The Global Health Network

National Skills Sharing Workshop

How to get the needle out the haystack

19th September 2014
Poor planning

GET ALL THE INFORMATION YOU CAN, WE'LL THINK OF A USE FOR IT LATER.
Endless frustration
"I think you should be more explicit here in step two."

Plan
We need a strategy to get from enrolling patients to answering questions.
Good data management practices are essential to the success of a trial because they help to ensure that the data collected is complete and accurate. Good data management requires proper planning and should begin in parallel with protocol development in order to ensure that all of the protocol-specified data is accurately captured. Data management begins with creating an overall data management plan, selecting and designing a database, the design of data capture instrument (e.g. Case Report Form) and continues with data collection and regular quality control procedures and ends with database cleaning and locking/freezing.
Data strategy

- Source
- CRF
- Database
- Reports
What do we want to be able to publish at the end of the study?

What do we have to report to sponsors?
Excel is not a database!

Don’t leave until after the fact

Well-structured to suit data needs of protocol
Stores like data together
Stores component variables
Accurate, secure and reliable
Compound variables
Too many ‘free text’ fields

Could be paper-based or electronic

Component variables
Choice fields
Logical flow
Follows protocol
Now we have a strategy to get from enrolling patients to answering questions.
Quality management

Need a detailed Data Management Plan

- Amendment and Change Procedures
- Definitions and Acronyms
- CRF section
- Database section
- Database validation section
- Data transfer section
- Coding section
- Quality Assurance/Control Processes
- Archiving and record retention process

NOT something the ‘data person’ can ‘go away and write on their own’!
DMP includes: **Quality Assurance/Control Processes**

- Quality assurance
- Quality control
- Quality management

A plan for **preventing** quality lapses:
- CRF checks
- Data entry checks
- Programmed checks

**Measures** data quality in terms of error rates to see that they are within acceptable limits

**Expand on these in SOPs**
Agreements phase

Develop Trial Management System

Information

Resources

In Articles

Could an Open-Source Clinical Trial Data-Management System Be What We Have All Been Looking For?
DATA MANAGEMENT / ADMIT

Clinical Trial Management Tool
GLOBAL HEALTH TRIALS

An approach to a centralized Clinical Data Management System - A story from Vietnam
GLOBAL HEALTH TRIALS

Managing Incidental Genomic Findings in Clinical Trials: Fulfillment of the principle of justice
GLOBAL HEALTH BIOETHICS
Data clarification
www.globalhealthtrials.org

www.coursera.org/course/datamanagement

www.lynda.com