

Statistical Analysis Plan Template

John M. Kibeleon, 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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Robert Steven Ledley



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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

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 issues mortality rate effect on hospitals and high transmission rate have made COVID 19 one of the worst health crises in recent times In this issue top experts in the field address key issues such as diagnostic testing COVID 19 in pediatrics post acute sequelae infection control and much more aiming to arm clinicians with the information they need to combat this deadly infection Contains 15 relevant practice oriented topics including COVID 19 and global pandemic response SARS CoV 2 transmission and prevention COVID 19 Vaccines COVID 19 treatment equity and racial ethnic disparities and more Provides in depth clinical reviews on COVID 19 offering actionable insights for clinical practice Presents the latest information on this timely focused topic under the leadership of experienced editors in the field Authors synthesize and distill the latest research and practice guidelines to create clinically significant topic based reviews

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 *PAREXEL's Pharmaceutical R & D Statistical Sourcebook* ,2005

Management, 7th Asia-Pacific Edition John R. Schermerhorn, Jr., Paul Davidson, Peter Woods, Aharon Factor, Alan Simon, Ellen McBarron, Fatima Junaid, 2020-01-21 Eldenburg's Management is an introductory text that focuses on presenting content in an easy to understand way that encourages students to think critically and draw connections between theory and practice This new seventh edition has a strengthened focus on technology and features have been updated to help students further consolidate their knowledge This includes various forms of revision materials such as auto graded knowledge check questions and self skill assessment There is also a broad variety of concise case studies including new ones with a strategic focus which enable instructors to have thought provoking and engaging tutorials An exciting addition to the interactive e text are the new ANZ videos that feature a diverse group of management thought leaders who give insights and tales from the front This will provide supplementary content for lectures or serve as pre work for a flipped classroom **Statistical**

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Documentation Abstracts ,1992 **News Letter - Society of American Bacteriologists** Society of American Bacteriologists, 1953 **AMSTAT News** American Statistical Association, 2009 Process Redesign Arthur R. Tenner, Irving J. DeToro, 1997 Comprehensive in scope this book integrates three major approaches to process redesign benchmarking continuous improvement and reengineering showing how to combine the three for maximum effectiveness Numerous examples from different industries demonstrate concepts and techniques in action and illustrate common mistakes Illustrated **The Annals of Pharmacotherapy** ,1994-07 *Resources in Education* ,1982

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