

Clinical Research Data Quality



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Four Questions


1. What is data quality?
2. Why is data quality important?
3. Why should we be addressing the level of data quality in clinical research now?
4. What is needed to improve data quality that should be addressed during the next decade?



Defining Data Quality

- Data - factual information (as measurements or statistics) used as a basis for reasoning, discussion, or calculation
- Quality - degree of excellence : **GRADE**; the character in a logical proposition of being affirmative or negative

Webster's



Data Quality

“data that support conclusions and interpretations equivalent to those derived from error free data”

*Institute of Medicine
Roundtable Report, April, 1999*



Defining Data Quality

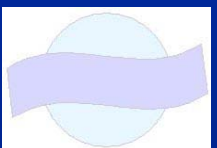
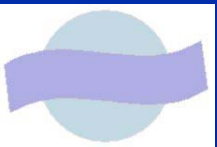
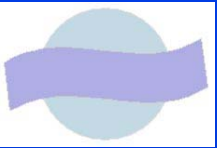
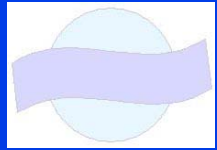
- Quality is fitness for all purposes of the data, including the likely future uses.
- Consistently meeting customer expectations ~ Total Quality Management

Larry English

Data Quality

Like obscenity ---

I know it when I see it.

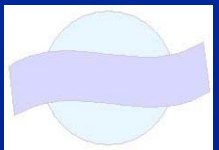
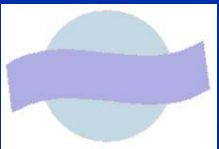
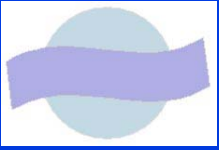
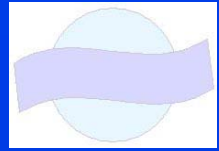


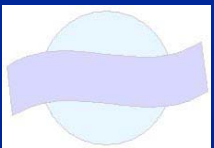
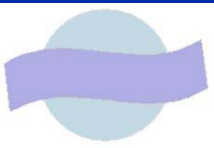
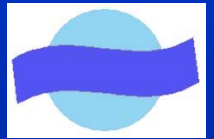
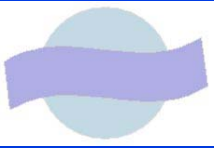
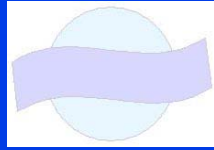
Data Quality

- Data quality is a matter of degree; not an absolute
- Need to determine what is acceptable
- It is important to provide a measure of confidence in the data quality
- Trust in the processes

Why is Data Quality Important?

Our medical-scientific-regulatory system is built upon the validity of clinical observations.





Why Address Now?

- Growing number of people (subjects and investigators) involved in trials -- Larger databases
- More reliance on data from international trials
- Cost of trials and drug development are continuing to rise
- Adoption of new technologies slow and difficult
- Patient and event registries
- Arena of sharing data

Why Now?

- Do not know what decisions data will support
- Information about data quality not being described and shared
- Measures of data quality kept private
- Audits not shared with other users
- Don't know what quality we are measuring
- Don't know what quality we need
- Don't know when we are compliant
- Need to know what “good enough” means

Why Now?

- The FDA has been part of the problem
 - Regulatory review of the quality of clinical trials data does not (at times) focus realistically on what is most important in making decisions: the “Gotcha” tradition of regulatory review
 - Even though these are large, complex experiments, there is an expectation that the data should be “squeaky” clean.
 - Not always science (Congressional oversight).
- There is a growing need for an “Adult Conversation” concerning data quality (e.g., EDC – electronic data capture).

Steve Wilson, SCDM, 2004

Why Now?

- Standards are now in place to support research in data quality
- We need a definition (Target) of data quality that allows the Industry to know when the data are clean enough.

Standards Developed

GCP
Standards for
data

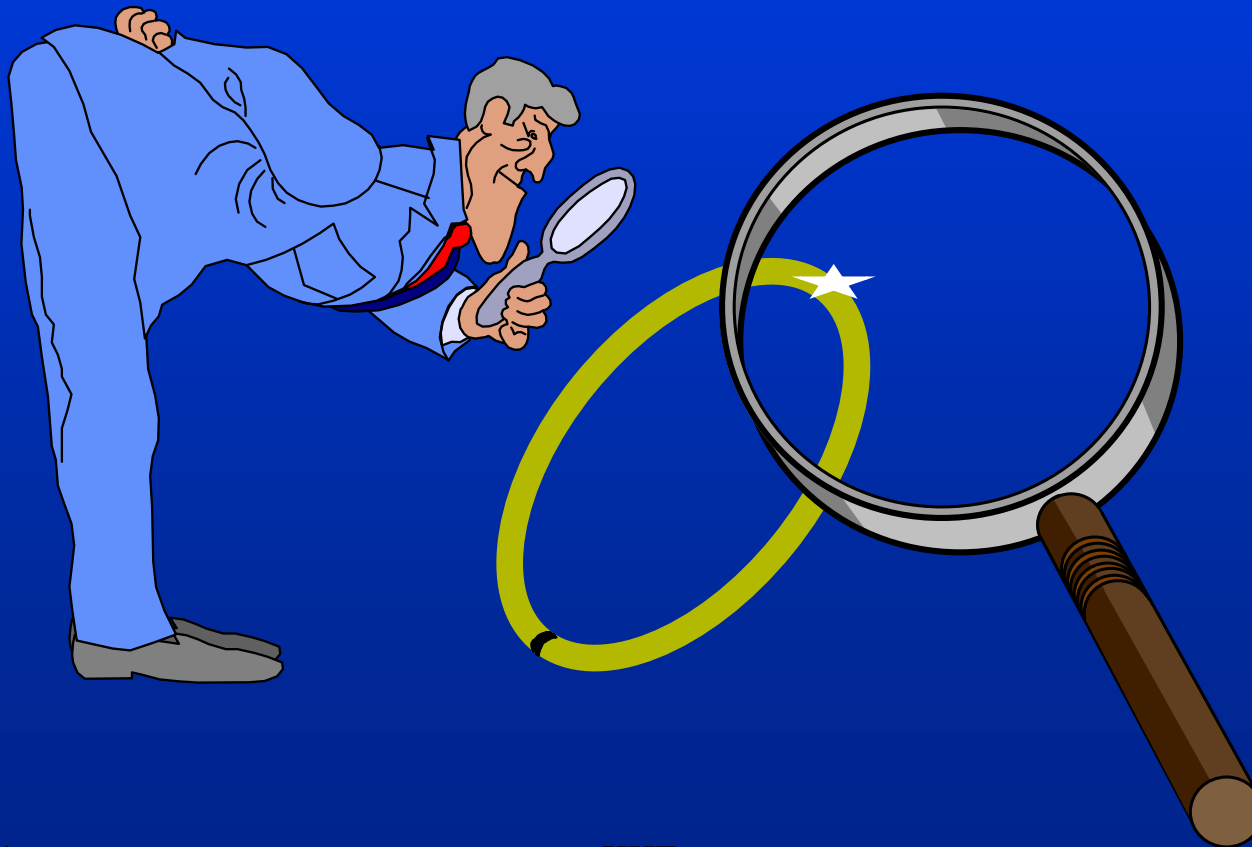
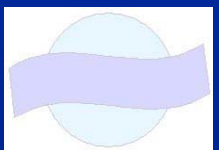
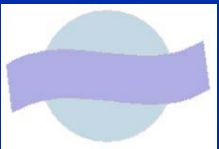
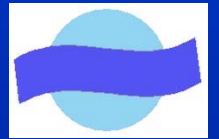
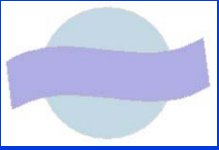
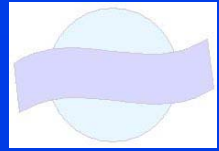


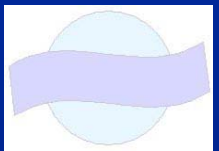
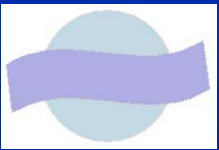
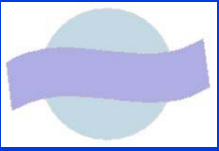
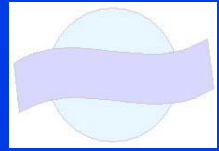
GCDMP



Quality Assurance
ICH E6

Opportunity

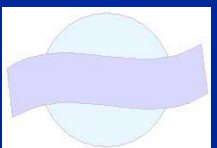
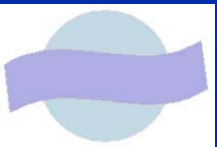
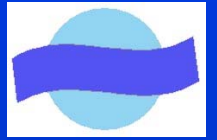
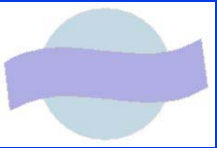
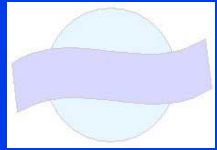
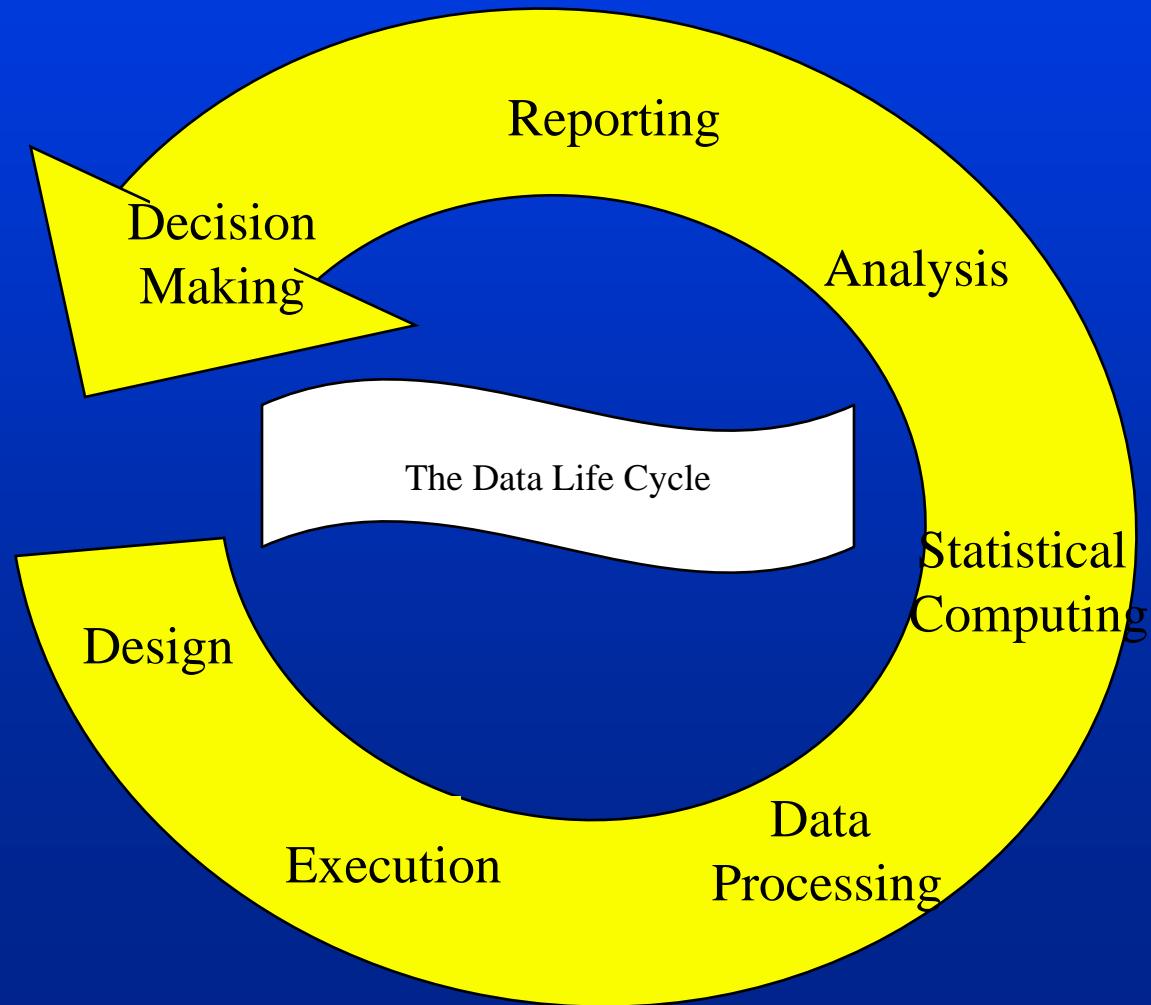




Possible Approaches

- Focus our attention on the quality of data/ information from clinical trials
- Revisit how we think about data quality
- Address quality of the data at every stage of the data life-cycle
- Collaborative research into the multiple dimensions of data quality

Risk Management Entire Data Life Cycle





Proposed Roadmap

- Embrace new approach since we don't know what is "good enough"
- Risk Modeling in all areas of Clinical Research
- Partnerships across Professional Societies in all disciplines
- Develop "The science of errors"

Proposed Roadmap

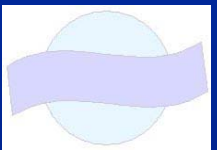
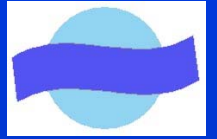
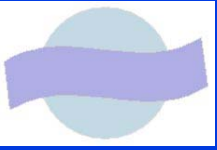
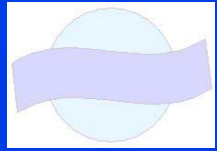
- Apply “Critical Path” criteria to clinical trials data quality
 - Focus on Process Understanding
 - What parameters are critical to the Data Quality?
 - How do we analyze these parameters?
 - How do we control these parameters throughout the process?
- Determine the risk factors in data collection and analysis

Proposed Roadmap

- Develop Statistical models for determining and assuring quality in clinical research data
- Areas of vulnerability in drug development and risks of action and inaction
- Research into value and appropriate methods of auditing and measuring data quality.
- Electronic Data Capture risk assessment and quality analysis

DQRI Approach: Quality by Design

- Data Quality Research Institute, a non-profit research organization
- The mission of the Data Quality Research Institute is to conduct research and provide education to assure the quality of biomedical scientific decisions affecting public health.



DQRI Approach: Quality by Design

Purpose:

- To provide an international scientific forum for academia, healthcare providers, industry, government, and other stakeholders to investigate the components of biomedical research that impact data quality
- To develop methodologies to assure data quality
- To apply principles of risk-assessment and risk-management to research data, and develop educational materials and programs related to research quality.

DQRI Approach: Quality by Design

Focus on Research Understanding

- What parameters are critical to Data Quality?
 - Experimental Design
- How do we analyze these parameters?
 - Appropriate Research and Measurement
- How do we control these parameters throughout the process?

Validations Committee

- Describing a risk assessment path towards an improved dialogue and a better understanding of one element of the systems employed to assure data quality – software development.
- Developing a Standard Risk Assessment Vocabulary for Clinical Trials

Validations Committee

- **DQRI risk assessment model**
 - **Impact of failures**
 - **Factors contributing to the likelihood of system failures**
 - **Dimensions on which validation procedures may vary as assessments of risk increase or decrease**
- **A useful framework for justifying decisions about any activity that affects the quality of ... data?**

Data Audit Committee

- Impact of the Audit process on data quality
- Newly formed committee
- All volunteers



Decision-Theoretic Framework for Data Quality

- **Collaboration with National Institute of Statistical Sciences (NISS)**
 - To determine of statistical models can be developed to guide decision making when selecting optimal data quality strategies
 - Plan to identify a test bed clinical database, focus on the clean-up strategies generally called Data Clarification, address evaluation measures, and develop predictive statistical models for selecting optimal clean-up strategies
- **Prospectus developed**
- **Discussions in process for federal funding**



Quality of Data Registries

Planning to kick off this project in this calendar year.

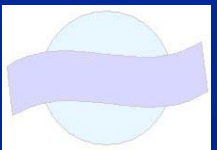
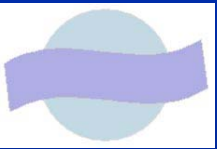
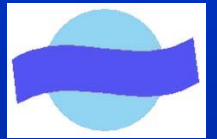
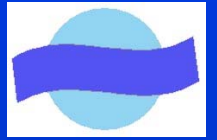
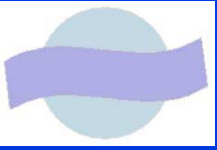
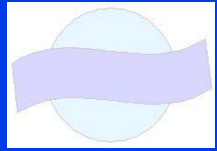
- Little to no data quality research has occurred is in patient data registries.
- Often these registries have been created for the purpose of producing publications.
- These same data are being targeted for inclusion in FDA submissions, a purpose for which they were not designed.
- Different standards are appropriate for these two applications.

Summary

- We have major opportunities for improvement of our understanding of what generates cost efficient quality data
- The time has finally come to do the needed research in this area.

Summary

- The DQRI has outlined a Roadmap for moving forward
- Two projects in process
- Other projects ready to start
- Many more topics to be addressed (see website)
- Seeking volunteers and funding



WWW.DQRI.ORG

