

Background for Dr. Woodcock's BIMO presentation

This presentation on data quality was presented in June 2005, and is intended as background for Dr. Woodcock's presentation to the FDA Science Board on November 4th, 2005

Defining Data Quality: The FDA Perspective

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High Quality Clinical Trial Data: A Shared Goal

- **Supports integrity of clinical research enterprise**
- **Supports confidence of public/patients in human studies**
- **Provides evidentiary base for product approvals and medical practices**

Clinical Trial Data Quality: A Shared Responsibility

- **Investigator/Site**
- **Sponsor**
- **FDA**
- **?Academia; Journal Editors**

Investigator/Site Responsibilities

- **Embodied in GCP's**
- **Accurate protocol compliance, observations, timing, & data entry**
- **Importance of study personnel**
- **?Patient Compliance**

Sponsor Responsibilities

- **Clear and achievable study plans and protocols**
- **Investigator & site training**
- **Monitoring and auditing**
- **“Data cleanup”**

FDA Responsibilities

- **Site inspections: “Bioresearch monitoring”**
- **Review of data: paper-based or electronic data audit**
- **Guidance: Framework for best practices and compliance with regulations**
- **Enforcement: sanctions against sloppy performers or fraud**

Additional System – Wide Issue: Automation and Standardization

- **Computer program validation and integrity (FDA Part 11, etc)**
- **Data and format standardization**
 - **Standard format CRF,**
 - **Standardized terminologies**
 - **Standardization best tool for decreasing variation**

Definition of “High Quality” Data?

- **“100% Accurate”**
- **“Fit for use”**
- **“Meets protocol – specified parameters”**
- **Arbitrary “acceptable levels of variation” per explicit protocol specification?**

Definition of “High Quality” Data: Considerations

- **Allow risk management approach**
- **Probability that “x” level of variation could affect conclusions – sensitivity analysis**
- **Are all questions equally important?
(Concomitant meds)**

General Definition of Quality

- **Meets needs of customer**
 - **Sponsor**
 - **Regulator**
 - **Ultimately patient and provider**
- **What, exactly, are customers needs?**
- **How to actually assess quality?**

Frequent Operational Definition of Quality

- **Control of variability**
- **Acceptable variability differs by use/customer (specification)**
- **?Trade offs between efficiency, productivity, and control of variability**
- **Need tools to assess and quantify**

Generally: Quality is a System Property

- **Difficult to inspect quality in – i.e., monitoring, auditing**
- **Need to build quality in (e.g., analogous to quality in other industries)**
- **How to obtain within the health care system**

FDA Role in Overall System for Data Quality

- **Oversee whole enterprise**
- **Evaluate level of data quality problems across all studies/development programs**
- **Not able to directly oversee each study – risk management approach**
 - High risk (experience, country, complexity, sponsor – investigator)**

Are There Opportunities for Improvement in Current System?

- **Large number of resources expended on insuring data quality**
- **Overall system has not been explicitly examined**
- **FDA currently evaluating; will need to includes many others in process**

Probable Opportunities

- **Automation, e.g., linked networks – e.g., Ca BIG project**
- **Standardization**
- **Establish common definitions of data quality and ways to assess quality**
- **Systems-based approach at FDA**

Summary

- **Need common definition of data quality**
- **Need methods to assess**
- **Need to assess current system for data quality**
- **Need to provide for continuous improvement**