

## Statistical Analysis Plan Template

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### 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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**Liyong Dong**



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### **Table of Contents Statistical Analysis Plan Sample Template Pfizer**

1. Understanding the eBook Statistical Analysis Plan Sample Template Pfizer
  - The Rise of Digital Reading Statistical Analysis Plan Sample Template Pfizer
  - Advantages of eBooks Over Traditional Books
2. Identifying Statistical Analysis Plan Sample Template Pfizer
  - Exploring Different Genres
  - Considering Fiction vs. Non-Fiction
  - Determining Your Reading Goals
3. Choosing the Right eBook Platform
  - Popular eBook Platforms
  - Features to Look for in an Statistical Analysis Plan Sample Template Pfizer
  - User-Friendly Interface
4. Exploring eBook Recommendations from Statistical Analysis Plan Sample Template Pfizer
  - Personalized Recommendations
  - Statistical Analysis Plan Sample Template Pfizer User Reviews and Ratings

- Statistical Analysis Plan Sample Template Pfizer and Bestseller Lists
- 5. Accessing Statistical Analysis Plan Sample Template Pfizer Free and Paid eBooks
  - Statistical Analysis Plan Sample Template Pfizer Public Domain eBooks
  - Statistical Analysis Plan Sample Template Pfizer eBook Subscription Services
  - Statistical Analysis Plan Sample Template Pfizer Budget-Friendly Options
- 6. Navigating Statistical Analysis Plan Sample Template Pfizer eBook Formats
  - ePub, PDF, MOBI, and More
  - Statistical Analysis Plan Sample Template Pfizer Compatibility with Devices
  - Statistical Analysis Plan Sample Template Pfizer Enhanced eBook Features
- 7. Enhancing Your Reading Experience
  - Adjustable Fonts and Text Sizes of Statistical Analysis Plan Sample Template Pfizer
  - Highlighting and Note-Taking Statistical Analysis Plan Sample Template Pfizer
  - Interactive Elements Statistical Analysis Plan Sample Template Pfizer
- 8. Staying Engaged with Statistical Analysis Plan Sample Template Pfizer
  - Joining Online Reading Communities
  - Participating in Virtual Book Clubs
  - Following Authors and Publishers Statistical Analysis Plan Sample Template Pfizer
- 9. Balancing eBooks and Physical Books Statistical Analysis Plan Sample Template Pfizer
  - Benefits of a Digital Library
  - Creating a Diverse Reading Collection Statistical Analysis Plan Sample Template Pfizer
- 10. Overcoming Reading Challenges
  - Dealing with Digital Eye Strain
  - Minimizing Distractions
  - Managing Screen Time
- 11. Cultivating a Reading Routine Statistical Analysis Plan Sample Template Pfizer
  - Setting Reading Goals Statistical Analysis Plan Sample Template Pfizer
  - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Statistical Analysis Plan Sample Template Pfizer
  - Fact-Checking eBook Content of Statistical Analysis Plan Sample Template Pfizer
  - Distinguishing Credible Sources

13. Promoting Lifelong Learning
  - Utilizing eBooks for Skill Development
  - Exploring Educational eBooks
14. Embracing eBook Trends
  - Integration of Multimedia Elements
  - Interactive and Gamified eBooks

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