Good Health Research Practice

Yodi Mahendradhata
Good Research Practice

- Scientific rigor
- Ethical practice
- High quality data
Quality management of research

• Ensure the research process will meet or exceed scientific, ethical and regulatory research standards
• To ensure data is credible, reliable, repeatable, auditable and transferable
• Should be embedded into all research activities
• Quality management is NOT optional
How to ensure quality of the research process?
How to ensure quality of the research process?

- Study planning & preparation
- Study conduct & Data collection
- Data management & analysis
- Report writing & dissemination
How to ensure quality of the research process?
Quality activities and research project process

- Study planning & preparation
- Study conduct & Data collection
- Data management & analysis
- Report writing & dissemination

Project Plan & budget, trainings, SOPs
Why do we need project planning for research?
Good research needs good scheduling
Good research needs good budgeting
Good research needs qualified manpower

• Dependent on study requirements
• All study members need to be qualified by
  – Education
  – Experience
  – Training
• Adequate number including standby staff for key critical activities
Why do you need to organize training?
Why do you need to develop SOPs?
SOPs - A case Study

• Routine quality assurance visit was done
• Discussed with two laboratory assistants how they read the slides
Reading blood smears

<table>
<thead>
<tr>
<th>Assistant 1</th>
<th>Assistant 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Used distilled water</td>
<td>Used rain water</td>
</tr>
<tr>
<td>Read slide once to determine positivity</td>
<td>Read slide three times to determine positivity</td>
</tr>
<tr>
<td>Read slide twice and took average to determine percentage</td>
<td>Read slide three times and took the highest number to determine percentage</td>
</tr>
<tr>
<td>Destroyed original paper with counts</td>
<td>Kept all records of readings</td>
</tr>
</tbody>
</table>

Are the results comparable? How does this affect the study?
Why do research projects need SOPs?*

- To establish procedures which will ensure quality and integrity of the data
- To communicate these procedures to those who will undertake them
- To leave a permanent record of the methodology employed

* Ref: Dumre & Elango (2010)
How to ensure quality of the research process?

- Study planning & preparation
- Study conduct & Data collection
- Data management & analysis
- Report writing & dissemination
Quality activities and research project process

- Study planning & preparation
- Study conduct & Data collection
- Data management & analysis
- Report writing & dissemination

Documentation, Monitoring & supervision, audit

Protocol, Project Plan, SOPs, trainings
Monitoring the project

- Regular project monitoring ensures that the team:
  - Knows whether or not the project is making progress towards its objectives
  - Can anticipate and respond quickly to problems and opportunities
  - Implements the project successfully
How to monitor?
Monitoring the project

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Milestones</strong></td>
<td><strong>Quality</strong></td>
<td><strong>Project</strong></td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td><strong>Time</strong></td>
<td></td>
</tr>
</tbody>
</table>

Measure… analyse… react…
Audit trails

• Documentation that allows reconstruction of the course of events

• All changes to forms and databases should be:
  – Dated
  – Initialled
  – Explained (if necessary)
  – Should not obscure the original entry
How to ensure quality of the research process?

- Study planning & preparation
- Study conduct & Data collection
- Data management & analysis
- Report writing & dissemination
Quality activities and research project process

- Study planning & preparation
- Study conduct & Data collection
- Datamanagement & analysis
- Report writing & dissemination

Monitoring & supervision
- Protocol, Project Plan, SOPs, trainings
- Double entry, validation
How to manage data?
Aims of Data Management

• Ensure:
  – Data is collected in accordance with study protocol and Good Research Practice
  – Data is accurate and complete
  – Study results are credible

• Can help to identify problems in study processes
Issues in data collection

• Data quality can be compromised by:
  – Observation not made
  – Observation not recorded
  – Data may be inaccurately recorded
  – Data forms may be lost
  – Data may be invented (fraud)
  – Data for each participant not processed consistently
Quantitative Data Management

- Form Completion
- Data Entry
- Data cleaning & Validation
- Double data entry
- Coding
- Data entry checks
- Post entry checks
- Training Investigators
- Monitoring visits & SDV
Post entry checks

Start
1. Data manager cleans & validates database

2. Problems such as missing values or inconsistencies

3. Queries addressed to the PI via paper query forms

4. PI resolves queries

5. Query resolutions put on query form

6. Monitor checks query resolutions

7. Query forms with resolution sent back to data manager

8. Corrections entered in database

Data validated

No

Yes
Qualitative Data Management

Data Recording → Data Preparation

Data Transcribing → Data Familiarity → Data Interpretation

Training Field Staff

Categorizing

Coding → Data Interpretation → Data Validation

Conceptualizing

Represent finding
Archiving principles

Who? Sponsor, Lead PI

What? All essential docs

When? End of study

Until when? Retain within agreed period after study end

Where? Stored in a secure, environmentally controlled area

How? In archive boxes
How to ensure quality of the research process?

- Study planning & preparation
- Study conduct & Data collection
- Data management & analysis
- Report writing & dissemination
Quality activities and research project process

- Study planning & preparation
  - Protocol, Project Plan, SOPs, trainings

- Study conduct & Data collection

- Datamanagement & analysis
  - Double entry, validation

- Monitoring & supervision

- Report writing & dissemination
  - Report review & approval
How to report and disseminate?
Read your thesis guideline!
## Key scientific report guides

<table>
<thead>
<tr>
<th>Guide</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONSORT</td>
<td>Reporting of randomized controlled trials</td>
</tr>
<tr>
<td>TREND</td>
<td>Reporting of non-randomized evaluations of behavioral and public health interventions</td>
</tr>
<tr>
<td>STROBE</td>
<td>Reporting of observational studies in epidemiology</td>
</tr>
<tr>
<td>STARD</td>
<td>Reporting of diagnostic accuracy studies</td>
</tr>
<tr>
<td>COREQ</td>
<td>Reporting of qualitative research</td>
</tr>
<tr>
<td>URM</td>
<td>Uniform Requirements for Manuscripts Submitted to Biomedical Journals</td>
</tr>
<tr>
<td>GPP</td>
<td>Reporting company sponsored medical research</td>
</tr>
<tr>
<td>GLISC</td>
<td>Reporting and distribution of grey literature</td>
</tr>
<tr>
<td>ICH E3</td>
<td>Reporting clinical studies for regulatory bodies (Europe, USA, Japan)</td>
</tr>
</tbody>
</table>
# Key questions

<table>
<thead>
<tr>
<th>Category</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Goal</strong></td>
<td>• What are the goals and objectives of the dissemination effort?</td>
</tr>
<tr>
<td></td>
<td>• What impact do you hope to have?</td>
</tr>
<tr>
<td><strong>Audience</strong></td>
<td>• Who is affected most by this research?</td>
</tr>
<tr>
<td></td>
<td>• Who would be interested in learning about the study findings?</td>
</tr>
<tr>
<td></td>
<td>• Is this of interest to a broader community?</td>
</tr>
<tr>
<td><strong>Medium</strong></td>
<td>• What is the most effective way to reach each audience?</td>
</tr>
<tr>
<td></td>
<td>• What resources does each group typically access?</td>
</tr>
<tr>
<td><strong>Execution</strong></td>
<td>• When should each aspect of the dissemination plan occur?</td>
</tr>
<tr>
<td></td>
<td>• Who will be responsible for dissemination activities?</td>
</tr>
</tbody>
</table>
How to ensure quality of the research process?

- Study planning & preparation
- Study conduct & Data collection
- Data management & analysis
- Report writing & dissemination