

Delivering Quality  
in  
Phase I  
Clinical Data Management

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# Topics/Agenda

- Background of Clinical Studies/Data
  - Beginning of a marketed drug
  - Clinical Studies/Clinical Data Collection
- Clinical Data Management
- Quality in Phase I Clinical Data Management
- Fit for Purpose vs Quality
- Final Thoughts

# Beginning of a marketed drug

- Pharmaceutical companies develop investigational products (IPs)
  - Novel therapeutic agents
  - Generics
  - Orphan drugs
- IPs go through testing and selection criteria
  - Pre-clinical testing
  - Other types of testing to determine best candidate(s)
  - Best candidate(s) go into clinical testing

# Clinical Studies / Clinical Data

- Clinical studies
  - Phases: I, II, III, IV
  - Healthy normal subjects, specialty populations, target population, post-marketing
- Data is generated
  - Types of data are varied
    - Demographics, vital signs, sample collections, adverse events, concomitant medications, reasons for completion/withdrawal from study, ECGs, physical exam findings, neurological findings, etc., etc.
  - May be specialized
    - Polysomnography, glucose monitoring, questionnaires, etc.

# Clinical Data Management

- Creation of Documentation
  - Case Report Form
  - Data Management Plan
  - Edit Check Specifications
- Database build/testing
  - What is used to house the data that is collected
- Quality needs to be ingrained
  - Each of these steps has its own quality processes and implications if quality is not maintained

# Clinical Data Management

- Processes for Captured Data and Quality Implications
  - Data Cleaning/Clarification
    - What the clinical people collect vs what we expected them to collect
    - Ranges/acceptability can be population dependent
    - Windows/deviations for collection and impact on the overall study objectives

# Quality in Phase I CDM

- Quality is not a sprint.....but a relay race
  - Creation of data collection tool
  - Use/understanding of that tool by the end users
  - Edit checks put into place and tested
  - Working across all operations/backgrounds/etc.
- The final deliverable is only as good as the weakest point in the race
  - Without one piece of quality work, the entire framework falls apart
  - Not one piece that is “above” the others

# Quality in Phase I CDM

- Handoffs are critical
  - Quality of Handoff
    - Old saying...what goes in is what comes out the other side
  - Timing of Handoff
    - If the first handoff is late, the rest of the process is already playing from behind
    - Lateness lends itself to process failures and quality gaps
  - Understanding of all parties
    - If you don't know what you are expecting, how can you know if it's done correctly?
    - Need to know your own part and how it's used later

# Fit for Purpose vs Quality

- Fit for purpose and Quality Implications
  - When is good enough considered good enough?
  - When passing data to another operational group or a client, what needs to be ensured?
  - Does timing affect the definition of fit for purpose and quality?

# Final Thoughts.....

- Quality is....
  - not the responsibility/accountability of one person, one group, or for a single point in time.
  - a work in progress for every process, every time.
  - something different for each study/project/person.
  - **REQUIRED** for all we do.