

## Postgraduate course in Clinical Data Management – MSc Project work

Dear clinical trial colleague,

I am a student pursuing a postgraduate qualification in Clinical Data Management at Kingston University. I will be evaluating processes which have been implemented through the life-cycle of the clinical data aimed at ensuring the data collected is integral, reliable and fit for submission in clinical trials. I will be comparing quality control (QC) procedures in a number of African medical research institutions with similar institutions in Europe, the United States of America and others to identify any differences in expectation or standards. If there are differences, then a gap analysis will be performed and improvements suggested with reference to Good Clinical Data Management Practice (GCDMP) produced by the Society of Clinical Data Management.

The topic for my industrial research is:-

**“An assessment of Clinical Data Management (CDM) procedures in some African research institutions to explore possible improvements in processes to better ensure data quality and auditability in clinical trials conducted in Africa”**

It is hoped that your responses to the questionnaire below will be used to evaluate the data quality challenges faced in clinical trials. You may consult other sections of your department or organization where applicable so as to have a representative response of activities in your institution.

The results of this project will be made available in early next year (2010).

Please select the option that is applicable to your institution/organisation/industry on the right side of the question from the combo box provided.

Thanks in advance for your help and support with this research.

If you would like to be involved with this industry research, please return completed questionnaire via one of the following methods:

**Email:** [sdonkor@mrc.gm](mailto:sdonkor@mrc.gm); or [simon\\_donkor@yahoo.com](mailto:simon_donkor@yahoo.com)

**Fax:** +220 4495919

**Tel:** +220 7030604

**Post: Simon Donkor**

Data Manager (Bacterial Diseases Prog.)  
Medical Research Council (MRC) Laboratories, Fajara  
P. O. Box 273  
Banjul-The Gambia  
West-Africa



## RESEARCH QUESTIONNAIRE

4. What are some of the quality measures/checks put in place to ensure data quality in the handling of clinical data in your institution? (write in the box provided)

5. Are these quality measures approved/reviewed by senior management, understood and accepted by all staff involved in the clinical trials? (Select from the combo box)

1=Yes, both senior management and all staff

2=Yes, only senior management

3=Yes, only staff

[ ]

4=No

5=Unsure

6=NA

6. Were all staff trained on understanding these quality measures before they became operational? (Select from the combo box)

1=Yes, all clinical staff

2=No, only data management staff

[ ]

3=No

4=Unsure

5=NA

## RESEARCH QUESTIONNAIRE

**7. Does your institution have clinical trials Standard Operating Procedures (SOPs) that are readily accessible by all staff?** ((Select from the combo box)

1=Yes, for all functions

2=Yes, for only specific functions

[ ]

3=No

4=Unsure

**8. Does the data management department have its own SOPs (e.g. data handling plan (DHP; working manual etc.) that are followed during the handling of clinical data?**  
(Select from the combo box)

1=Yes

2=No

[ ]

3=Unsure

4=NA

**9. Is there a well established quality assurance department in your institution that interacts with the data management department?** (Select from the combo box)

1=Yes

2=No

[ ]

3=Unsure

4=NA

**10. Has there ever been auditing of clinical data in your institution in the last 3 years to assess data quality?** (Select from the combo box)

1=Yes, both internal and external auditing

2=Yes, only internal auditing

3=Yes, only external auditing

[ ]

4=No

5=Unsure

6=NA

## RESEARCH QUESTIONNAIRE

**11. During the auditing, were there any findings related to data processing/management that was reported by the auditor?** (Select from the combo box)

1=Yes, (both major and minor)

2=Yes, (only minor)

3=None

[ ]

4=Unsure

5=NA

**12. How were these findings resolved by the data management department if any?**  
(write in the box provided)

**13. By what means is data collected/handled in your institution (i.e CRF, EDC, etc)**  
(write in the box provided)

**14. Are these data handling processes standardised across team and projects?**  
(Select from the combo box)

1=Yes

2=No

[ ]

3=Unsure

4=NA

**15. Have these standard tools/processes been validated?** (Select from the combo box)

1=Yes

2=No

[ ]

3=Unsure

4=NA

**RESEARCH QUESTIONNAIRE**

**16. Which of the following methods are/is mostly used in processing/capturing data in your institution?** (Please check all that apply)

- Single data entry
- Double data entry
- Electronic data capture
- Others, (if others, please specify:.....)

**17. How are laboratories data handled in your institution?** (Please check all that apply)

- Results are uploaded directly onto central database and then electronically transferred to the clinical database
- Results are entered by laboratory staff (single entry)
- Results are entered by laboratory staff (double entry)
- Results are transcribed onto Case Report Forms(CRFs)/reports for data management staff to enter
- Unsure

**18. Are there standardised documented checks and procedures that are followed to ensure data quality in your institution when undertaking clinical trials?** (Select from the combo box)

1=Yes

2=Yes, but not standardized

3= No

4=Unsure

5=NA

**19. Which of the following method(s) is/are primarily used in detecting common errors in clinical trial data in your institution?**( Please check all that apply)

- Data validation
- CRF to database inspection
- Source Data Verification (SDV)
- Programmatic Data Checks
- Aggregate Statistics
- None of the above (specify if possible).....

## RESEARCH QUESTIONNAIRE

**20. Are data management metrics for QC evaluated during clinical trials?** (Select from the combo box)

1=Yes

2=No

[ ]

3=Unsure

4=NA

**21. At what stage do you think it is appropriate to start ensuring data quality?**

(Select from the combo box)

1=At the design of the trial

2=After the first subject is recruited

3=During the designing of database

[ ]

4=Before any data analysis is carried on

5=Just before database closure

6=Other, please specify below

**22. Is there a means of calculating error rate in your institution?**

**noncritical fields if any?** ((Select from the combo box) [If Yes, *goto* Question 23 else 24]

1=Yes

2=No

[ ]

3=Unsure

4=NA

**23. What is the acceptable data error rate within your institution for both critical and noncritical fields?** (fill in the appropriate rate in column provided for both if any)

| Critical fields | Noncritical fields |
|-----------------|--------------------|
|                 |                    |

## RESEARCH QUESTIONNAIRE

**24. What is your institution's philosophy on how data validation should be performed to ensure that data are cleaned effectively?** (write in the box provided)

**25. What do you consider to be the most important step within your institution to ensure quality and integrity of the data?** (write in the box provided)

**Thank you for taking your time to respond to these questions. Please kindly look through the questionnaire before sending it back to the sender.**

If you would be willing for me to contact you for further discussion on your responses, please complete the details below:

Name:.....

Position:.....

Company /Institution:.....

Contact telephone/Mobile No:.....

E-mail address:.....