

Launching the REDe scheme for Assuring Data Quality & Introducing Reciprocal Monitoring

Cuba, August 2017

The REDe Quality Management Toolkit

Aims to provide the following:

1. An overview on quality management
2. A guide to assessing risk and identifying possible errors that matter
3. A guide for writing a Quality Management Plan (QMP) for their study
4. A tool set of templates, Standard Operating Procedures (SOPs) and forms to implement QMP
5. An introduction to reciprocal and in-house monitoring



Why?

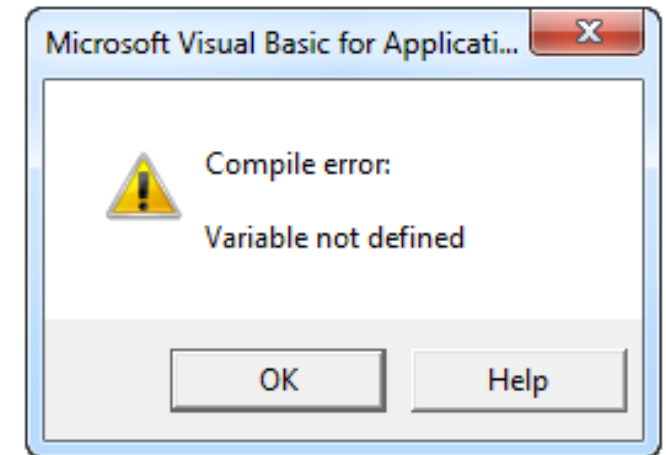
- What errors that matter could happen
 - how likely would these be, and
- How can these be avoided?



What are the errors that matter?

Errors that matter could be....

- Data inaccuracies – unreliable or wrong answers
- Mistakes – participant safety
- Mistakes – harm the reputation of research in the community



STEP 1: How are each consortia wanting to approach this?



Are you going to have a consortia wide policy?



Are you going to leave it up to each study to decide?

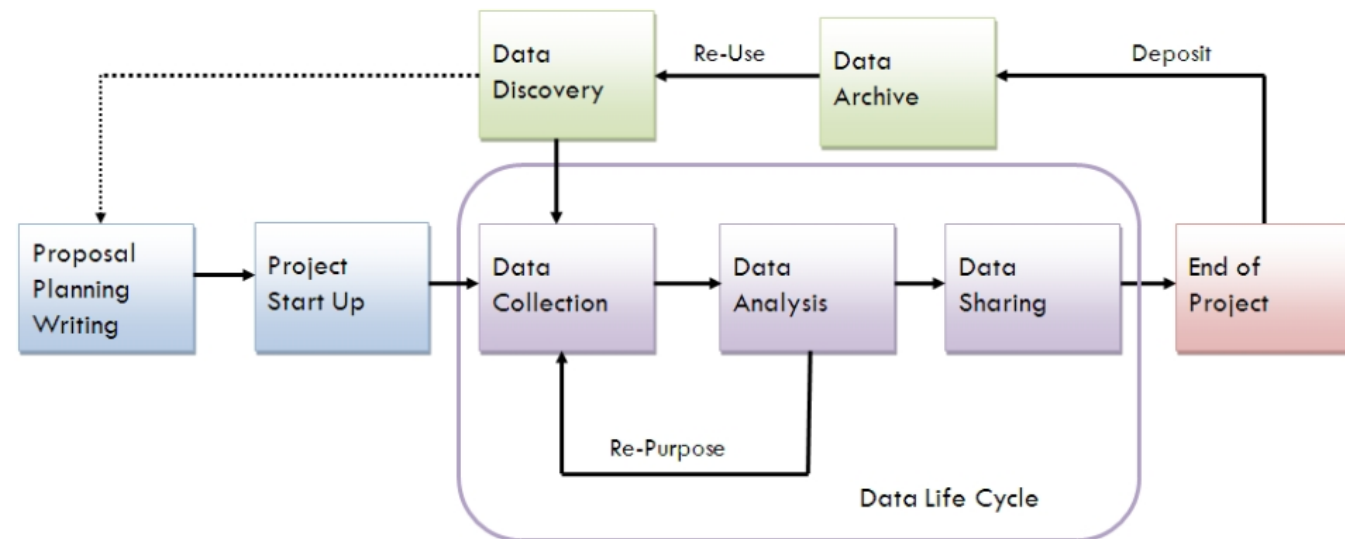


Are you going to deliver the monitoring?
(if this is the selected plan)

REDe can help by providing the tools, training and support.

STEP 2: Study specific Quality Management

- Assessment of risk
- Develop a QMP
- Create an SOP



STEP 3: Implementing Quality Management

- Level of checking?
 - ✓ Database level?
 - ✓ Site level with Source Data Validation



Who can monitor?

- Anyone who is an experienced research team member can take on the responsibility for assuring quality management within a study



What is reciprocal monitoring?

- The need to ensure that the question set is being answered, and that the answer can be relied upon

Chilengi R, Ogetii G, Lang T. A Sensible Approach to Monitoring Trials: Finding effective solutions in-house. WebmedCentral CLINICAL TRIALS 2010;1(10):WMC00891 doi: 10.9754/journal.wmc.2010.00891

Photo credit: <http://kemri-wellcome.org/>



What are the advantages of reciprocal monitoring?

- ✓ It is easy to set up and low cost
- ✓ It gives a new element to research staff careers and roles
- ✓ Best practice is shared and standards are raised (this is probably the best bit!)
- ✓ It can be implemented with a hospital, research centre or
- ✓ within a multi-centre regional study between the sites
- ✓ It brings sustainable and continuous process improvement

How to implement reciprocal monitoring

- **Decide who** is going to join your scheme
- **Find** your monitors
- **Train them** as monitors
- **Set up** your scheme: each study taking part needs a:
(i) Monitoring plan, (ii) schedule and (iii) monitor

REDe is here to help!! REDe@theglobalhealthnetwork.org

Now some work to do!

1. Break into your study teams
2. Think about the needs and risks within your study
3. Come up with what approach you would like to use
4. Tell us what you need to write your data quality plan and to then implement them



To summarise

- Assuring data quality is an essential element of conducting good research
- It does not need to be daunting, time consuming or expensive
- Focussing on the errors that matter is appropriate and works
- Training your staff as monitors is good for their career development and will raise your research standards

The REDe Team are here to help you:

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