UGANDA MANAGEMENT INSTITUTE

THE CONTRIBUTION OF QUALITY CONTROL IN THE MANAGEMENT OF CLINICAL TRIAL DATA: A CASE OF MAKERERE UNIVERSITY-JOHNS HOPKINS UNIVERSITY HEALTH CARE LTD

BY

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DECLARATION

I, **Judith Namata**, hereby declare that this study is my original work and has, to the best of my knowledge, never been submitted for the award of a degree or any other award in a university or other institutions of higher learning.

Signed…….. Date…….

Judith Namata

APPROVAL

This is to certify that this study has been carried out under my supervision and has been submitted for examination with my approval.

Signed…… Date……..

Dr. Maria Barifaijo

UMI based supervisor

Signed…… Date……..

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Work based supervisor

DEDICATION

This piece of work is dedicated to my dear parents Mrs. and Mr. George Martin Lutajjumwa who have been so supportive to me and have made me realize my dreams.

ACKNOWLEDGEMENT

I acknowledge with gratitude the following academics whose input greatly enhanced the accomplishment of this piece of work. Firstly, I wish to thank my supervisors Dr. Maria Barifaijo and Mr. Michael Mubiru for the relentless professional input they put in to ensure this work is accomplished in time. They, with commitment, read and reviewed my work several times. Their encouragement and advice are highly appreciated.

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LIST OF ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
CQMP	Clinical Quality Management Plan
CRFs	Case Report Forms
CSR	Clinical Statistical Report
DAIDS	Division of AIDS
GCP	Good Clinical Practice
HIV	Human Immune Virus
MUJHU	Makerere University Johns Hopkins University
MU-WRP	Makerere University Water Reed Project
QC	Quality Control
QMP	Quality Management Plan
SOPs	Standard Operating Procedures
SPSS	Statistical Programme for Social Scientists
SQC	Statistical Quality Control
UNBS	Uganda National Bureau of Standards
UNCST	Uganda National Council of Science and Technology

ABSTRACT

The purpose of this study was to assess the contribution of QC in the management of clinical trial data at Makerere University Johns Hopkins University (MUJHU) Health Care Limited. The study was guided by the following specific objectives: - To examine the effect of compliance with clinical trial requirements on the management of clinical trial data in MUJHU Health Care Limited; To analyze the effect of an operational quality management plan on the management of clinical trial data in MUJHU Health Care Limited; and To establish the effect of quality control measures on the management of clinical trial data in MUJHU Health Care Limited. This study used a cross sectional case study design and employed both qualitative and quantitative data collection approaches to address the different aspects of the research problem. Both purposive and random samplings were used to select the respondents. The study employed both the quantitative (semi-structured questionnaire) and qualitative (key informant interviews) data collection methods. Data were analyzed using statistical methods such as frequencies and percentages including Spearman correlation and coefficient of determination and were presented in tabular form. Findings revealed that compliance with clinical trial requirements had a significant but weak effect on the management of clinical trial data. Operational quality management plan had a significant very strong effect on the management of clinical trial data. Quality control measures had a significant but moderate effect on the management of clinical trial data. It is recommended that compliance with clinical trial requirements, operational quality management plan and quality control measures should be improved for the better management of clinical trial data in MUJHU Health Care Limited.

CHAPTER ONE

INTRODUCTION

1.1 Introduction

This study investigated the contribution of quality control in the management of clinical trial data: a case of Makerere University-Johns Hopkins University Health Care Ltd. This was because clinical trials face data management challenges, leading to questioning of the quality of the data that is generated from such clinical trials. The rest of this chapter is divided into the following major sections: background to the study, statement of the problem, general objective of the study, specific objectives of the study, research questions, conceptual framework, scope of the study, significance of the study, justification of the study, limitations of the study, operational definitions and conclusion.

1.2 Background to the Study

The concept of "quality" is elusive, because it expresses a relative, though, noticeable difference between one thing and another. Relative terms such as "better", "superior", "acceptable" as applied to judge quality. However, quality is a universally acknowledged factor in successful business. Winning organizations are those that meet quality standards and for whom customer services is an obsession in every single market in which they operate (ESIB, 2003). According to Madison (2000), to ensure quality standards, businesses are concerned with checking and reviewing work that has been done hence quality control. To Madison; quality control (QC) is a process employed to ensure a certain level of quality in a product or service. It may include whatever actions a business deems necessary to provide for the control and verification of certain characteristics of a product or service. He emphasizes that the products, services, or processes must meet specific requirements and is dependable, satisfactory, and fiscally

sound. He further alludes to the fact that quality control does not cover just products, services, and processes, but also people. It is therefore important to note that employees are an important part of any company. If a company has employees that do not have adequate skills or training, have trouble understanding directions, or are misinformed, quality may be severely diminished. When quality control is considered in terms of human beings, it concerns correctable issues. This section therefore presents a historical, theoretical, contextual and conceptual background to the study, regarding quality control in the management of clinical trials data with specific reference to Makerere University Johns Hopkins University (MUJHU); that enhanced the researcher's interests to undertake the study.

1.2.1 Historical Background

The systematic approach to quality started during the industrial manufacture in the 1930s, mostly in the USA, when some attention was given to the cost of scrap and rework. Notably, with the impact of mass production during the World War (1939-1945), it became necessary to introduce a more appropriate form of quality control. That is Statistical Quality Control (SQC). To this effect, standard statistical techniques allowed the producer to sample and test a certain proportion of the products for quality to achieve the desired level of confidence in the quality of the entire batch or production run Shewhart (1939).

In the field of Public Health Services internationally, there have been many reports of unethical practices. Pimple (2002), argues that a number of highly publicized cases of misconduct in science occurred in the late 1980s. Sponholz (2000), who states that misconduct in science is an old problem where fabrication, falsification, plagiarism, or

other practices seriously deviate from normal practice, also alluded to this. Most of such practice is due to either lack of QC systems or failure to enforce or abide by the ones in place. Hence, it is remarkable, that the reliability and effectiveness of data in clinical trials depends so much on the existence of a reliable QC system that can guarantee the objectives of such clinical trials.

The history of clinical trials before 1750 is brief (Green, Benedetti & Crowley, 2003; Gad, 2009). The concepts behind clinical trials, however, are ancient. The Book of Daniel chapter 1, verses 12 through 15, for instance, describes a planned experiment with both baseline and follow-up observations of two groups who either partook of, or did not partake of, "the King's meat" over a trial period of ten days. Persian physician and philosopher, Avicenna, gave such inquiries a more formal structure (Curtis & Meinert, 2006). In The Canon of Medicine in 1025 AD, he laid down rules for the experimental use and testing of drugs and wrote a precise guide for practical experimentation in the process of discovering and proving the effectiveness of medical drugs and substances (Toby 2003). He laid out the following rules and principles for testing the effectiveness of new drugs and medications (Tschanz, 2007; Craig & Daly, 2000):

1. The drug must be free from any extraneous accidental quality.
2. It must be used on a simple, not a composite, disease.
3. The drug must be tested with two contrary types of diseases, because sometimes a drug cures one disease by its essential qualities and another by its accidental ones.
4. The quality of the drug must correspond to the strength of the disease. For example, there are some drugs whose heat is less than the coldness of certain diseases, so that they would have no effect on them.

5. The time of action must be observed, so that essence and accident are not confused.
6. The effect of the drug must be seen to occur constantly or in many cases, for if this did not happen, it was an accidental effect.
7. The experimentation must be done with the human body, for testing a drug on a lion or a horse might not prove anything about its effect on man.

One of the most famous clinical trials was James Lind's demonstration in 1747 that citrus fruits cure scurvy (Lind, 2001). He compared the effects of various different acidic substances, ranging from vinegar to cider, on groups of afflicted sailors, and found that the group who were given oranges and lemons had largely recovered from scurvy after 6 days.

Frederick Akbar Mahomed (1884), who worked at Guy's Hospital in London (O'Rourke, 2002), made substantial contributions to the process of clinical trials during his detailed clinical studies, where "he separated chronic nephritis with secondary hypertension from what we now term essential hypertension". He also founded "the Collective Investigation Record for the British Medical Association; this organization collected data from physicians practicing outside the hospital setting and was the precursor of modern collaborative clinical trials and t123" (O'Rourke, 2002).

It is also noticeable that the need for quality therefore proves to be the decisive factor in determining the success or failure of many products and services, including findings of medical research. Currently, most governmental regulatory bodies ranging from Food and Drug Administration, to factory inspection, aim at assuring the quality of products produced for consumers. Perhaps this is the reason why the Uganda government established the Uganda National Bureau of Standards (UNBS) in 1983, Uganda National

Council of Science and Technology (UNCST) in 1990 and National Drug Authority (NDA) in 1993. In view of the above background, it is very important to take note of the foundations on which the concept of QC is based. This historical foundation forms our next discussion.

1.2.2 Theoretical Background

The study focused on Juran's quality trilogy theory. According to Juran (1975), Good quality management requires quality actions to be planned out, improved and controlled. The process achieves control at one level of quality performance, and then plans are made to improve the performance on a project by project basis, using tools and techniques such as Pareto analysis. This activity eventually achieves breakthrough to an improved level, which is again controlled, to prevent any deterioration. Likewise, MUJHU implements a similar approach, whereby quality is planned with a systematic process specifying necessary operational processes and related resources to fulfill quality objectives. MUHJU has developed a Clinical Quality Management Plan (CQMP) with methods and QC procedures that help her to optimize resources, maximize error detection, and minimize repetition guaranteeing the necessary quality needed. The stated theory is therefore completely in line with what MUJHU is practicing, but to understand the issues in this study more, there is need to discuss the concepts that make it meaningful. This forms the next part of the discussion.

1.2.3 Conceptual Background

Green (1994), states that quality control is 'testing the product or service to see whether it meets the standards [i.e. precise specification] set and rejecting those that do not conform, while Terry Melia (1994), is rather more general when stating that 'quality

control embraces the methods used to maintain and enhance quality. For this study however, Quality Control is operationalized as internal standards, processes and procedures established to control and monitor quality (refered to here as accuracy and reliability) of clinical trial data. Similarly, MUJHU defines QC as the conduct of ongoing, day to day activities of checking completed forms i.e. Case Report Forms (CRFs) for logical completion. This is to ensure that quality of clinical data are accurate and of integrity. Hence, it is necessary that during the management of clinical trial data, to thoroughly review, assess the validity of outlying data points, and to carefully document query identification as well as resolution throughout a clinical trial's duration.

To agree with above descriptions, Valania (2006) says that in a clinical setting where MUJHU is categorized as one, QC refers to periodic operational checks within each functional department to verify that clinical data are generated, collected, handled, analyzed and reported according to protocol, Standard Operating Procedures (SOPs) and Good Clinical Practices (GCPs). These are process of quality evaluation that focuses on the internal measurement of the quality of clinical trial data. Here a set of operational activities and techniques including monitoring activities, structured internally planned and implemented policy are elaborated and applied to fulfill requirements of quality. Hence various actions and measures are taken regularly to ensure quality is met. It aims both at monitoring the process and at eliminating certain causes generating an unsatisfactory functioning. In effect, QC is a precondition for Clinical trial data management; hence, it's critical to explore the context in which the above concepts are being discussed of which the contextual background forms our next discussion.

1.2.4 Contextual Background

It is prominent that the quality of clinical research is dependent on the compliance with the requirements in relation to protocol, which *contains a study plan on which the clinical trial is based*, SOPs *with detailed, written instructions to achieve uniformity* and GCP *a quality standard for designing, conducting, recording and reporting trials that involve human participants* resulting into credibility and reliability of the data obtained. For this reason, as MUJHU conducts clinical trials, its QC ensures that there is an on going day-to-day activity of checking completed CRFs *(an official clinical data recording document tool or tool used in clinical study*) for logic and completion. The QC measures are continuous and apply to 100% of all source documents *(proves the existence of the subject and substantiates integrity of trial data collected)* and CRFs with an expected minimum accuracy rate of 99.95%. However, with all the QC measures in place, expectations and requirements can change and if not effectively communicated may affect quality of the collected data. This may result into variation with data generated from what is specified in the protocol. Secondly, it may lead to contradiction of data in the CRF and data collected in source documents and lastly, discrepancy of data analyzed and data recorded in the CRF may arise. This effect is more compounded by an inadequate operational QC where a QC plan for each key operational stage of the trial that defines standards against which QC will be conducted is insufficient. Hence, the need to continually monitor data collection procedures and data management practices at every level of the trial. This however is a complex process that evolves over time and it requires that clinical data management teams work closely to guarantee quality.

There was a time at MUJHU when a therapy that was developed was queried. This therefore, raised questions on the management of clinical trial data in this institution. It is on the basis that this study sought to assess the contribution of QC on the management of clinical trial data of MUJHU Care Ltd.

1.3 Statement of the Problem

The management of clinical data, from its collection to its extraction for analysis, has become a critical element in the steps to prepare a regulatory submission and to obtain approval to market a treatment (Sidharthan, 2009). The quality of a clinical trial determines the acceptability of the results and care must be taken to ensure that high standards of quality are present both in the clinical trial design and in the integrity and interpretation of data (Curtis & Meinert, 2006). To this end, all participants in the clinical trial have a role to play in safeguarding data integrity. Data validation activities start at the investigator site and end with a statement in clinical or expert reports to indicate that the clinical trial was conducted in accordance with GCP and that the report provides a complete and accurate account of the data collected during the trial (Green, Benedetti & Crowley, 2003). Procedures should be established for managing the trial data, and steps taken to ensure that the quality of data is high throughout a trial.

In Uganda, management of clinical data should adhere to the above stated. Uganda has been hailed as a centre for HIV and AIDS clinical research trials in Africa in the last two decades. The clinical trials however face data management challenges, leading to questioning of the quality of the data that is generated from such clinical trials. In MUJHU, various interventions including study requirements have been carefully set forth initially in detailed documents such as an approved clinical protocol, a quality

management plan, and an accompanying project plan by different stakeholders for quality control. Expectations and requirements can change during a clinical trial and if not effectively communicated quality can be severely diminished. The ongoing challenge therefore for MUJHU in managing the quality of clinical data is to continually monitor data collection procedures and data management practices at every level of the clinical trial for compliance. Consequently, failure to plan and implement an effective QC program may not only adversely affect the scientific impact of the trial itself, but can also affect public confidence in the reliability and effectiveness of clinical trials within medical research. Therefore, QC of data in clinical trials is critical, given that potential bias could change not only the results of a trial but also the future direction of development of therapies

1.4 General Objective of the Study

The purpose of this study was to assess the contribution of QC in the management of clinical trial data at Makerere University Johns Hopkins University (MUJHU) Health Care Limited.

1.5 Specific Objectives

The study was guided by the following specific objectives: -

1. To examine the effect of compliance with clinical trial requirements on the management of clinical trial data in MUJHU Health Care Limited.
2. To analyze the effect of an operational quality management plan on the management of clinical trial data in MUJHU Health Care Limited.
3. To establish the effect of quality control measures on the management of clinical trial data in MUJHU Health Care Limited.

1.6 Hypotheses

The study tested the following hypotheses;

1. Compliance with clinical trial requirements has a significant positive effect on the management of clinical trial data in MUJHU Health Care Limited
2. Quality management plan has a significant positive effect on the management of clinical trial data in MUJHU Health Care Limited
3. Quality control measures have a significant positive effect on the management of clinical trial data in MUJHU Health Care Limited

1.7 Scope of the study

The study was conducted in MUJHU Health Care Limited located on Mulago Hill road, in Mulago Hospital, in Kawempe Division, Kampala District. The major focus of the study was to assess the contribution of QC in the management of clinical trial data with particular concern on internal standards, processes and procedures established to control and monitor quality. The study limited itself to information in the period between 2006 and 2011 when quality management was seriously taken on as an integral plan in clinical data management at MUJHU Health Care Limited.

1.8 Significance of the study

The study may benefit the following stakeholders. The MUJHU management may benefit from the findings of the study in that they may use them to improve quality control in the management of clinical trial data. Findings of the study may be useful to the academicians and scholars who may use them to enrich their knowledge about quality control in the management of clinical trial data and even quote the findings in their

academic work as their literature. Other similar institutions like MUJHU may also use the findings of this study to improve their quality control in the management of clinical trial data.

1.9 Justification of the Study

Due to the future of development of therapies particularly in MUJHU, there is critical importance of ensuring adequacy of quality sustained clinical research. This study therefore was expected to highlight the existing QC measures that are appropriate to MUJHU Care Limited clinical research endeavors for purposes of improving it and hence boost public confidence in the outcomes of clinical research trials in Uganda.

1.10 Limitations of the Study

The study met limited cooperation from some respondents in terms of giving information. However, extensive explanations and support from top management helped to mitigate this problem.

1.12 Operational definitions

Compliance with clinical trial requirements: Adhere to set standards in clinical trials

Quality management plan: A quality management plan is a document that is used to specify the procedures and resources that will be needed to carry out a project, perform a process, realize a product, or manage a contract. Quality plans also specify who will do what and when.

Quality control measures: Are a set of activities intended to ensure that quality requirements are actually being met.

Management of clinical trial data: Clinical data management" is a profession with increasing importance in product research and development process and is considered as an integral part of clinical trials. It is now firmly established discipline in its own right, and is becoming an area that researchers know about and can progress their careers within.

Quality control: a process employed to ensure a certain level of required set standard in a product or service

Clinical trials: Are a set of procedures in medical research and drug development that are conducted to allow safety (or more specifically, information about adverse drug reactions and adverse effects of other treatments) and efficacy data to be collected for health interventions (e.g., drugs, diagnostics, devices, therapy protocols).

Quality: Quality is the degree to which a set of inherent characteristics fulfils requirements. Furthermore, it refers to accuracy and reliability of something. In clinical data management, quality is the critical element with an expected minimum accuracy rate of 99.95% and is assessed at all stages from double data entry till study lock.

Clinical data: This is data generated during a clinical investigation or data obtained from a review of the literature, which may include clinical experience.

Quality management: includes all the activities that organizations use to direct, control, and coordinate quality. These activities include formulating a quality policy and setting quality objectives. They also include quality planning, quality control, quality assurance, and quality improvement.

1.13 Conclusion

This chapter focused on the concepts used in the study, the problem that aroused interest in the study, what the study sought to achieve, the importance of the study and

key definition of terms. It emphasized the importance of management of clinical trial data the ideal in its management and its shortcoming at MUJHU. The second chapter presents the literature review.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Establishing quality levels for goods or services and ensuring that those levels are achieved are vital tasks for virtually every type of business organization and government agency because having quality or lack of it can have far-reaching consequences. According to Richardson and Chen (2001), quality affects an organization through various ways, namely; the reputation and image. Failure to devote adequate attention to quality can damage an organization's image. Conversely, improving and maintaining good quality can have a positive effect on productivity. It is therefore important for management to recognize the different ways in which quality of a firm's product or services can affect the organization and to take this into account in developing and maintaining a quality control program. Stevenson (1986)

In the medical field, malpractice claims are skyrocketing and this is the more reason as to why quality control issues should be put in place. Valania, 2006 states that, Quality Control is a precondition for clinical trial data management- a process that ensures the integrity and quality of data. This guarantees the objectives of such clinical trials. The need for quality has therefore proves to be the decisive factor in determining the success or failure of many products and services. Hence Quality Control is applied at various stages in the Clinical Data Management process and is normally mandated by Standard Operating Procedures (SOP).

While each of the above factors is an important determinant of quality, it is important to recognize that management has the ultimate responsibility for quality. Management

initially establishes the desired level of quality being sought provides the necessary funding, is responsible for creating a supportive environment and for conveying to employees the importance of quality and seeing that employees reflect this in their work (Vijayananthan & Nawawi, 2007).

2.2 Theoretical Review

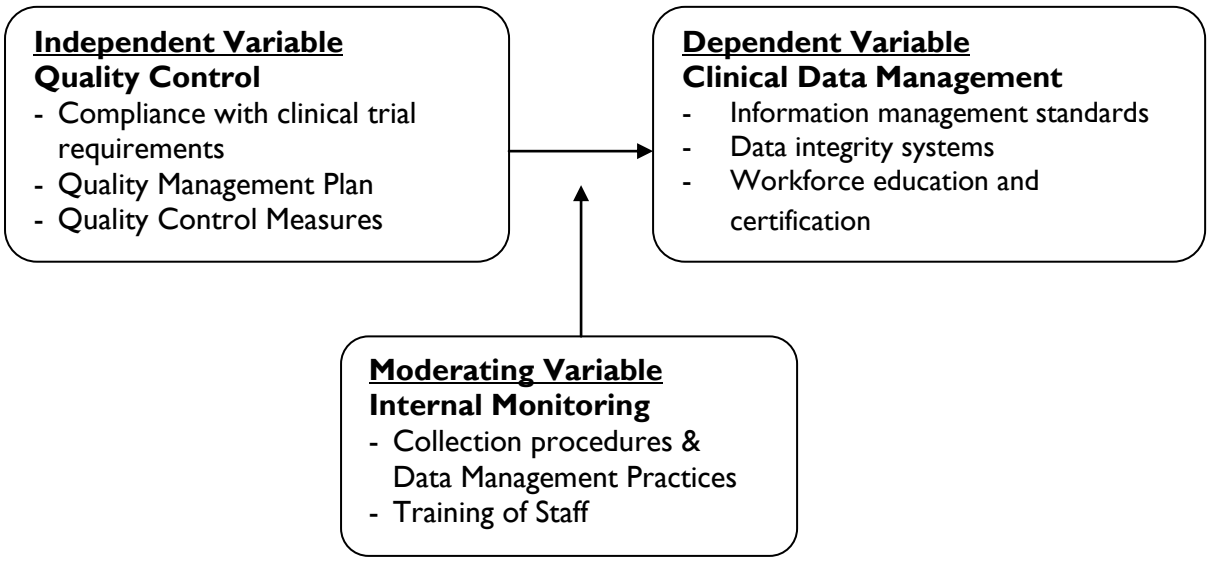
This study adopted the theory by Juran (1904-2008) one of the many management "gurus" whose philosophies and ideas are important to quality management (Department of Trade and Industry, 2002). Juran (1904-2008) developed the '*quality trilogy*', namely; quality planning, quality control and quality improvement. He well articulated that good quality management requires quality actions to be planned out, improved and controlled. Juran's quality trilogy theory the "Juran's trilogy" is an approach to cross-functional management that is composed of three managerial processes: quality planning, quality control and quality improvement. According to Juran (1975), Juran believed quality is associated with customer satisfaction and dissatisfaction with the product, and emphasized the necessity for ongoing quality improvement through a succession of small improvement projects carried out throughout the organization. He concentrated not just on the end customer, but on other external and internal customers. Each person along the chain, from product designer to final user, is a supplier and a customer. In addition, the person will be a process, carrying out some transformation or activity. Hence, quality is planned with a systematic process specifying necessary operational processes and related resources to fulfill quality objectives. Quality Planning involves selecting methods and implementing QC procedures in order to do a better job thus helping to optimize resources, maximize error detection, and minimize repetition guaranteeing the necessary quality needed. This process eliminates

operator method error or transcription issues. Therefore, the QC process must be ongoing to ensure that remedial efforts, if required, have produced satisfactory results and to immediately detect recurrences or new instances of trouble.

2.3 Conceptual Framework

This conceptual structure gives explanation on how quality control and clinical data management affect quality of data and reliability of results. The model further explains how other than the independent variables, there are some moderating variables that are likely to affect the relationship between the independent and dependent variables through monitoring systems and point person staffs.

Figure 1: Conceptual framework of quality control on clinical data management



Source: MU-JHU 2009, *Adopted with modifications from the MUJHU Clinical Quality Management Plan*

2.4 Explanation of the Conceptual Framework

Prior to the conduct of a clinical trial, it's eminent that, the quality of clinical research is dependent on the compliance with the Protocol which describes the objective(s), design, methodology, statistical considerations, and organization of a trial, secondly, with the

SOPs which help to maintain the consistency of data quality throughout the duration of the trial and lastly, GCP guidelines which are an international ethical and scientific quality standard for conducting clinical trials. All these ensure credibility and reliability of the data obtained. Therefore, there is need to develop and implement systems that ensure quality at every step of the data management process in order to provide reliable an accurate results. Hence, a Quality Management Plan is laid with QC measures that facilitate periodic operational checks at every stage of a clinical trial to verify that clinical data are generated, collected, handled, analyzed and reported according to protocol, SOPs and GCPs. This helps to maintain the consistency of data quality across the trials.

The above is a complex process which evolves over time and it requires that Clinical Data Management teams work closely to ensure that the data obtained is in line with the expectation of the trial. To this effect, the QC data team (mainly clinical reviewers and data entry clerks) is remunerated and trained to effectively under take quality management activities of identifying errors during patient data capture and manage administration tasks more efficiently to ensure correction of these errors. In addition to the above, Monitoring (periodic internal audits) is done by technical staff basically to oversee the progress of a clinical trial and ensure that it is conducted, recorded, and reported in accordance with the protocol, SOPs and GCP. Managing the quality of clinical data requires to continually monitor data collection procedures and data management practices at every level of the clinical trial to ensure that data generated during the trial reflect what is specified in the protocol, accuracy of data in the CRF and data collected in source documents as well as ensure that the data analyzed are the data recorded in the CRF. These efforts ensure that the data used during analysis meet a reasonable quality level.

All in all, with better planning, appropriate systems when incorporated, can help make clinical trials easier to successfully plan, document patient data and handle clinical data management errands more proficiently. Managing the clinical process is one of the significant areas that will contribute to quality of the end product.

2.5 Related Literature

Regardless of size, type, or complexity, accurate results for any clinical trial are ultimately determined by the quality of the collected data (Eleanor, 2007). To this effect, managing the clinical process is one of the significant areas that will contribute to quality of the end product. Quality Control therefore assures the quality of data and avoids systematic biases as well as random errors that could lead to erroneous or uninterruptible results (Williams & Wilkins, 1988).

2.5.1 Quality control and clinical data management

Quality control is critical to the effective conduct of a clinical trial. Other than standard quality control techniques, there are developed novel methods to enhance the entire process. Central to the methods is the use of clinical monitors who are trained in the technique of data monitoring. Clinical monitors are assigned to each local site (Richard & Chen, 2001). This is true and important since monitors serve both clinical and data management functions. They provide information and guidance on the management of study patients, in accordance with study protocol. They also review source materials that document patient eligibility and review study notebooks for each patient in order to ensure that the protocol is being followed properly. In addition, monitoring often prevents errors occurring that may not be detected by the usual computer based logical

checking system. Hence, monitors add an additional level of quality control and increased efficiency through earlier error detection. However, this feature does not replace computer-based data checking, hence the importance of employing multiple methods for maintaining quality control (Richard & Chen, 2001). Therefore, one can observe that throughout the process of clinical trials data management is crucial for the integrity of any given research.

2.5.2 Compliance with clinical trial requirements and clinical data management

Every research study requires sound design, careful planning and proper analysis. An obvious component is the protocol*, which* describes the objective(s), design, methodology, statistical considerations, and organization of a trial. It is however important that these protocols are accompanied with Standard Operating Procedures (SOPs) which are essential documents to maintain the consistency of data quality across trials, sites, time, and clinical data management personnel. These ensure standardization, uniformity of procedures, high data quality, and collaboration across sites. Notably, is Good Clinical Practice (GCP) a key and an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with GCP provides public assurance that the rights and safety of study participants have been protected and that the clinical study data are credible. It is therefore imperative that a better understanding of these regulatory guidance leads to adherence with the clinical requirements and to high quality in the implementation (Shrikant, 2005). In MUJHU, this assurance is commonly provided by developing adequate systems for staff training and quality assurance of all study aspects, especially for collecting, reviewing, entering, managing and analyzing data.

2.5.3 Quality management plan and clinical data management

Quality management is concerned with getting things right. It may be critically important to drive out all possibility of errors or it may be acceptable to take delivery of a product or service that is good enough. However for the design of a new business service, there may be a number of prototypes that gradually improve as understanding of the customer requirement increases; this is about achieving quality that is fit for the purpose where it is recognized that perfection cannot be achieved in one step.

The term Operational Quality Management (OQM) is defined as a continual cyclic process, which includes quality assessment, quality decision-making, and implementation of quality controls, which results in acceptance, mitigation, or avoidance of errors (Samsona & Terziovskib, 2009). OQM is the oversight of operational quality, including the management risk of loss resulting from inadequate or failed internal processes and systems; human factors; or external events.

There are three level of an operational quality management plan and these are in Depth, deliberate and time critical (Samsona & Terziovskib, 2009). In depth quality management is used before a clinical trial is conducted, when there is plenty of time to plan and prepare. Examples of in depth methods include training, drafting instructions and requirements, and acquiring personal protective equipment. Deliberate quality management is used at routine periods through the clinical trial process. Examples include quality assurance, on-the-job training, safety briefs, performance reviews, and safety checks. Time critical quality management is used during operational clinical trial exercises or execution of clinical tasks. It is defined as the effective use of all available resources by individuals, crews, and teams to safely and effectively accomplish the

mission or task using risk management concepts when time and resources are limited. Examples of tools used includes execution check-lists and change management.

The International Organization for Standardization defines the risk management process in a four-step model: 1) Establish context, 2) Risk assessment, which involves risk identification, risk analysis and risk evaluation, 3) risk treatment and 4) monitor and review. This process is cyclic as any changes to the situation (such as operating environment or needs of the unit) requires re-evaluation per step one. The International Organization for Standardization summarizes the deliberate level of operational quality management process in a five-step model: 1) Identify hazards, 2) Assess hazards, 3) Make risk decisions, 4) Implement controls and 5) Supervise (and watch for changes).

Deming (2005) recognized that all processes are vulnerable to loss of quality through variation; therefore management needs to be aware of, and manage possible levels of variation in order that they might be decreased and quality raised. He recommended a simple yet practical approach known as the management cycle of planning, implementation, check and action. On the other hand, Friedman et al (2006) argues that during all phases of a study, sufficient effort is spent to ensure that all key data critical to the interpretation of the trial are of high quality and amongst so many strategies is the QMP. Valania, (2006; 23) describes a QMP as something that definitively defines the various quality-related tasks in the study or a quality plan that documents specific quality practices, resources, and activities relevant to a specific project, including operational QC. The National Institute of Allergy and Infectious Diseases (Mar 2003) define a clinical quality management plan as a written document that encompasses both quality assurance

and quality control procedures and details the responsibility, scope, and frequency of these activities. A CQMP is designed to assess the site performance of clinical research.

To agree with above, it is notable that, clinical trials are managed to addresses the key aspects of clinical research conducted at the research site to assess the quality of the operational procedures and recording of the research data. These procedures are subject to approval by the Division of AIDS (DAIDS) and apply to main unit performance sites and affiliated performance sites where research subjects are seen. With the above arrangement in place, Shrikant (2005) notes that every research study requires a sound design, careful planning, good management and proper analysis, which leads to adherence with the protocol and to high quality in its implementation.

It would however be plausible that a component of training in the specifics of the study protocol be embedded in any research of this nature. A well-conducted multi-centre study needs to assure standardization, uniformity of procedures, high quality and collaboration across sites. In addition to this, for any collaborative activity and especially in multi-centre studies, it is necessary that the activities be shared among the trial personnel, where they feel scientifically responsible and accountable for the integrity of the trial. To strengthen the activity, research organizations should not only be involved in training sessions, but also in conducting continuing education short courses.

Even with the above, however, Shrikant (2005) warns that implementing of such training may be a costly investment, but costs can be minimized if training is conducted alongside scheduled study team meetings. He emphasizes that this assurance is commonly provided by developing adequate systems for the staff training and quality control of all

trial aspects, especially for collecting, entering, managing and analyzing the data. Training, as part of the QMP, instills commitment and ownership to the Quality Management system, which, if well or poorly managed, impacts squarely on the perception the implementers will have on the system as a whole. Hence, failure to plan and operationalize a quality management plan may not only adversely affect the scientific impact of the trial itself, but can also affect public confidence in the reliability and effectiveness of clinical trials within medical research (DeJuran & Shande, 2001).

2.5.4 Quality control measures and clinical data management

Martin (2006) argues that many institutions in the business of conducting clinical research recognize the benefits of carefully managing the quality of data. To ensure clinical data accuracy and integrity, it is necessary to have QC measures for thorough review of data, assessment of validity of outlying data points, and to carefully document query identification and resolution throughout a study's duration. Such measures used include, but may not be limited to, Protocol Development, Standard Operating Procedures (SOP), Staff Training, Good Clinical Practice (GCP), Monitoring, and Data Management (Shrikant, 2005).

To this effect therefore, QC system will depend on a number of factors and the interface they have with the quality control process. The implication of this is multifaceted, in that it could be mild or extreme, negative or positive, continuous or intermittent. Either way, it is vital to note that data quality is a central requirement of scientific research and quality is an obligation of clinical research (Favalli et al, 2000). This ensures that adverse effects are avoided to ensure high quality research, particularly in collaborative and international studies (Pandav, 2002). However, Fong and Daniel,

(2001), state that there are bad and good clinical data management practices, which could lead to differentiated effects on clinical data trials in Research Institutions. On this issue, Fong and Daniel (2001); argue that Poor data quality during data collection generally comes from management and trial design. Limited resources, lack of training, competition, and insufficient company standards are some of the most common managerial constraints on data quality. On the other hand, poor data structure and unnecessary trial complexity are also common sources of poor data quality. The most irresponsible source of error, however, is the assumption that the data are automatically error-free. Poor data quality of an "analysis-ready" database resulting from bad clinical data management will certainly have an adverse impact on the final trial conclusions. The trial statistician would be frustrated with missing values, excessive outliers, and values that are not legitimate. Moreover, investigators may be misled by the distorted results into drawing conclusions and thus, the time and resources invested by the sponsor are wasted. Most seriously, it is likely that the public and patients are put in jeopardy, and suboptimal treatments are being administered.

In view of the above arguments, it is important to note and mitigate the adverse effects that poor data or poor QC measures, (including data management), can have on the final outcomes from clinical studies. It is therefore imperative that good clinical data management practices, be adopted because they will lead to desirable effects of the QC in clinical research. Fong and Daniel (2001) allude that the requirements of good clinical data management practice have been inherently stated in the ICH guidelines, which indicates that quality control should be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly. This, inter alia, is a critical factor for any successful implementation of a QC measures.

2.6 Summary of literature review

In conclusion, the literature search well articulates the researcher quest for the contribution of quality control in the management of clinical trial data. Many authors have emphasized thus that the quality of a clinical trial determines the acceptability of the results and care must be taken to ensure that high standards of quality are present both in the clinical trial design and in the integrity and interpretation of data. It has also marked out that, all participants in the clinical trial have a role to play in safeguarding data integrity. Also important to note is that data validation activities start at the investigator site and end with a statement in clinical or expert reports to indicate that the clinical trial was conducted in accordance with GCP and that the report provides a complete and accurate account of the data collected during the trial. Procedures should be established for managing the trial data, and steps taken to ensure that the quality of data is high throughout a trial. Involvement of clinical data management team into initial planning of the study is very essential and will lead to improvement of data quality.

Therefore, managing the quality of clinical data does not only ensure management of compliance with the protocol, SOPs, and GCPs but also enables systemic problems to be resolved before the end of the study. Notably, it also helps reduce data queries; ensures data integrity throughout the study's course and that the data collected are the data required by the protocol. Lastly, it ensures the accuracy and consistency of data from entry into the CRF to final datasets reported in the final Clinical Statistical Report (CSR) as well as plays a critical role in dealing with instances of nonconformity while carrying out clinical trials.

The literature shows that quality control has been a widely applied process for improving the management of clinical trial data around the world, but with mixed success. The literature revealed gaps in research in this area of quality control in relation to compliance with clinical trial requirements, operational quality management plan and quality control measures, particularly in the area of empirical testing of their effect on the management of clinical trial data. The aim of this study was to assess the effect of compliance with clinical trial requirements, operational quality management plan and quality control measures on the management of clinical trial data.

CHAPTER THREE

METHODOLOGY

3.1 Introduction

This chapter presents the research techniques that were used to obtain relevant and required data and information for the study. It discusses the research design, area of study and population. It further gives information about the sample size and selection, sampling techniques and procedure, methods used in data collection, the data collection tools, research procedure, how the quality of research was ensured, the ethical code, research limitations, as well as the ways in which data was analyzed and presented.

3.2 Research Design

This study used a cross sectional case study design and employed both qualitative and quantitative approaches to address the different aspects of the research problem. The case study was used because it focused on one unit of the study - MUJHU, which enabled to solicit in-depth information about quality controls in the management of clinical trial data. This study was cross sectional because according to Sekaran (2003), with a cross sectional study, a large group of respondents can be targeted to obtain information about issues under investigation without making a follow up of the respondents once information from them is obtained. Therefore, the cross sectional survey helped to save on time and resources during data collection. The quantitative approach allowed the researcher to solicit information that was expressed numerically while the qualitative approach allowed the researcher to solicit narrative and descriptive information that can be expressed in textual format (Mugenda & Mugenda, 1999). Combining numerical and textual information helped the researcher enrich the interpretation of findings of the study.

3.3 Study area and population

This research study was carried out at MUJHU Health Care Limited located on Mulago Hill road, within Mulago Hospital, in Kawempe Division, Kampala District. The study population consisted of the 109 MU-JHU employees (MU-JHU staff List, 2006) who were drawn from various divisions and sections referred to as the target population (Table 1). These included 8 Regulatory Officers, 46 Nurses, 28 Doctors, 13 Laboratory Officers, 11 Data Centre Officers and 3 Principal Investigators.

3.4 Sample size and Sampling Techniques

Krejcie and Morgan (1970) sample size table was used to determine the actual sample size for all the categories of respondents. Table 1 presents the divisions/stations with their total existing staff, the target sample, actual sample and sampling technique.

Table 1: The study Population and selection of the Sample size

Division/Section	Existing Staff Number (ESN)	Target sample (N) 50% of ESN	Actual sample size (S)	Sampling technique
Regulatory ➢ QC	8	4	3	Random and purposive
Nurses ➢ MUJHU Clinic ➢ Hospital	46	23	22	Random and purposive
Doctors ➢ MUJHU Clinic ➢ Pharmacy	28	24	23	Random and purposive
Laboratory	13	6	5	Random and purposive
Data Centre ➢ Technical ➢ Data management	11	5	4	Random and purposive
Principal Investigators	3	1	1	Random and purposive
TOTAL	**109**	**63**	**58**	

Both purposive and random samplings were used. Purposive sampling was used to select departments involved in quality control and management of clinical trial data activities. Simple random sampling was used to select the respondents in the departments. This gave each respondent an equal opportunity to participate in the study.

3.5 Data Collection Methods

The study employed both the quantitative and qualitative data collection methods. The main method was however quantitative, involving using a semi-structured questionnaire and the key informant interviews (for key staff and project leaders); which was purely qualitative. The sustainability of the predominant data collection method lay in allowing participants to freely provide their responses to varied questions the researcher sought to investigate.

3.5.1 Questionnaires

A semi-structured questionnaire was developed, pre-tested and administered to the personnel working at MU-JHU, most specifically those involved in data collection and management. The questionnaires were used in this study to solicit from the large number of respondents. Thus, this helped the researcher to save on time used for collecting data. The questionnaires had close-ended questions to cater for quantitative data and open-ended questions to cater for some qualitative views and opinions about quality assurance and clinical trials data.

3.5.2 Structured face-to-face interviews

Structured face-to-face interviews were further held with selected MU-JHU staff especially project leaders considered as key informants. Structured face-to-face

interviews were used to collect data from these respondents. Structured face-to-face interviews were used in this study to enable the researcher to establish rapport with these categories of respondents and therefore gain their cooperation (Amin, 2005). They also used to allow the researcher to clarify ambiguous answers and obtain in-depth information through probing. Using structured interviews ensured that the respondents were asked exactly the same set of questions in the same sequence. These interviews allowed gathering of detailed information related to quality control at MU-JHU.

3.5.3 Documentary review

The researcher reviewed both primary and secondary documents, reports and other information relevant to the study subject, to obtain background information relevant to the research, obtain information to enable the researcher make decisions on selection of the study area, population, and to back-up the findings of the research. Also included in the review were internet sources.

3.6 Data Collection Tools

Two major data collection tools were used. The questionnaires; for the staff and key informant interview guides, for key informants.

3.6.1 Self-Administered Questionnaire

The self-administered questionnaire, which is a pre-formulated written set of questions for respondents to record their answers by choosing from closely defined alternatives (Sekaran, 2003) was used to gather data. The self-administered questionnaire was the main data collection tool. Amin (2005) and Sekaran (2003) contend that self-administered questionnaires are efficient and convenient in collecting quantitative data.

In addition, Mugenda and Mugenda (1999) observe that using self-administered questionnaires minimizes bias; they are less costly and can have a wider circulation in a short time. In this study, a self-administered questionnaire was administered on 52 respondents (90%). The use of a self-administered questionnaire was considered because it is convenient for collection of adequate quantitative and the respondents were learned and thus able to interpret the questions on their own.

3.6.2 Interview Guide

Further to the self-administered questionnaire, an interview guide was administered on key informants, that is, 10% (6) key respondents, who were basically drawn from the key staff of the Senior Management Team. These were particularly targeted for interviews so that they could provide critical information regarding the study objectives. Interview guides were used to collect qualitative data. Data obtained during the interviews supplemented that obtained through the questionnaire.

3.6.3 Documentary Review Checklist

A number of documents were reviewed to capture written records and boost the researcher's theoretical and conceptual knowledge of the subject under study. The documentary review included review of seminal works and or publications on the subject, reports, plans, manuals, policies, and lists among others. The approach was also important for verification and authentication of data collected using other instruments.

3.7 Data Collection and Quality Control

3.7.1 Validity

Since validity was a very important psychometric property of measurement, there was need to establish it before the instruments were used by doing the following. The questions in the questionnaire were subjected to face validity by the supervisor; their appropriateness and generalization to the topic was validated by use of two raters who were experts in the field of study under research. The content validity index of the questionnaire items was then computed using the formula:

$$\text{CVI} = \frac{\text{Number of items rated as relevant}}{\text{Total number of items in the questionnaire}}$$

Summary of ratings are presented in the following table.

Table 2: Sample and sampling technique

Raters	Relevant items	Not relevant items	Total
Rater 1	33	10	43
Rater 2	30	13	43
Total	**63**	**23**	**86**

$$CVI = \frac{63}{86} \approx 0.73$$

Since CVI was 0.73, which was above 0.7, the questionnaire was considered valid. According to Gay (2000), 0.7 is the least recommended coefficient of validity in survey studies. In order to ensure validity, the supervisor had to judge their suitability, aptness, appropriateness and scrutinized the objectives of the study. Adjustments were made to improve on clarity and comprehensiveness aimed at covering the relevant information.

3.7.2 Reliability

The self-administered questionnaire was pilot-tested on 10% of the respondents from Makerere University Water Reed Project (MUWRP) to establish their reliability. A computer Programme known as the Statistical Package for Social Scientists (SPSS) was used to compute the reliability of the questionnaire. The following formula was used

$$\text{Reliability} = \frac{K}{K-1}\left[1 - \frac{\sum Sdi^2}{SDt^2}\right]$$

Where; $\sum Sdi^2$ = Sum of variance of individual items in the questionnaire

SDt^2 = Variance of the entire questionnaire

K = Number of items in the questionnaire

According to Gay (2000), since the reliability was 0.718 above 0.7, the questionnaire was regarded reliable for use during the study because Gay (2000) recommended for a reliability coefficient of at least 0.7 in survey studies.

3.7.3 Quality control

The following measures were taken:

Pre-testing of Research Instruments: The draft research instruments were pre-tested to ensure that the questions included would elicit the information needed. The pretest also checked for clarity and proper sequencing of the questions. The instruments were cross-checked and edited for completeness. For objectivity, quantitative methodology in data collection was applied to enable the researcher obtain objective and representative data to back up the views and opinions provided, through the qualitative data collection methods. In addition, a validity check was done. The selection criteria of the study area

and respondents, helped in ensuring validity of the research findings. Whereas the study respondents selected had characteristics which were to a degree representative of the characteristics of the various clinical trial settings in Uganda and elsewhere. The results can therefore apply to the clinical trial settings. Lastly, was Reliability where the researcher employed different data collection methods, to cross-check the consistency of findings generated and ultimately the reliability of data collected. Various data collection methods as outlined above were used to generate a wide range of views as well as consistency of information from the different data sources.

3.7.4 Research procedure

The researcher did discuss the content of the research instruments with the both supervisors so that the instruments could capture the required information. Thereafter a letter of introduction was obtained from Uganda Management Institute by the researcher and handed in to the Principal Investigator (Head) of MU-JHU, seeking permission to conduct the study at the organization. The researcher introduced herself and the purpose of the study to the senior managers at MUJHU to obtain permission to undertake the research. The researcher also identified and trained one research assistant who later assisted in delivering, administering the questionnaire where necessary and collecting them from the respondents after completion. Self-administered questionnaires were distributed to the respondents by the researcher and research assistant after getting consent from them to freely participate in the study. Then, they were instructed to fill in the questionnaire during a specific period after which they were collected by the researcher. For key informants appointments were made with the different respondents at MUJHU, for interviews at hours and dates of their convenience.

Most interviews were carried out in offices at the times, which the respondents had agreed to with the researcher.

3.8 Data Analysis

After data collection, both quantitative and qualitative data analysis procedures were applied. The following section presents what was involved in the two approaches of data analysis.

3.8.1 Quantitative data analysis

The data collection instruments were checked for completeness, accuracy and uniformity. Specifically, the researcher undertook the following steps. The first step was the coding the self-administered questionnaire. This involved assigning codes to all questions under each variable. In addition, numerical numbers were assigned to the responses to each of the questions. Creating a variable view entry following the coding on the self-administered questionnaire using a computer programme known as the Statistical Package for Social Sciences (SPSS) was the second step. Thereafter, raw data from the self-administered questionnaire was entered into the SPSS data view entry. The next step was data cleaning, which involved checking were data was correctly entered in the SPSS programme. Data analysis then followed.

Descriptive and inferential statistics were used to analyze the quantitative data captured in the SPSS programme. Descriptive statistics involved statistical methods such as frequencies and percentages, which were presented in tabular form. Frequencies and percentages were used to determine the proportion of respondents against responses to the questions about the study variables. This helped to make interpretation on how

respondents thought about the compliance with clinical trial requirements, operational quality management plan, quality control measures and management of clinical trial data at MUJHU.

In addition, inferential statistics, which included Spearman correlation and coefficient of determination, were used to determine the effect of the independent variables (that is, compliance with clinical trial requirements, operational quality management plan, quality control measures) on the dependent variable (management of clinical trial data) as stated in the objectives of this study. Spearman was used because the scale that accompanied the questionnaire was ordinal. The correlation coefficient (*rho*) was used to determine the strength of the relationship between the variables. The sign of the correlation coefficient (+ or -) was used to determine the direction of the relationship between the variables. The coefficient of determination, which was a square of the correlation coefficient was to determine the effect of the independent variables on the dependent variables. The significance of the correlation coefficient (p) was used to determine the confidence in the findings.

3.8.2 Qualitative data analysis

The researcher familiarized herself with the data collected by cross-checking and reading through all information from key informant interviews and then edited the data. The researcher thereafter identified and named the themes emerging from the raw data, grouping together words, phrases, statements appearing to be similar. This was aimed at creating categories, which were used as quotations to supplement the quantitative data in order to enhance interpretation of the results.

3.9 Ethical Conduct

The researcher employed various measures to ensure that the study adhered to the research ethical standards in the following ways. A consent to participate in the research was sought from the respondents, and they were free either to or not to participate in the research. This was made clear in the background of all the research instruments and in introductory remarks before each data collection session. To this effect confidentiality of information obtained was ensured, and only quotations of specific individuals were made with their approval. All research respondents were acknowledged for their valuable contribution to the research and in particular for providing data that formed the basis for the research and the researcher further acknowledged all works consulted, through the bibliographical reference.

3.10 Conclusion

This chapter presented the methods the study employed to achieve the objectives of the study and thus answer the research questions. These methods also ensured that data collected from the sample was representative of the population from which the sample was drawn, quality data and that the procedures used in data collection adhered to research ethics. The following chapter presents, analyzes and interprets the findings.

CHAPTER FOUR

PRESENTATION, ANALYSIS AND INTERPRETATION OF FINDINGS

4.1 Introduction

This chapter presents, analyzes and interprets the results. It is divided into three major sections. The first section presents results related to the effect of compliance with clinical trial requirements on the management of clinical trial data in MUJHU Health Care Limited. The second section presents results related the effect of an operational quality management plan on the management of clinical trial data in MUJHU Health Care Limited. The third section presents results related the effect of quality control measures on the management of clinical trial data in MUJHU Health Care Limited.

4.2 Effect of Compliance with Clinical Trial Requirements on the Management of Clinical Trial Data in MUJHU Health Care Limited

It is recommended that when presenting the results of statistical tests, the researcher should give descriptive statistics before the corresponding inferential statistics (Plonsky, 2007). In other words, the researcher should give means, frequencies and/or percentages (perhaps referring to a table or figure), before talking about the results of any statistical tests performed. Thus, in this chapter, this advice was adopted. Therefore, descriptive statistics (frequencies and percentages) relating to compliance with clinical trial requirements and management of clinical trial data were presented, analyzed and interpreted before conducting a statistical test on the effect of compliance with clinical trial requirements on the management of clinical trial data. Findings are presented in the following first and second subsection and the results of statistical test are presented in the third subsection.

4.2.1 Descriptive results about compliance with clinical trial requirements

Respondents were requested to respond to eleven (11) items about compliance with clinical trial requirements using the following five-point Likert scale: "Strongly disagree", "Disagree", "Not sure", "Agree", and "Strongly agree" as shown in Table 3. The items are presented in the first column of Table 3 and the proportion of respondents to the responses on each of the items is presented in form of frequencies and percentages in columns 2 to 6. The last column presents the total number and percentage of respondents on each of the items. The analysis and interpretation of the findings about compliance with clinical trial requirements follows the presentation of findings in Table 3.

Table 3: Findings about compliance with clinical trial requirements

Items about compliance with clinical trial requirements	SD	D	NS	A	SA	Total
1. This organization has reliable Standard Operating Procedures for describing the objective(s) of clinical trials	0 (0%)	6 (13%)	5 (11%)	17 (37%)	18 (39%)	46 (100%)
2. This organization has reliable Standard Operating Procedures for describing the design of clinical trials	0 (0%)	6 (13%)	7 (15%)	16 (35%)	17 (37%)	46 (100%)
3. This organization has reliable Standard Operating Procedures for describing the methodology of clinical trials	1 (2%)	5 (11%)	9 (20%)	15 (33%)	16 (35%)	46 (100%)
4. This organization has reliable Standard Operating Procedures for describing the statistical considerations of clinical trials	3 (7%)	4 (9%)	3 (7%)	19 (41%)	17 (37%)	46 (100%)
5. This organization has reliable Standard Operating Procedures for describing the organization of clinical trials	11 (24%)	9 (20%)	0 (0%)	7 (15%)	19 (41%)	46 (100%)
6. This organization's Standard Operating Procedures satisfactorily ensure standardization in clinical trials	1 (2%)	6 (13%)	7 (15%)	24 (52%)	8 (17%)	46 (100%)
7. This organization's Standard Operating Procedures satisfactorily ensure uniformity of procedures in clinical trials	7 (15%)	9 (20%)	5 (11%)	10 (22%)	15 (33%)	46 (100%)
8. This organization's Standard Operating Procedures satisfactorily ensure high data quality in clinical trials	4 (9%)	3 (7%)	6 (13%)	21 (46%)	12 (26%)	46 (100%)
9. This organization's Standard Operating Procedures satisfactorily ensure collaboration across sites in clinical trials	11 (24%)	21 (46%)	6 (13%)	3 (7%)	5 (11%)	46 (100%)
10. There is satisfactory compliance with Good Clinical Practice in this organization	15 (33%)	17 (37%)	10 (22%)	4 (9%)	0 (0%)	46 (100%)
11. I have better understanding of the regulatory guidance in clinical trials	16 (35%)	11 (24%)	3 (7%)	14 (30%)	2 (4%)	46 (100%)

Source: Field

To analyze the findings, respondents who strongly disagreed and those who disagreed were combined into one category of respondents who "opposed" the items. In addition, respondents who strongly agreed and those who agreed were combined into another category of respondents who "concurred" with the items. Thus, three categories of respondents were compared, that is "respondents who opposed the items", "respondents who were not sure about the items" and "respondents who concurred with the items". Interpretation was then drawn from the comparisons of the three categories as shown in the following paragraph.

The analysis of the findings shows that more respondents concurred to the first-eight items (items 1 to 8) about compliance with clinical trial requirements compared to those who concurred and those who were not sure. For example, from items 1 to 8, the least percentage of the respondents (55%) concurred to the item 7 that stated, "This organization's Standard Operating Procedures satisfactorily ensure uniformity of procedures in clinical trials". The highest percentage of respondents 78%) concurred to item 4 that stated, "This organization has reliable Standard Operating Procedures for describing the statistical considerations of clinical trials". Thus, the percentage of respondents who concurred to the other 6 remaining items lies between 55% and 78%. Therefore, these findings show that in most cases in MUJHU, there were reliable Standard Operating Procedures for describing the objective(s), the design, and the methodology of clinical trials. Findings also show that MUJHU had reliable Standard Operating Procedures for describing the statistical considerations and the organization of clinical trials. Lastly, it is shown that MUJHU's Standard Operating Procedures satisfactorily ensured standardization, uniformity of procedures and high data quality in

clinical trials. However, all these had shortfalls given the small percentages of respondents who were opposed to them. Interview findings were supportive these findings as shown in the following quotation:

> Among the clinical requirements is the project document, which is not usually shared among staff due to its technicalities. The protocol is shared but at times violated due to a number of different studies taking place at the same time where one can be misguided by one if not careful. However, in instances of protocol violation there is usually procedure to observe and report any violations.

However, more respondents were opposed to the last-three items (items 9 to 11) about compliance with clinical trial requirements compared to those who concurred and those who were not sure. For example, the least percentage of respondents (59%) was opposed to the item 11 that stated, "I have better understanding of the regulatory guidance in clinical trials". The highest percentage of respondents (70%) was opposed to items 9 and 10 that stated, "This organization's Standard Operating Procedures satisfactorily ensure collaboration across sites in clinical trials" and "There is satisfactory compliance with Good Clinical Practice in this organization". Thus, these findings show that in most cases in MUJHU, employees lacked a better understanding of the regulatory guidance in clinical trials, the Standard Operating Procedures did not satisfactorily ensure collaboration across sites in clinical trials and compliance with Good Clinical Practice at MUJHU was not satisfactory.

4.2.2 Descriptive results about management of clinical trial data

Respondents were requested to respond to eight (8 items about management of clinical trial data using the following five-point Likert scale: "Strongly disagree", "Disagree", "Not sure", "Agree", and "Strongly agree" as shown in Table 4. The items are presented

in the first column of Table 4 and the proportion of respondents to the responses on each of the items is presented in form of frequencies and percentages in columns 2 to 6. The last column presents the total number and percentage of respondents on each of the items. The analysis and interpretation of the findings about management of clinical trial data follows the presentation of findings in Table 4.

Table 4: Findings about management of clinical trial data

Items about management of clinical trials	SD	D	NS	A	SA	Total
1. This organization satisfactorily ensures clinical data accuracy	5 (11%)	3 (7%)	7 (15%)	26 (57%)	5 (11%)	46 (100%)
2. This organization satisfactorily ensures clinical data integrity	1 (2%)	6 (13%)	0 (0%)	26 (57%)	13 (28%)	46 (100%)
3. This organization thoroughly reviews clinical data	3 (7%)	3 (7%)	0 (0%)	26 (57%)	14 (30%)	46 (100%)
4. This organization thoroughly assesses the clinical data	3 (7%)	3 (7%)	0 (0%)	32 (70%)	8 (17%)	46 (100%)
5. This organization carefully documents queries in clinical data	4 (9%)	6 (13%)	0 (0%)	25 (54%)	11 (24%)	46 (100%)
6. This organization carefully monitors clinical data	7 (15%)	4 (9%)	2 (4%)	22 (48%)	11 (24%)	46 (100%)
7. In this organization adverse effects are satisfactorily avoided to ensure high quality clinical data	4 (9%)	30 (65%)	3 (7%)	1 (2%)	8 (17%)	46 (100%)
8. This organization's clinical data management practices are satisfactory	7 (15%)	3 (7%)	2 (4%)	26 (57%)	8 (17%)	46 (100%)

Source: Field

The analysis of the findings shows that more respondents concurred to 7 out of 8 items (that is items 1, 2, 3, 4, 5, 6 and 8) about management of clinical trial data compared to those who concurred and those who were not sure. For example, the least percentage of respondents (68%) concurred to item 1 that stated, "This organization satisfactorily ensures clinical data accuracy". The highest percentage (87%) concurred to items 3 and 4 that stated, "This organization thoroughly reviews clinical data" and "This organization thoroughly assesses the clinical data". The percentages of respondents who concurred to the other four remaining items lie between 68% and 87%. Therefore, these findings show that MUJHU satisfactorily ensured clinical data accuracy and integrity, thoroughly

reviewed and assessed the clinical data, carefully documented queries in clinical data and monitored clinical data, and its clinical data management practices were satisfactory.

Lastly, the findings shows that the highest percentage of respondents were opposed to one item (that is items 7) about management of clinical trial data compared to those who concurred and those who were not sure. This item was "In this organization adverse effects are satisfactorily avoided to ensure high quality clinical data". This implied that at MUJHU, adverse effects were not satisfactorily avoided to ensure high quality clinical data.

In support of these findings were the interview findings, which in particular highlight the strengths and shortcomings in the management of clinical trials. For example, relating to ensuring clinical trial data accuracy one of the respondents had this to say,

> There is accuracy, though in some instances some studies on electronic data capture have single entry rather that double which might jeopardize quality.

In respect to through reviewing clinical data, one interview findings revealed thus,

> This is ensured at all levels right from collection to electronic data capture.

Relating to assessing the clinical data, other interview findings revealed the following:

> This is where quality assurance is applied, also during external monitoring where a percentage is reviewed.

As for the carefully documentation of clinical data, interview findings revealed thus,

> There are tools to keep track of queries. However, whether these are kept for reference to keep track of the trend of queries is not clear.

From the analysis in the previous paragraph, the following is interpretation. The findings show that in most cases, MUJHU did satisfactorily ensured clinical data accuracy and integrity, thoroughly reviewed and assessed the clinical data, carefully documented queries in clinical data, monitored clinical data and its clinical data management practices were not satisfactory. However, findings show that in most cases, MUJHU did not satisfactorily avoid adverse effects to ensure high quality clinical data.

4.2.3 Results of Statistical Test for First Objective

The study tested the following first hypothesis, "Compliance with clinical trial requirements has a significant positive effect on the management of clinical trial data in MUJHU Health Care Limited". Spearman correlation coefficient (rho) was used to determine the strength of the relationship between compliance with clinical trial requirements and management of clinical trial data. The sign of the coefficient (positive or negative sign) was used to determine the change in direction in the relationship between compliance with clinical trial requirements and management of clinical trial data. The significance of the coefficient (p) was used to test the relationship between compliance with clinical trial requirements and management of clinical trial data by comparing it to the critical significance level at (0.05). Lastly, the coefficient of determination (rho^2) was used to determine the effect of compliance with clinical trial requirements on management of clinical trial data. Table 5 presents the test results and interpretation of the results follow it.

Table 5: Correlation between compliance with clinical trial requirements and management of clinical trial data

	Compliance with clinical trial requirements
Management of clinical trial data	*rho* = .370 rho^2 = .136 p = .011 n = 46

Source: Field

Findings show a weak positive correlation (r = .370) between compliance with clinical trial requirements and management of clinical trial data. Since the correlation does not indicate cause effect in terms of the percentage variance in the dependent variable caused by the independent variable, a coefficient of determination (rho^2 = .136), which is a square of the correlation coefficient was computed. The coefficient of determination was expressed into percentage to determine the effect of compliance with clinical trial requirements on management of clinical trial data. Thus, it is shown that compliance with clinical trial requirements accounted for 13.6% of variance in management of clinical trial data.

These findings were subjected to a test of significance (p) and it is shown that the significance of the correlation (p = .011) is less than the recommended critical significance at 0.05. Thus, the findings of this study were accepted. This implies that compliance with clinical trial requirements had a significant but weak effect on the management of clinical trial data.

The weak correlation implied that a change in compliance with clinical trial requirements was related to a small change in management of clinical trial data. The positive nature of the correlation implied that the change in compliance with clinical trial requirements and management of clinical trial data was in the same direction whereby more compliance

with clinical trial requirements was related to better management of clinical trial data and vice versa.

4.3 Effect of an Operational Quality Management Plan on the Management of Clinical Trial Data

Descriptive statistics (frequencies and percentages) relating to operational quality management plan were presented, analyzed and interpreted before conducting a statistical test on the effect of operational quality management plan on the management of clinical trial data. Findings are presented in the following first subsection and the results of statistical test are presented in the second subsection.

4.3.1 Descriptive results about operational quality management plan

Respondents were requested to respond to ten (10) items about operational quality management plan using the following five-point Likert scale: "Strongly disagree", "Disagree", "Not sure", "Agree", and "Strongly agree" as shown in Table 6. The items are presented in the first column of Table 6 and the proportion of respondents to the responses on each of the items is presented in form of frequencies and percentages in columns 2 to 6. The last column presents the total number and percentage of respondents on each of the items. The analysis and interpretation of the findings about operational quality management plan follows the presentation of findings in Table 6.

Table 6: Findings about operational quality management plan

Items about operational quality management plan	SD	D	NS	A	SA	Total
1. This organization always achieve the quality that is fit for the purpose of clinical trials	11 (24%)	20 (43%)	8 (17%)	2 (4%)	5 (11%)	46 (100%)
2. This organization spends sufficient efforts to ensure that all key data critical to the interpretation of the trial are of high quality	5 (11%)	9 (20%)	3 (7%)	16 (35%)	13 (28%)	46 (100%)
3. This organization has a quality plan that satisfactorily documents specific quality in clinical trial practices	5 (11%)	6 (13%)	3 (7%)	19 (41%)	13 (28%)	46 (100%)
4. This organization has a quality plan that satisfactorily documents specific resources in clinical trial practices	6 (13%)	3 (7%)	4 (9%)	19 (41%)	14 (30%)	46 (100%)
5. This organization has a quality plan that satisfactorily documents specific activities in clinical trial practices	7 (15%)	3 (7%)	3 (7%)	25 (54%)	8 (17%)	46 (100%)
6. This organization has a sound design for the management of clinical trials	7 (15%)	6 (13%)	4 (9%)	18 (39%)	11 (24%)	46 (100%)
7. This organization follows a sound careful planning for the management of clinical trials	7 (15%)	4 (9%)	2 (4%)	22 (48%)	11 (24%)	46 (100%)
8. This organization has a good management procedure for the clinical trials	17 (37%)	9 (20%)	4 (9%)	9 (20%)	7 (15%)	46 (100%)
9. This organization has a proper analysis for the management of clinical trials	4 (9%)	23 (50%)	3 (7%)	12 (26%)	4 (9%)	46 (100%)
10. This organization conducts a satisfactory training of its staff in clinical trials	1 (2%)	3 (7%)	2 (4%)	35 (76%)	5 (11%)	46 (100%)

Source: Field

The analysis of the findings show that more respondents concurred to 6 out of 10 items (2, 4, 5, 6, 7 and 10) about operational quality management plan compared to those who concurred and those who were not sure. For example, the least percentage of respondents (63%) concurred to the items 2 and 6 that stated, "This organization spends sufficient efforts to ensure that all key data critical to the interpretation of the trial are of high quality" and "This organization has a sound design for the management of clinical trials". The highest percentage of respondents (87%) concurred to items 10 that stated, "This organization conducts a satisfactory training of its staff in clinical trials". The percentage of respondents who concurred to the other three remaining items lies between 63% and 87%. These findings, therefore, show that in most cases, MUJHU spent sufficient efforts to ensure that all key data critical to the interpretation of the trial were of high quality. Furthermore, it had a quality plan that satisfactorily documents specific quality, resources and activities in clinical trial practices including a sound design for the

management of clinical trials. Lastly, it followed a sound careful planning for the management of clinical trials. In support of these findings were the following interview findings.

One of the key informants during the interview reported in the following:

> There is a MUHU CQMP, which acts as the quality plan. The documentation of quality clinical trial practices and resources used in clinical trials is well articulated in the MUJHU CQMP 2009".

A second key informant had this to say,

> There is a design for the management of clinical trials but few know the details and steps. This is because it is limited to principle investigators but not rolled out to staff'.

However, findings also show that more respondents opposed to 4 out of 10 items (1, 3, 8 and 9) about operational quality management plan compared to those who concurred and those who were not sure. For example, the least percentage of respondents (24%) was opposed to the item 3 that stated "This organization has a quality plan that satisfactorily documents specific quality in clinical trial practices. The highest percentage of respondents (67%) was opposed to item 1 that stated, "This organization always achieves the quality that is fit for the purpose of clinical trials. The percentages of respondents opposed to the other two remaining items lies between 24% and 67%. Thus, these findings show that MUJHU did not always achieve the quality that was fit for the purpose of clinical trials, did not have a quality plan that satisfactorily documented specific quality in clinical trial practices, did not have a good management procedure for the clinical trials and did not have a proper analysis for the management of clinical trials.

4.3.2 Results of Statistical Test for Second Objective

The study tested the following second hypothesis, "Quality management plan has a significant positive effect on the management of clinical trial data in MUJHU Health Care Limited". Spearman correlation coefficient (rho) was used to determine the strength of the relationship between operational quality management plan and management of clinical trial data. The sign of the coefficient (positive or negative sign) was used to determine the change in direction in the relationship between operational quality management plan and management of clinical trial data. The significance of the coefficient (p) was used to test the relationship between operational quality management plan and management of clinical trial data by comparing it to the critical significance level at (0.05). Lastly, the coefficient of determination (rho^2) was used to determine the effect of operational quality management plan on management of clinical trial data. Table 7 presents the test results and the analysis and interpretation of the results follow it.

Table 7: Correlation between operational quality management plan and management of clinical trial data

	Operational quality management plan
Management of clinical trial data	*rho* = .861 rho^2 = .741 p = .000 n = 46

Source: Field

Findings show a very strong positive correlation (r = .861) between operational quality management plan and management of clinical trial data. Since the correlation does not indicate cause effect in terms of the percentage variance in the dependent variable caused by the independent variable, a coefficient of determination (rho^2 = .741), which is a square of the correlation coefficient was computed. The coefficient of determination was expressed into percentage to determine the effect of operational quality management plan on management of clinical trial data. Thus, it is shown that operational

quality management plan accounted for 74.1% of variance in management of clinical trial data.

These findings were subjected to a test of significance (p) and it is shown that the significance of the correlation (p = .000) is less than the recommended critical significance at 0.05. Thus, the findings of this study were accepted. This implies that operational quality management plan had a significant very strong effect on the management of clinical trial data.

The very strong correlation implied that a change in operational quality management plan was related to a very big change in management of clinical trial data. The positive nature of the correlation implied that the change in operational quality management plan and management of clinical trial data was in the same direction whereby a better operational quality management plan was related to better management of clinical trial data and vice versa.

4.4 Effect of Quality Control Measures on the Management of Clinical Trial Data

Descriptive statistics (frequencies and percentages) relating to quality control measures were presented, analyzed and interpreted before conducting a statistical test on the effect of quality control measures on the management of clinical trial data. Findings are presented in the following first subsection and the results of statistical test are presented in the second subsection.

4.4.1 Descriptive results about quality control measures

Respondents were requested to respond to eight (8) items about quality control measures using the following five-point Likert scale: "Strongly disagree", "Disagree", "Not sure", "Agree", and "Strongly agree" as shown in Table 8. The items are presented in the first column of Table 8 and the proportion of respondents to the responses on each of the items is presented in form of frequencies and percentages in columns 2 to 6. The last column presents the total number and percentage of respondents on each of the items. The analysis and interpretation of the findings about quality control measures follows the presentation of findings in Table 8.

Table 8: Findings about operational quality management plan

Items about	SD	D	NS	A	SA	Total
1. There are standard quality control techniques for this organization for the management of clinical trial data	2 (4%)	9 (20%)	3 (7%)	24 (52%)	8 (17%)	46 (100%)
2. This organization uses clinical monitors trained in the technique of data monitoring	7 (15%)	5 (11%)	0 (0%)	30 (65%)	4 (9%)	46 (100%)
3. This organization's clinical monitors provide reliable information on the management of study patients, in accordance with study protocol	0 (0%)	37 (80%)	0 (0%)	7 (15%)	2 (4%)	46 (100%)
4. This organization's clinical monitors provide reliable guidance on the management of study patients, in accordance with study protocol	3 (7%)	33 (72%)	0 (0%)	6 (13%)	4 (9%)	46 (100%)
5. This organization's clinical monitors satisfactory review source materials that document patient eligibility	2 (4%)	8 (17%)	0 (0%)	33 (72%)	3 (7%)	46 (100%)
6. This organization's clinical monitors satisfactory review study notebooks for each patient in order to ensure that the protocol is being followed properly	2 (4%)	6 (13%)	0 (0%)	38 (83%)	0 (0%)	46 (100%)
7. Monitoring of clinical trials in this organization is satisfactory	7 (15%)	22 (48%)	3 (7%)	12 (26%)	2 (4%)	46 (100%)
8. There are multiple methods for monitoring clinical trials in this organization is satisfactory	5 (11%)	29 (63%)	5 (11%)	3 (7%)	4 (9%)	46 (100%)

Source: Field

The analysis of the findings show that more respondents concurred to 4 out of 8 items about quality control measures compared to those who concurred and those who were not sure. For example, the least percentage of respondents (69%) concurred to item 1 that stated, "There are standard quality control techniques for this organization for the management of clinical trial data". The highest percentage (83%) concurred to item 6

that stated "This organization's clinical monitors satisfactory review study notebooks for each patient in order to ensure that the protocol is being followed properly". The percentage opposed to the other remaining items lies between 69% and 83%. These findings show that in most cases, MUJHU had standard quality control techniques for the management of clinical trial data and used clinical monitors trained in the technique of data monitoring. Furthermore, MUJHU's clinical monitors satisfactory reviewed source materials that documented patient eligibility and notebooks for each patient in order to ensure that the protocol was being followed properly.

However, findings show that more respondents opposed to 4 out of 8 items about quality control measures compared to those who opposed and those who were not sure. For example, the least percentage of respondents (63%) opposed item 8 that stated, "Monitoring of clinical trials in this organization is satisfactory". The highest percentage of respondents (80%) opposed item 3 that stated, "This organization's clinical monitors provide reliable information on the management of study patients, in accordance with study protocol". The percentage of respondents opposed to the other remaining items lies between 69% and 83%. Thus, these findings show that MUJHU's clinical monitors did not provide reliable information and guidance on the management of study patients in accordance with study protocol. Furthermore, monitoring of clinical trials was unsatisfactory and there was few methods for monitoring clinical trials and was unsatisfactory.

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4.4.2 Results of Statistical Test for Third Objective

The study tested the following third hypothesis, "Quality control measures have a significant positive effect on the management of clinical trial data in MUJHU Health Care

Limited". Spearman correlation coefficient (rho) was used to determine the strength of the relationship between quality control measures and management of clinical trial data. The sign of the coefficient (positive or negative sign) was used to determine the change in direction in the relationship between quality control measures and management of clinical trial data. The significance of the coefficient (p) was used to test the relationship between quality control measures and management of clinical trial data by comparing it the critical significance level at (0.05). Lastly, the coefficient of determination (rho^2) was used to determine the effect of quality control measures on management of clinical trial data. Table 9 presents the test results and interpretation of the results follow it.

Table 9: Correlation between quality control measures and management of clinical trial data

	Quality control measures
Management of clinical trial data	*rho* = .361 rho^2 = .130 p = .014 n = 46

Source: Field

Findings show a weak positive correlation (r = .361) between quality control measures and management of clinical trial data. Since the correlation does not indicate cause effect in terms of the percentage variance in the dependent variable caused by the independent variable, a coefficient of determination (rho^2 = .130), which is a square of the correlation coefficient was computed. The coefficient of determination was expressed into percentage to determine the effect of quality control measures on management of clinical trial data. Thus, it is shown that quality control measures accounted for 13.0% of variance in management of clinical trial data.

These findings were subjected to a test of significance (p) and it is shown that the significance of the correlation (p = .014) is less than the recommended critical

significance at 0.05. Thus, the findings of this study were accepted. This implies that quality control measures had a significant but moderate effect on the management of clinical trial data.

The weak correlation implied that a change in quality control measures was related to a small change in management of clinical trial data. The positive nature of the correlation implied that the change in quality control measures and management of clinical trial data was in the same direction whereby better quality control measures was related to better management of clinical trial data and vice versa.

4.5 Conclusion

The findings in this section revealed strengths and weaknesses in compliance with clinical trial requirements, operational quality management plan and quality control measures at MUJHU. The strengths in compliance with clinical trial requirements, operational quality management plan and quality control measures enhanced the management of clinical trial data at MUJHU while the weaknesses in compliance with clinical trial requirements, operational quality management plan and quality control measures compromised the management of clinical trial data at MUJHU. The following chapter summaries these findings, discusses the findings in detail, draws conclusions and recommendations from the findings.

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

This chapter presents the discussion, conclusions and recommendations. It is divided into three major sections. The first section presents the discussion according to the objectives of the study. The second section presents the conclusions according to the objectives of the study. The third section presents the recommendations according to the objectives of the study.

5.2 Summary of findings

Compliance with clinical trial requirements had a significant but weak effect on the management of clinical trial data. In particular, compliance with clinical trial requirements accounted for 13.6% of variance in management of clinical trial data, whereby more compliance with clinical trial requirements was related to better management of clinical trial data and vice versa.

Operational quality management plan had a significant very strong effect on the management of clinical trial data. Findings showed that operational quality management plan accounted for 74.1% of variance in management of clinical trial data, whereby a better operational quality management plan was related to better management of clinical trial data and vice versa.

Quality control measures had a significant but weak effect on the management of clinical trial data. Specifically, findings showed that quality control measures accounted for 13.0%

of variance in management of clinical trial data, whereby more quality control measures was related to better management of clinical trial data and vice versa.

5.3 Discussion

5.3.1 Effect of compliance with clinical trial requirements on the management of clinical trial data in MUJHU Health Care Limited

The positive aspects in compliance with clinical trials included the following: MUJHU, had a reliable Standard Operating Procedures for describing the objective(s), the design and the methodology of clinical trials. It had reliable Standard Operating Procedures for describing the statistical considerations and the organization of clinical trials and its Standard Operating Procedures satisfactorily ensured standardization, uniformity of procedures and high data quality in clinical trials. These findings support Shrikant (2005) who emphasized that clinical trial protocols should be accompanied with sound Standard Operating Procedures (SOPs), which are essential documents to maintain the consistency of data quality across trials, sites, time, and clinical data management personnel.

In this study, compliance with clinical trial requirements was generally unsatisfactory. This was because employees lacked a better understanding of the regulatory guidance in clinical trials, the Standard Operating Procedures did not satisfactorily ensure collaboration across sites in clinical trials and compliance with Good Clinical Practice at MUJHU was not satisfactory. Yet according to Shrikant (2005), GCP a key and an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.

The unsatisfactory compliance with clinical trial requirements was explanatory to the poor management of clinical trial data at MUJHU. The poor management of clinical trial data at MUJHU was in terms of failure to satisfactorily ensure clinical data accuracy and clinical data integrity, to thoroughly review clinical data, and assess the clinical data. Poor management of clinical trial data at MUJHU was also in terms, failure to carefully document queries in clinical data, monitor clinical data, avoid adverse effects to ensure high quality clinical data and use satisfactory clinical data management practices.

5.3.2 Effect of an operational quality management plan on the management of clinical trial data in MUJHU Health Care Limited

It was established in this study that operational quality management plan had a significant very strong effect on the management of clinical trial data. Thus, given that the operational quality management plan had shortcomings, they compromised the management of clinical trial data at MUJHU. These findings support DeJuran & Shande (2001) who observed that failure to plan and operationalize a quality management plan might adversely affect the scientific impact of the trial itself.

This study established operational quality management plan at MUJHU was unsatisfactory. This is in support contrary to Shrikant (2005) who noted that every research study requires a sound design, careful planning, good management and proper analysis, which leads to adherence with the protocol and to high quality in its implementation.

The operational quality management plan at MUJHU was unsatisfactory because MUJHU MUJHU did not always achieve the quality that was fit for the purpose of clinical trials,

have a quality plan that satisfactorily documented specific quality in clinical trial practices, and a good management procedure for the clinical trials and a proper analysis for the management of clinical trials. This fell short of what The National Institute of Allergy and Infectious Diseases (Mar, 2003) considers as a clinical quality management plan, which encompasses both quality assurance and quality control procedures and details the responsibility, scope, and frequency of these activities.

However, the good aspects operational quality management plan at MUJHU included the following. MUJHU spending sufficient efforts to ensure that all key data critical to the interpretation of the trial were of high quality, having a quality plan that satisfactorily documents specific quality, resources and activities in clinical trial practices including a sound design for the management of clinical trials and following a sound careful planning for the management of clinical trials. These findings support Valania (2006) recommendations about an effective operational quality management plan.

5.3.3 Effect of quality control measures on the management of clinical trial data in MUJHU Health Care Limited

Findings of this study revealed that quality control measures had a significant but weak effect on the management of clinical trial data. Although quality control measures had a significant but weak effect on the management of clinical trial data, these findings support Favalli Vantongelen and Oosterom (2000) who observed that it is vital to note that data quality is a central requirement of scientific research. Findings of this study also support Pandav (2002) who emphasized that better quality control measures ensure that adverse effects are avoided to ensure high quality research.

Findings of this study revealed that quality control measures at MUJHU Health Care Limited were unsatisfactory. This was because MUJHU's clinical monitors did not provide reliable information and guidance on the management of study patients, in accordance with study protocol. Furthermore, monitoring of clinical trials was unsatisfactory and there were few methods for monitoring clinical trials and were unsatisfactory. The findings of this study support Fong and Daniel, (2001) who stated that there are bad and good clinical data management practices, which could lead to differentiated effects on clinical data trials in Research Institutions.

However, the study established that in most cases, MUJHU had standard quality control techniques for the management of clinical trial data and used clinical monitors trained in the technique of data monitoring. In addition, its clinical monitors satisfactory reviewed source materials that documented patient eligibility and notebooks for each patient in order to ensure that the protocol was being followed properly. These findings support Martin (2006) who emphasized that it is necessary to have QC measures for thorough review of data, assessment of validity of outlying data points, and to carefully document query identification and resolution throughout a study's duration.

5.4 Conclusions

5.4.1 Effect of compliance with clinical trial requirements on the management of clinical trial data in MUJHU Health Care Limited

Compliance with clinical trial requirements had a significant but weak effect on the management of clinical trial data. In particular, compliance with clinical trial requirements accounted for 13.6% of variance in management of clinical trial data, whereby more

compliance with clinical trial requirements was related to better management of clinical trial data and vice versa.

5.4.2 Effect of an operational quality management plan on the management of clinical trial data in MUJHU Health Care Limited

Operational quality management plan had a significant very strong effect on the management of clinical trial data. Findings showed that operational quality management plan accounted for 74.1% of variance in management of clinical trial data, whereby a better operational quality management plan was related to better management of clinical trial data and vice versa.

5.4.3 Effect of quality control measures on the management of clinical trial data in MUJHU Health Care Limited

Quality control measures had a significant but weak effect on the management of clinical trial data. Specifically, findings showed that quality control measures accounted for 13.0% of variance in management of clinical trial data, whereby more quality control measures was related to better management of clinical trial data and vice versa.

5.5 Recommendations

5.5.1 Effect of compliance with clinical trial requirements on the management of clinical trial data in MUJHU Health Care Limited

There is need to improve compliance with clinical trial requirements for the better management of clinical trial data in MUJHU Health Care Limited. This can be achieved by having reliable Standard Operating Procedures for describing the objective(s) of clinical trials, the design of clinical trials, the methodology of clinical trials, the statistical

considerations of clinical trials and the organization of clinical trials. This would ensure standardization in clinical trials, uniformity of procedures in clinical trials, high data quality in clinical trials and collaboration across sites in clinical trials.

5.5.2 Effect of an operational quality management plan on the management of clinical trial data in MUJHU Health Care Limited

Operational quality management plan in MUJHU Health Care Limited should be improved for the management of clinical trial data. This can be achieved through spending sufficient efforts to ensure that all key data critical to the interpretation of the trial are of high quality and having a quality plan that satisfactorily documented specific quality in clinical trial practices, specific resources in clinical trial practices and specific activities in clinical trial practices. In addition, it can be achieved by having a sound design for the management of clinical trials, a sound careful planning for the management of clinical trials, a good management procedure for the clinical trials and a proper analysis for the management of clinical trials including conducting satisfactory staff training in clinical trials.

5.5.3 Effect of quality control measures on the management of clinical trial data in MUJHU Health Care Limited

Quality control measures in MUJHU Health Care Limited for the management of clinical trial data. In can be achieved through having in place standard quality control techniques for the management of clinical trial data, always using clinical monitors trained in the technique of data monitoring. Clinical monitors should always provide reliable information on the management of study patients, in accordance with study protocol and guidance on the management of study patients in accordance with study protocol.

They should also thoroughly review source materials that document patient eligibility and study notebooks for each patient in order to ensure that the protocol is being followed properly. Lastly, monitoring of clinical trials and the methods for monitoring clinical trials should be continuous and thorough.

5.6 Areas for Further Research

Pharmaceutical industry and cooperative group sponsors extend reimbursement at varying levels, but it is far from clear how much of the effort is covered by these funds. Thus this study proposes a further area of research to find out the effect funding quality controls on the management of clinical trial data.

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APPENDICES

Appendix 1: Consent Form for Respondents

My name is Judith Namata from Makerere university-Johns Hopkins University (MU-JHU) Health Care Limited. I am undertaking a research study on "The contribution of quality control in management in clinical trial data" A Case study of the Makerere university-Johns Hopkins University (MU-JHU) Health Care Limited. You have been selected as a key respondent to participate in this study.

I'm gathering this data in an attempt to obtain your views about the effectiveness of quality control systems in management of clinical trial data, and whether these quality systems are adequate, or match the demand for the requirements of clinical trials in Uganda today. You are also required to give your opinions/views on their effectiveness and how they can be exploited to build to enhance the research in clinical trial settings.

The information I'm gathering from you will remain confidential. You do not have to answer any questions that you are not comfortable with. The information is going to be used for study purposes, and is critical for guiding future improvement and strengthening of data management and clinical studies. Therefore, I would appreciate if you would accept to be part of this study.

Appendix 2: Questionnaire

Dear Respondent,
Please kindly spare some few minutes to respond to the following questions. Information received from you is for academic purposes and will be kept confidential. You will not be victimized for whatever answer you have given and to ensure this you are not required to identify yourself anywhere on the questionnaire.

Section A: Compliance with clinical trial requirements

Please use the following scale to tick or circle your response to the statements presented in the table.

SD= Strongly disagree D = Disagree NS = Not sure A = Agree
SA = Strongly agree

Statements about compliance with clinical trial requirements	SD	D	NS	A	SA
1. This organization has reliable Standard Operating Procedures for describing the objective(s) of clinical trials	1	2	3	4	5
2. This organization has reliable Standard Operating Procedures for describing the design of clinical trials	1	2	3	4	5
3. This organization has reliable Standard Operating Procedures for describing the methodology of clinical trials	1	2	3	4	5
4. This organization has reliable Standard Operating Procedures for describing the statistical considerations of clinical trials	1	2	3	4	5
5. This organization has reliable Standard Operating Procedures for describing the organization of clinical trials	1	2	3	4	5
6. This organization's Standard Operating Procedures satisfactorily ensure standardization in clinical trials	1	2	3	4	5
7. This organization's Standard Operating Procedures satisfactorily ensure uniformity of procedures in clinical trials	1	2	3	4	5
8. This organization's Standard Operating Procedures satisfactorily ensure high data quality in clinical trials	1	2	3	4	5
9. This organization's Standard Operating Procedures satisfactorily ensure collaboration across sites in clinical trials	1	2	3	4	5
10. There is satisfactory compliance with Good Clinical Practice in this organization	1	2	3	4	5
11. I have better understanding of the regulatory guidance in clinical trials	1	2	3	4	5

Section B: Quality management plan

Please use the following scale to tick or circle your response to the statements presented in the table.

SD= Strongly disagree D = Disagree NS = Not sure A = Agree
SA = Strongly agree

Statements about quality management plan	SD	D	NS	A	SA
1. This organization always achieve the quality that is fit for the purpose of clinical trials	1	2	3	4	5
2. This organization spends sufficient efforts to ensure that all key data critical to the interpretation of the trial are of high quality	1	2	3	4	5
3. This organization has a quality plan that satisfactorily documents specific quality in clinical trial practices	1	2	3	4	5
4. This organization has a quality plan that satisfactorily documents specific resources in clinical trial practices	1	2	3	4	5
5. This organization has a quality plan that satisfactorily documents specific activities in clinical trial practices	1	2	3	4	5
6. This organization has a sound design for the management of clinical trials	1	2	3	4	5
7. This organization follows a sound careful planning for the management of clinical trials	1	2	3	4	5
8. This organization has a good management procedure for the clinical trials	1	2	3	4	5
9. This organization has a proper analysis for the management of clinical trials	1	2	3	4	5
10. This organization conducts a satisfactory training of its staff in clinical trials	1	2	3	4	5

Section C: Control measures

Please use the following scale to tick or circle your response to the statements presented in the table.

SD= Strongly disagree D = Disagree NS = Not sure A = Agree
SA = Strongly agree

Statements about control measures	SD	D	NS	A	SA
1. There are standard quality control techniques for this organization for the management of clinical trial data	1	2	3	4	5
2. This organization uses clinical monitors trained in the technique of data monitoring	1	2	3	4	5
3. This organization's clinical monitors provide reliable information on the management of study patients, in accordance with study protocol	1	2	3	4	5
4. This organization's clinical monitors provide reliable guidance on the management of study patients, in accordance with study protocol	1	2	3	4	5
5. This organization's clinical monitors satisfactory review source materials that document patient eligibility	1	2	3	4	5
6. This organization's clinical monitors satisfactory review study notebooks for each patient in order to ensure that the protocol is being followed properly	1	2	3	4	5
7. Monitoring of clinical trials in this organization is satisfactory	1	2	3	4	5
8. There are multiple methods for monitoring clinical trials in this organization is satisfactory	1	2	3	4	5

Section D: Management of clinical trial data
Please use the following scale to tick or circle your response to the statements presented in the table.

SD= Strongly disagree D = Disagree NS = Not sure A = Agree
SA = Strongly agree

Statements about management of clinical trial data	SD	D	NS	A	SA
1. This organization satisfactorily ensures clinical data accuracy	1	2	3	4	5
2. This organization satisfactorily ensures clinical data integrity	1	2	3	4	5
3. This organization thoroughly reviews clinical data	1	2	3	4	5
4. This organization thoroughly assesses the clinical data	1	2	3	4	5
5. This organization carefully documents queries in clinical data	1	2	3	4	5
6. This organization carefully monitors clinical data	1	2	3	4	5
7. In this organization adverse effects are satisfactorily avoided to ensure high quality clinical data	1	2	3	4	5
8. This organization's clinical data management practices are satisfactory	1	2	3	4	5

Thank you for your cooperation

Appendix 3: Key Informant Interview Guide

Dear Respondent,
Please kindly spare some few minutes to respond to the following questions. Information received from you is for academic purposes and will be kept confidential. You will not be victimized for whatever answer you have given and to ensure this you are not required to identify yourself anywhere on the questionnaire.

1. Is there compliance with clinical trial requirements in this organization?
2. If yes, are you satisfied with the compliance with clinical trial requirements in this organization?
3. If you are satisfied compliance with clinical trial requirements in this organization, please explain why you feel that.
4. How has compliance with clinical trial requirements in this organization affected the management of clinical trial data?
5. Is there an operational quality management plan in this organization?
6. If yes, are you satisfied with the operational quality management plan in this organization?
7. If you are satisfied operational quality management plan in this organization, please explain why you feel that.
8. How has operational quality management plan in this organization affected the management of clinical trial data?
9. Are there quality control measures in this organization?
10. If yes, are you satisfied with the quality control measures in this organization?
11. If you are satisfied quality control measures in this organization, please explain why you feel that.
12. How has quality control measures in this organization affected the management of clinical trial data

Thank you for your cooperation