protocol including:

- Primary and secondary hypotheses
- Sample size evaluation
- Analysis plan (primary and secondary as stated in the protocol)

Note: this can be a direct copy of the relevant parts of the protocol. The purpose is to establish that the analysis plan follows exactly from the trial design.

2. Analysis Plan

2.1 Preliminary evaluation of data:

Purpose: To identify issues that will affect our approach to the primary analysis. Specifically:

- To summarize the amount of missing data for key variables.
- To summarize time between baseline and follow-up key measurements.
- To examine the distributional characteristics of key variables in order to detect potential data entry/reduction errors.

Methods: (Combined intervention groups). Relevant approaches may include:

- Tabulation of descriptive statistics for key variables (including missing observations).
- Histograms, quantile plots of baseline levels and follow-up measures and changes in those measures.

2.2 Description of study process

Purpose: To compare how the study unfolded with the pre-trial plan in order to determine if changes in the pre-trial analysis plans are warranted.

Methods/Approach:

- Study flow figure (see CONSORT statement)
- Number screened; number enrolled
- Subjects randomized (number to each group)
- Retention by group
- Final completion rates
- Number of subjects in analysis data sets

2.3 Description of participant

Purpose:

Methods/Approach: Construct "table 1" describing the baseline characteristics of each intervention group including:

- Demographic characteristics (e.g., age, sex, socioeconomic status)
- Baseline exposure characteristics (e.g., smoke exposure)
- Baseline disease characteristics
- Baseline values of primary and/or secondary outcome variables (note, this may be a separate table)

2.4 Primary analysis/results

Purpose: Primary results for the intention to treat (ITT) analysis.

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Kathleen Armour



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Global Clinical Trials Playbook Menghis Bairu, Richard Chin, 2012-06-12 Pharmaceuticals companies biotech companies and CROs regardless of size all face the same challenge of managing costs and operational execution associated with bringing a valuable drugs and devices to market Because of timeline pressures and cost as well as the growing interest in neglected diseases and diseases affecting the emerging nations clinical trials are increasingly conducted in emerging markets and developing countries where infrastructure leadership skilled personnel and a governance are at a premium Working with academics regulatory professionals safety officers experts from the pharma industry and CROs the editors have put together this up to date step by step guide book to building and enhancing global clinical trial capacity in emerging markets and developing countries This book covers the design conduct and tools to build and or enhance human capacity to execute such trials appealing to individuals in health ministries pharmaceutical companies world health organizations academia industry and non governmental organizations NGOs who are managing global clinical trials Gives medical professionals the business tools needed to effectively execute clinical trials throughout the world Provides real world international examples which illustrate the practical translation of principles Includes forms templates and additional references for standardization in a number of global scenarios

The Ebola Virus and West Africa Dr. Felix I. Ikuomola, 2015-07-10 The Ebola Virus and West Africa Medical and Sociocultural Aspects provides a compact summary of the Ebola virus outlining its nature history epidemiology and methods of treatment In addition the work examines the context of the diseases outbreak by describing the people politics and policies in West Africa before during and after the recent outbreak Finally chapters summarize and explore the ethical issues that arise in pursuing treatments and discuss methods for improving control and prevention of additional outbreaks Dr Felix I Ikuomola a medical doctor who is pursuing additional advanced degrees in clinical research UH and surgical sciences RCSEd Edin brings to bear his practice of medicine and surgery in Liberia Nigeria Sierra Leone and the Gambia and his direct knowledge of the cultural practices and factors at play in the countries of West Africa to ground the presentation in The Ebola Virus and West Africa in the realities of the current situation in the region The Ebola Virus and West Africa Medical and Sociocultural Aspects will provide a highly organized comprehensive and insightful treatment of this virulent disease and its sociocultural elements to people with medical backgrounds and to individuals desiring to understand more comprehensively the impact of this disease on West Africa In either case time spent with The Ebola Virus and West Africa will give you the background and analysis you need to respond intelligently to the challenges the virus presents to an increasingly globalized culture

Covid 19 Infection, An Issue of Infectious Disease Clinics of North America, E-Book Rachel Bender Ignacio, Rajesh T. Gandhi, 2022-06-02 In this issue of Infectious Disease Clinics of North America guest editors Drs Rachel Bender Ignacio and Rajesh T Gandhi bring their considerable expertise to the topic of COVID 19 Infection The evolving virology wide range of symptoms long term health

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