Clinical Trials in Drug Development – From a Statistical Programmer’s Point of View

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Agenda

- What is a clinical trial?
- How does the data flow through a clinical trial?
- Roles and responsibilities of a statistical programmer.
What Is a Clinical Trial

- Research study to answer specific questions about a new therapy or new way of using known treatment
  - Determine if a drug is safe and effective in humans
  - Determine at what doses the drug works best
Clinical Trial Phases

- Phase I
- Phase II
- Phase III
- Phase IV
- Phase 0
Clinical Trial Phases (Phase I)

- Test a new drug or a treatment in a small group (20-80) for the first time.
- Evaluate Safety
- Dose escalation
- Healthy volunteers for most studies
- Several months in duration
Clinical Trial Phases (Phase II)

- Includes controlled clinical studies
- Evaluate effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and
- Determines the common short-term side effects and risks associated with the drug
- In a relatively small number of patients (no more than several hundred)
Clinical Trial Phases (Phase III)

- Expanded controlled and uncontrolled studies
- Intend to gather additional information about effectiveness and safety after preliminary evidence of effectiveness
- Usually include from several hundred to several thousand patients
Clinical Trial Phases (Phase IV)

- After New drug Application (NDA) is submitted to FDA
- After drug or treatment has been marketed
- Continue collecting efficacy information and long term safety information.
- Also called post-marketing studies
Clinical Trial Phases (Phase 0)

- Does not involve any study drugs
- May involve known treatment already on the market
- Understand disease and patient behavior, social-economic outcome of patient population
How does data flow through a clinical trial
CLINICAL OPERATIONS

Study

Patient Recruiting

Consent

Site Monitoring

Protocol

Sites Set-Up

Case Report Forms

Formal, written document specifying the purpose, design, conduct, and analysis of a clinical trial.
Clinical Data Management

Data Collection

- On Paper: CRF
- Electronic Data Capture (EDC)
- Non-CRF Data

Data Processing

Data Entry

- Data Coding
- Data Editing (SQL, SAS, or Other)

Query Generating & Resolution

DB Fit for Reporting
Clinical Study Report

Analysis

Biostatistics

Statistical Programming

SAP, Table Shell, Analysis Specs

Prog Specs, TLGs, Validation, ISS/ISE

Manuscripts

Papers
Roles and Responsibilities of a Statistical Programmer
Functional Relationships

- Programming
- Clinical
- Regulatory
- Statistics
- Data Management
Relationship of Functional Areas

- **Our Customers**
  - Statisticians
  - Clinical Department
  - Regulatory
  - Medical Writers
  - Etc

- **Our Suppliers**
  - Data Management
    - Clinical Programming
    - Clinical Data Analyst
  - Statisticians
  - Etc
Statistical Analysis

- Statisticians Write Statistical Analysis Plans (SAPs)
- SAP Drives
  - Requirement Documents
    - Table Shells and Annotated Table Shells
    - Data Definition Tables
    - Statistical Programming Plans
  - Planned Analysis Package
    - Analysis Datasets, Tables, Listings and Graphs (TLGs)
  - Validation Plans
    - Validation programs
    - Validation Documents
- Ad-Hocs
Thank You

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