Role of a statistician, programming

NTE

, N

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Role of Biostatistician

Defining Research Question
 Reasonable & Worthwhile

Defining Hypothesis Null hypothesis - H₀ Alternate hypothesis - H₁

Based upon: Study Design Observed Differences Incidence & prevalence of said condition/outcome



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Planning of the study?

- Study Design
 - Superiority / Non-inferiority
 - Open / blind
 - Controlled / uncontrolled / Stratified

To Minimize bias

To enable appropriate data collection for analysis

- Sample Size Is it Appropriate?
 - Adequate to answer research question
 - Sample size should be the minimum required to detect a desirable difference
 - Larger size more precise estimates
 - Funds ? Time ? Ethical issues ?



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Planning of the study contd...

- Assessment parameters
 - Which?
 - **Objective Vs Subjective**
 - How often?
 Frequency
 - How many?
 Too many parameters Failure of conclusion



Randomization

Random allocation of intervention

- RCTs
 Gold standard in CTs
- Randomization Crucial in RCTs
- Stratified randomization
- Block randomization
- Randomization Code
- Randomization Ratio

1:1, 1:2, 1:3, 1:1:2

- Serial assignment / chronological order
- Web based central randomization



Data Collection

Designing of CRF

– Log

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- Visit-wise
- Forward / Backward
- Open / Closed
- e-CRF / e-Data Capture [Web based trials]

To <u>standardize</u> capture of relevant data

To facilitate <u>efficient & complete</u> data recording,

processing, analysis & reporting

Data entry in CRF

- Minimum text
- Unambiguous
- Options for tick-mark answers
- Numerical data entry /decimals
- Data Processing
 - Tests for normality, skewness & homogeneity of variances
 - Data arrangement
 - Use of PC Based software for analysis

SAS, STATA, SPSS, NCSS, Add-ons (Excelstat,

Analyze-IT)

Comparison of various groups, inferences, correlations, etc

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Interpretation & Conclusions

- Statistical significance ≠ biological/ clinical significance
- In-vitro significance ≠ in-vivo significance
- To derive reasonable conclusions



Data Presentation

- Tabulation
 - Simple table
 - Frequency distribution table
- Charts & Diagrams
 - Qualitative data

Histogram

- Freq. plygon
- Line diagram
- Frequency Curve
 - Bar diagram
 - Pie /sector diagram
 - Scatter plot
- Box plot
- Pictogram

Quantitative data

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Line Diagram





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Multiple Bar Diagram







antagonists [34%]

3-D Pie Diagram

Duration of Aspirin therapy in Diabetics as reported by the physicians [N=1486]



Scatter Plot





Statistical Programming

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- When a CRF is being annotated, statistical programmers map it to SDTM
- SDTM is Standard Data Tabulation Model
- He creates the final Analysis Data Sets
- He creates Dummy Tables Figures Listings
- He programmes the data to fall into these Tables
- All this is done during data base build stage
 - Finally analysisand statistical report generation

Role of statistician vs time in a trial

- Statistician has a role at various stages in a trial
- Initiation and data base build stage
 - Inputs in protocol creation
 - CRF creation
 - Dummy TFLs

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- Statistical analysis plan
- Trial conduct- programming for creation of ADS(Analysis Data Sets) and TFLs(Tables, Figures and Listings)

Trial close - Creation of ADS, TFLs, analysis and stats report