



The Global Health Network

National Skills Sharing Workshop

How to get the needle out the haystack



Enabling research by sharing knowledge

19TH SEPTEMBER 2014

www.theglobalhealthnetwork.org

Poor planning



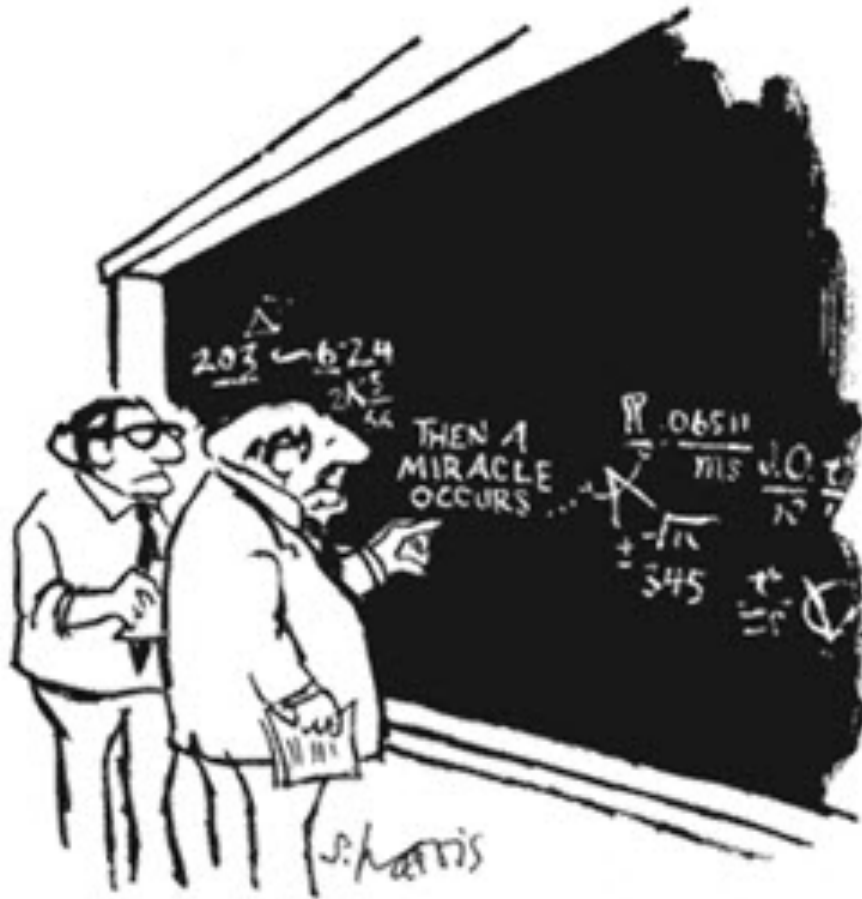
Endless frustration



Enabling research by sharing knowledge



Plan



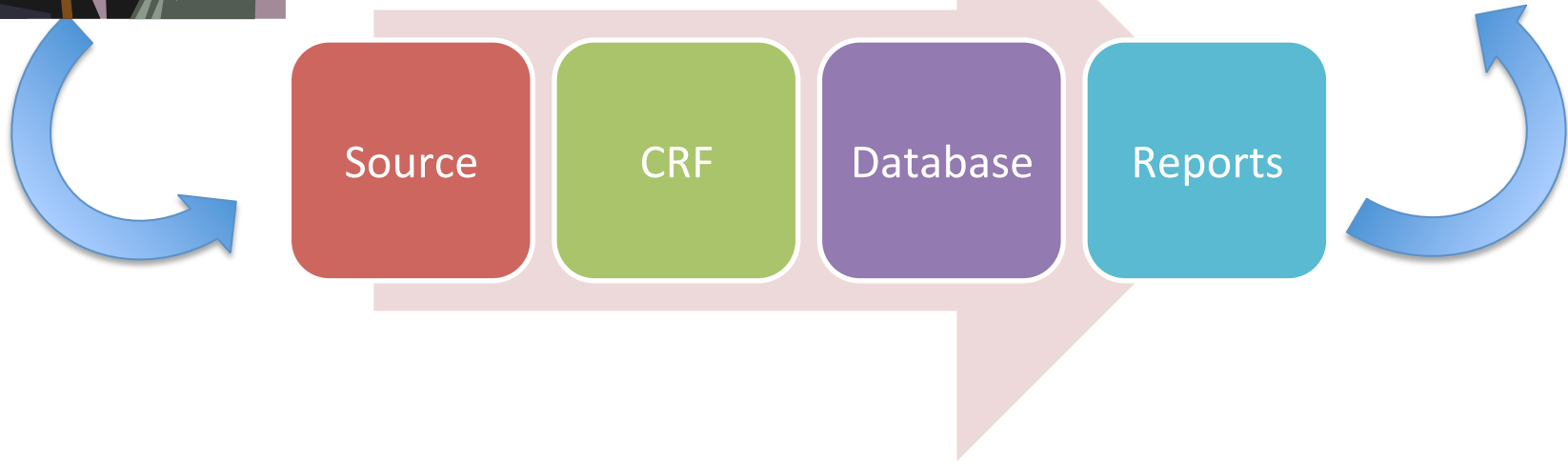
"I THINK YOU SHOULD BE MORE EXPLICIT HERE IN STEP TWO."

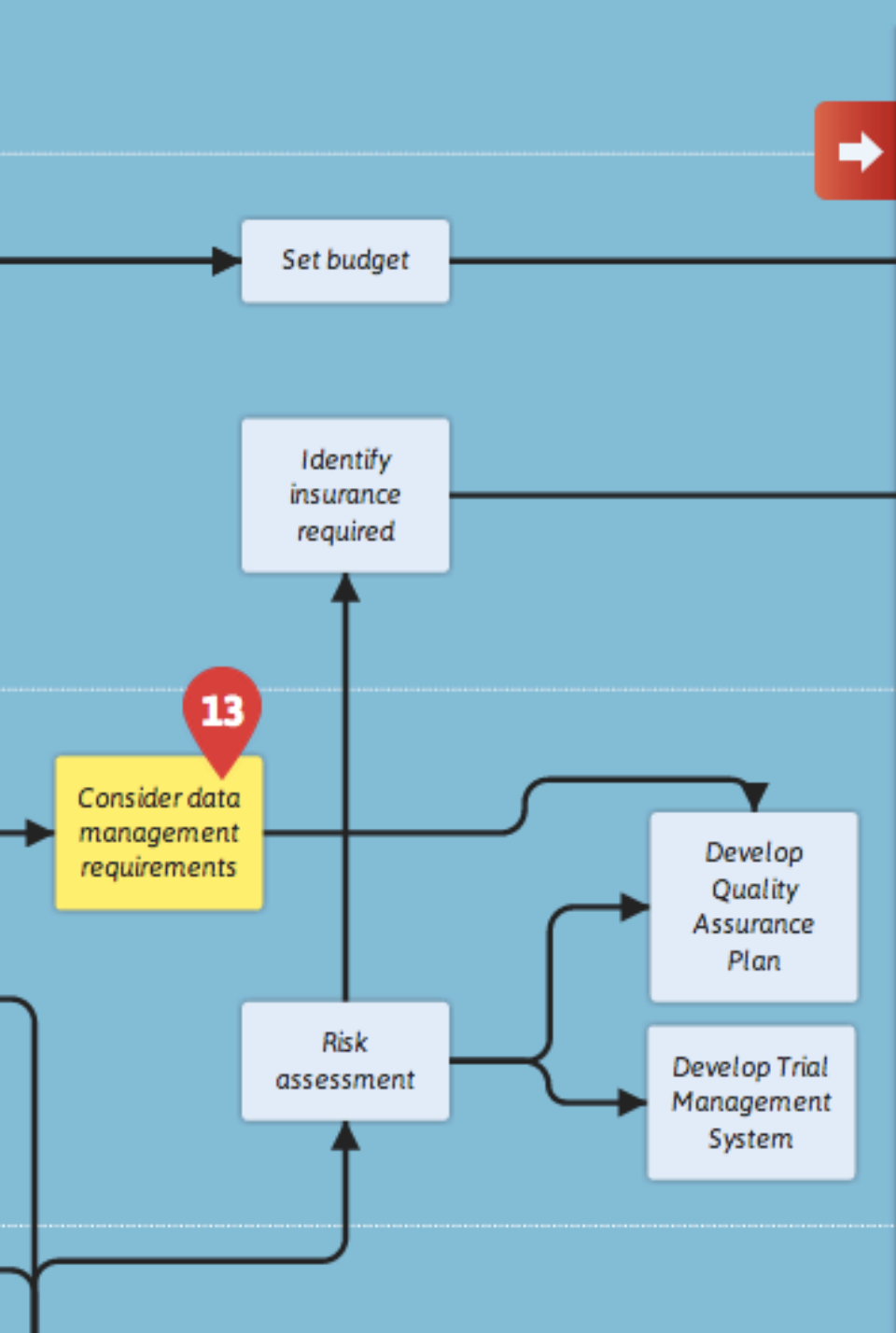


Data strategy



We need a strategy to get from enrolling patients to answering questions





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Consider data management requirements

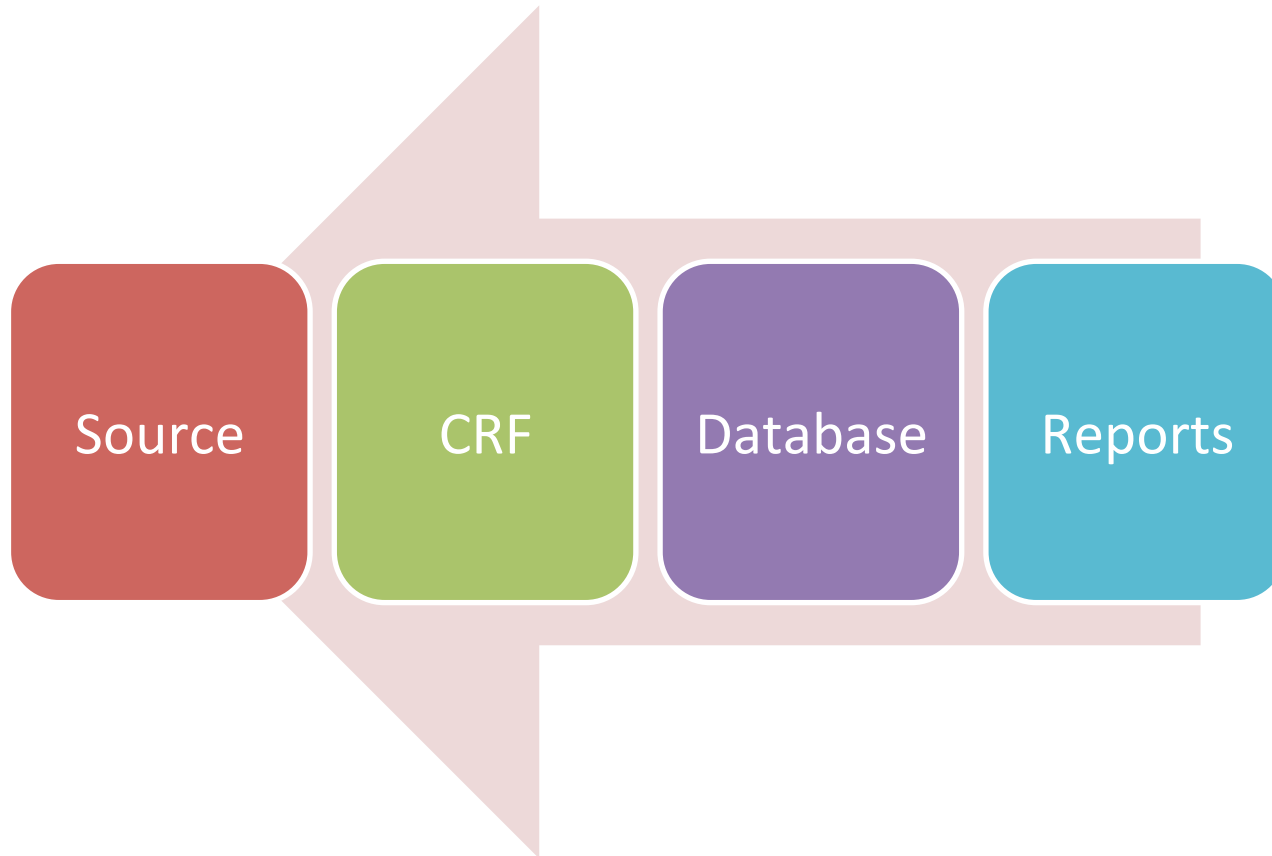


Information ^



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



Reports



† What do we *want to* be able to publish at the end of the study?

† What do we *have to* report to sponsors?

Reports



Database



Excel is not a database!

Don't leave until after the fact

Database



Well-structured to suit data needs of protocol

Stores **like** data together
Stores component variables

Accurate, secure and reliable

CRF



Compound variables
Too many 'free text' fields



Component variables
Choice fields
Logical flow
Follows protocol

Could be paper-based or electronic

Source



Test results

ECG report

Questionnaires

Medication diary



Clinical notes



Pharmacy records



DM Plan



Now we have a strategy to get from enrolling patients to answering questions



Source

CRF

Database

Reports



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

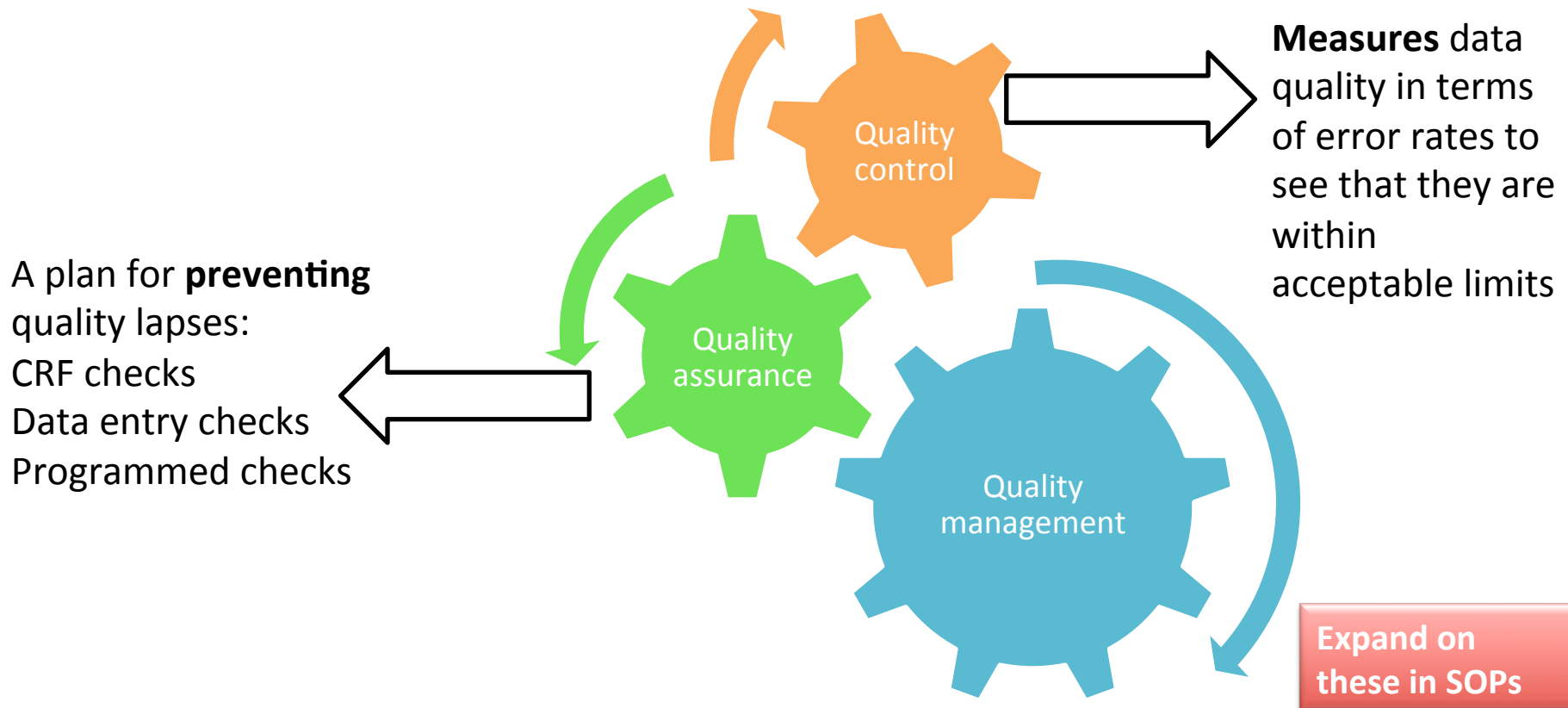
Archiving and record retention process

NOT something
the 'data person'
can 'go away
and write on
their own'!

Quality management



DMP includes: **Quality Assurance/Control Processes**



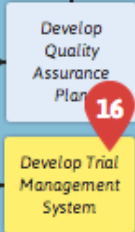
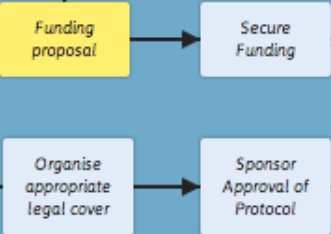


16 Develop Trial Management System

Information ▾

Resources ^

Peer review - may be part of funding proposal. If not, peer review may be sought for further guidance and additional good practice



Enabling research by sharing knowledge

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



Free online courses



www.globalhealthtrials.org

www.coursera.org/course/datamanagement

www.lynda.com