Clinical Data Management: Strategies for unregulated data

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RDAP Summit: April 4, 2013
Regulation → Standard Practice

- Efficiency
- Efficacy*
- Safety*
- Accuracy
- Confidentiality/Privacy*
- Clear expectations
- Standards
- Best practices established

- Burdensome
- Inflexible
- Expensive
Good Clinical Data Management Practices

• 20 areas in 2011 document

• General themes
  – Plan, test, revise, test...implement
  – All stakeholders involved in design of protocol, data collection tools, data management plan, etc.
  – Document, document, document
  – Rule: the bigger the study (sites, data, people), the more planning you need
Good Clinical Data Management Practices

• Specify documents required for reproducible research
  – Organization: SOP
  – Study: Protocol, Manual of procedures, Data management plan, Statistical analysis plan

• Documentation serves practical purposes and benefits the team immediately

• Allows specification of roles and responsibilities from the beginning
Good Clinical Data Management Practices

Begin with the end in mind OR
Produce report-ready output

Collect data in a way that allows for efficient data entry, processing, validation, and analysis

Enabled by standardized data collection tools (CRF)
Case Report Forms (CRF)

- Efficient (concise)
- Effective (clear)
- Minimize redundancy
- Minimize human error – consider completeness, accuracy, legibility, timeliness
- Enables fast data transfer across studies
Raw data → Processed data → Analysis

1. Raw data: Input from various sources such as experiments, surveys, or observations.
2. Processed data: The raw data is transformed and analyzed to extract meaningful information.
3. Analysis: The processed data is evaluated to draw conclusions and insights.
Checklist + Form
CRF + Instructions = CRF Book
Why do these strategies work?

• Save time and money
• Regulated environment – compliance is enforced
• Clinical trials are similar in structure and question are fairly narrow in scope

BUT!!!

• GCDMP provide practical strategies that meet regulatory requirements

