

5-2009

Developing a Strategic Approach to Drive Training Excellence for Clinical Research Professionals

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Abstract

Ali, Asif Jaffer, Developing a Strategic Approach to Drive Training Excellence for Clinical Research Professionals. Master of Science (Clinical Research Management), January, 2008
73pp, 4 tables, 1 Figure, Reference List, Daily Journal of Internship.

Purpose: To evaluate and assess the current training models in relation to the core knowledge and skills requirements for clinical professionals specifically of Clinical Research Associates (CRAs) and Clinical Research Coordinators (CRCs).

Hypothesis: Current training of CRAs and CRCs is inadequate due to a number of reasons. Teaching core necessary research skills is a basic foundation for the development of specific training models for CRAs and CRCs.

Design: Study modules and training presentations were created for the purpose of teaching the company's standard operating procedures (SOP) to MedTrials Employees. Research journal articles were searched for roles of CRAs and CRCs. The data gathered helped identify and analyze training gap seen between research professionals.

Results: Roles of CRCs proved to be multiple and varied between sites and trials. CRAs tasks were more stable and mainly involved having expertise in the overall process of clinical trials. However, both positions showed a necessity to improve their current model of training.

UNIVERSITY OF NORTH TEXAS HEALTH SCIENCE CENTER

INTERNSHIP PRACTICUM REPORT

Developing a Strategic Approach to Drive Training
Excellence for Clinical Research Professionals

By

Asif Ali

January, 2009

*Internship practicum report for Graduate School of Biomedical Science at U.N.T.
H.S.C. in Fort Worth, in fulfillment of requirement for Degree of Master of Science
in Clinical Research Management.*

Acknowledgements

I want to thank Dr. Patricia Gwartz for her invaluable guidance throughout my graduate school as my major professor and advisor. I would like to thank Dr. Michael Oglesby for his generous suggestions as one of my committee members. I would like to thank Lynn VanDermark for helping me develop the necessary skills for clinical research management. Also, I would like to thank all of the employees of MedTrials for being gracious enough to have me work with them and participating in the development of the practicum report. And finally, I want to thank my family and friends for all of the necessary support and encouragement in the process.

Table of Contents

	Page
List of Tables and Figures.....	vi
I. Chapter 1.....	1-3
a. Introduction.....	1-3
II. Chapter 2.....	4-38
a. Internship Subject.....	4
b. Background and Literature Review.....	5-14
c. Specific Aims.....	15-16
d. Significance.....	17
e. Materials and Methods.....	18-23
f. Results.....	24-30
g. Discussion.....	31-37
h. Summary.....	38
III. Chapter 3.....	39-40
a. Internship Site and Experience.....	39
b. Journal Summary.....	40
c. Appendix A (Surveys, Training Modules, Quizzes).....	41-58
d. Appendix B(Daily Journal).....	59-71
e. Bibliography.....	72-73

List of Tables and Figures

	Page
Figure1. Process Map.....	11
Table1. Top Roles of a CRA.....	27
Table 2. Top Roles of a CRC.....	28
Table 3. Top Roles that may overlap between CRAs and CRCs.....	29
Table 4. Comparing MedTrials GCP training programs to other training Programs.....	29-30
Appendix 1 Questionnaire created for participants (CRAs and CRCs).....	41-43
Appendix 2 Power-Point Presentation created for SOP training.....	44-45
Appendix 3 Audio transcript of SOP training on Escalation Procedures.....	46-49
Appendix 4 Quiz created for SOP training module.....	50
Appendix 5 Post-presentation survey given to all SOP training modules.....	51
Appendix 6 One of ten questionnaires created that was filled out by a CRA.....	52-53
Appendix 7 One of ten questionnaires created that was filled out by a CRA/CRC.....	54-56
Appendix 8 One of two interviews (MedTrials Employees).....	57
Appendix 9 Two of two interviews (MedTrials Employees).....	58

Chapter I

Introduction

History of clinical research regulations

Since the establishment of the U.S. Food and Drugs Administration (FDA) in 1907, federal regulations have been introduced to the process of clinical trials in order to ensure the quality and safety of all medical products developed. Drug and device regulation may have evolved in the past 20 years in response to general public outcry over harmful products being distributed in the market. In order to protect healthcare consumers, the FDA has placed the responsibility upon researchers to enhance product safety and efficacy through the increased requirement for product testing and re-testing, implementation of user fees to increase the resources of the FDA, and through FDA inspections to ensure that regulatory standards are upheld. Historical events such as the Biologics Control Act of 1902, Pure Food Drug Act of 1906, and Food, Drug and Cosmetic Act of 1938 have been pivotal to assert the FDA's role and responsibility as the main source and sustainer of all clinical research regulations (14). For example, on certain long-term medical device such as stents and implants, the FDA has requested post-market surveillance to measure long-term side effects of developed products. In order to follow the standards set by the FDA, research organizations have implemented changes in clinical research infrastructure by the hiring of qualified clinical research professionals.

Regulations created by the FDA have led to a greater range in the roles of clinical research professionals. There is a heightened interest of research institutions to hire staff that

cannot only provide optimal healthcare to subjects but also encompass the necessary mindset for clinical research and product development. The knowledge and skill sets of clinical research professionals are specialized and a researcher's obligation and duties are subjected to public scrutiny. Research professionals must maintain and uphold ethical boundaries that are firm and clear in order to satisfy demands of industry. To comply with regulatory obligations, clinical research professionals must demonstrate mastery of their knowledge and continually seek opportunities to add to their education and contribute to the advancement of their profession (12).

Organizations that participate in research must also meet extremely high standards if they are to compete for clinical research and scientific accomplishments. Achieving these standards will require that competing organizations make research a top priority, especially through investment in the development of proper training and technology (11). MedTrials Incorporated is such a research organization that is dedicated to training their employees in order to generate top products and services.

MedTrials Incorporated is a contract research organization (CRO) based in Dallas, Texas, with an informatics division located in Media, Pennsylvania. As an intern at MedTrials, I worked out of the Dallas office with clinical research professionals, who have varied backgrounds and experience. Some had prior industry experience obtained from working for clinical research companies or medical product manufacturers. Others have transitioned into the role of a clinical researcher after working in bench research positions or after completing graduate studies. Many have previous work experience as clinical research coordinators (CRCs) and/or nurses, who switched career paths from clinical to industry to work as Clinical Research Associates (CRA).

Topic of practicum report

The focus of my internship practicum was to assist with the strategic development of clinical research professional training programs. My primary responsibilities were to support internal compliance initiatives across the training and quality assurance departments. However, as an intern, I also had the opportunity to work with the other technical departments, such as clinical operations and data management to obtain hands-on experience with other areas including study file management, adverse event reporting, monitoring, and interactions with other clinical research personnel.

My practicum project involved the evaluation and assessment of current training models for clinical research professionals in relation to the identification of core knowledge and skills requirements. This report specifically focused on training methodology and options directed at CRCs and CRAs. My final report was the result of the work I performed at MedTrials, my interaction with MedTrials employees, and literature research.

Clinical research professionals are required by regulation to be qualified by training and experience. Although the roles of a CRC and a CRA are different, as clinical research professionals, both must have the knowledge, skills, and abilities to execute their duties to not only assure high quality research but also to protect the research subject volunteers. CRAs represent the research sponsor company, and as such, function to monitor clinical trials. Alternatively, CRCs work for the clinical investigators, who are also referred to as principal investigators (PIs). The CRCs assist the PIs in conducting the clinical research at the investigational site. This internship practicum report will address strategic approaches to train clinical research professionals who work in the roles of CRC and CRA.

Chapter II

Internship Subject

The internship practicum focused upon defining the roles of CRCs and CRAs. Even though the two research positions are highly specialized, there are overlapping knowledge and skills required of both. The goal of my practicum report was to delineate the necessary skills that new CRCs and CRAs should master in order to be considered as qualified to perform duties necessary for their roles. At the same time, the report highlights some common mistakes and misunderstandings of new CRCs and CRAs. The Internship practicum demonstrated and differentiated the varying methods and modules utilized to train clinical researchers with a special focus on the positions of CRAs and CRCs. Employee questionnaires and interviews were given to supplement resources such as clinical research journals and clinical research website such as ACRP.net (Association of Clinical Research Professionals) so that proper methods to effectively train CRAs and CRCs can be established.

There are numerous commercially available and on-site training programs for clinical research professionals. This internship report classified the core necessities of all effective training programs. Study modules and presentation were created for the purpose of teaching the company standard operating procedures (SOP) to MedTrials employees. Quizzes and post-presentation surveys were developed to measure and document employee progress, feedback, and effectiveness of the SOP training modules.

Background and Literature Review

History of control and experimental groups in clinical trials

Clinical trials are conducted on human subjects in order to analyze investigational products and therapies intended to help future patients. Today, such investigations are accomplished by researchers who follow detailed protocols that should protect subject safety and data integrity. James Lind, considered the father of clinical trials, was the first individual to introduce a control group for cross-analysis in addition to a test group into his experiments conducted in 1747 (10). He proposed the hypothesis that eating limes could prevent scurvy, and conducted his studies using sailors, who contracted this disease. All subjects were placed on a similar diet of foods but the test group was given additional supplements such as cider, elixir vitriol, vinegar, seawater, nutmeg, oranges and lemons (10). After six days, subjects that had eaten the additional citrus fruits recovered from scurvy and returned to active duty (10). In order to limit outside variables, he made sure that all subjects were given exact amounts of food and/or supplement. Standard operating procedures (SOP), as much as theory, became significant in the success of a clinical trial. Safety standards and data integrity in clinical trials have improved dynamically since Lind's trials. Laws, which require a subject's informed consent and established governing bodies such as the FDA, have been implemented to enhance the safety of subjects and integrity of data (5). Roles of subjects as the main source of data have remained steady over time, but the roles of the scientific investigator team have changed to meet the standards of current clinical trials.

Current research on the roles of CRCs and CRAs

In clinical trials conducted today, roles of research team members have evolved and become specialized to such positions as clinical research associate (CRA), principal investigator (PI), and clinical research coordinator (CRC). Entities such as a sponsor and contract research organization (CRO) provide support to the research team. The sponsor, an individual or group of persons, initiates the conduct of the clinical trial but may or may not personally investigate the product (6). The sponsor is usually in charge of garnering the monetary funds to conduct the research (8). CROs are independent contractors or companies that are hired by sponsors to provide specialized services such as regulatory support, data management, biostatistics analysis, and quality assurance monitoring of the trial. CRAs act on the behalf of the sponsor to monitor the ongoing progression of clinical investigations from beginning to the end. The leader of the investigational research team at a site is the PI, who is solely responsible for the research team to adhere to the requirements outlined in the research protocol and applicable regulations.

CRCs work at the investigational sites under the oversight of the CRA and direction of the PI (6). CRC responsibilities most commonly include activities such as recruiting, screening, enrolling clinical study participants, organizing follow-up visits, dispensing investigational product, completing and ensuring the accuracy of regulatory documents, and ensuring that the clinical trial complies with Good Clinical Practice (GCP) guidelines; Good Clinical Practice is a set of international standards to be followed when performing research with human subjects (2). CRC roles often vary from one trial to another, depending upon the needs of the project, their ability, and the organizational structure of the investigational site. Although the PI is responsible for the conduct of a clinical trial, experts argue that the most pivotal person in assuring the success of the research is the CRC (7).

CRCs have an important role in resolving conflicts at study sites and assuring timely decisions within a study from the beginning to the end of clinical trial. CRCs act as liaisons between the different entities involved in a clinical trial. The CRC is on the front line, interacting with research subjects and their significant others, CRAs and other sponsor representatives, Institution Review Board (IRB) members, and other investigational site personnel including the PI. CRCs carry out the protocol required tasks at the site. From a PI's perspective, the CRC is critical to the success of a study and helps to ensure the forward progress of the research (7). It can be argued that the various duties of a CRC have outdated the title of Clinical Research Coordinator.

Research professional organizations such as the Association of Clinical Research Professionals (ACRP) recognize titles such as Clinical Research Coordinator, Study Coordinator or Research Coordinator for the people who work directly for the PI in all major aspects of a clinical trial (2). A CRC can be a nurse, physician assistant (PA), or other professional. They can choose to be certified via an accredited program or attend training programs offered by their employers, sponsor companies or professional training organizations. The diversity of CRC educational backgrounds and experience can be a positive tool to have during a clinical trial. Although diversity can be beneficial, the lack of unified standards required to become a qualified CRC has caused a gap between newly hired and experienced CRCs. Common standards such as a technical degree or professional degree is not required to work as a CRC.

CRAs have noted during the monitoring of clinical sites that many CRCs are placed into positions for which they are not qualified (9). Whether due to sense of a pride or in response to working independently without adequate support from the PI, CRCs often take on roles and responsibilities for which they have not been sufficiently trained. It is therefore imperative for

employers during the initial phase of hiring to identify necessary opportunities to increase clinical research education and training, clinical experience, and job retention. Though unified educational training of clinical research is improbable, core educational training will help decrease some of the education and experience gap sensed among hired CRCs (7).

Staff training is pivotal to the success and survival of any type of business. Training seeks to build knowledge and skills of an individual as well demonstrating commitment to producing excellent products. Training supplements the growth of the company and the individual by creating synergy between both with a common goal in mind. Training becomes particularly vital in a clinical trial because the safety of human subjects involved in the study and future treatment of patients is of critical importance. Untrained research professionals may be not only harmful to themselves but also to the people they encounter in their daily work activities. Even though there are specific documentation requirements for education and training of PIs, the CRCs have not been subjected to similar inspection (9). This can be attributed to the FDA lesser qualification requirements for CRCs while providing more strict standards for PIs

Most CRC training is completed informally at study sites. If formal training is offered and pursued, teaching is often done through small workshops or web based programs that are too short, or not focused enough to be effective (9). A survey conducted by ACRP in 2005, revealed that CRCs enter their field with varied clinical experiences and that most CRCs, themselves, feel that they are inadequately trained (4). Thus, it is agreed by CRCs and other research professionals that training of newly hired CRCs is insufficient, which has led to the experience gap seen.

Some coordinators, if fortunate, will have valuable experience from working with generous mentors at clinical research sites, while other coordinators are experts in specific

medical fields but do not have the adequate clinical research backgrounds. Even with the growing number of research training programs available to CRCs, there is lack of initiative taken by research institutions to provide such educational opportunities to their employees. Because of the lack of research on CRC's roles, duties, and core necessary skills, research companies are finding difficulties in identifying the effective research training programs. However, such effective training is a definite necessity to the success of a clinical trial. There are common strategic approaches to ensure efficacy of the teaching programs regardless of the specialization of research professionals.

Significance of SOPs

A strategic approach to ensuring core training of clinical research professionals starts with identifying the standard operating procedures (SOP) of the organization. SOP training can be an effective catalyst to drive employee performance improvements and increase company production (11). Clinical Trials SOPs are defined by the International Conference on Harmonization (ICH) as "detailed, written instructions to achieve uniformity of the performance of a specific function"(15). SOPs are required for all research institutions including a pharmaceutical company, a sponsor, a contract research organization, and Ethics Committee/IRBs. SOPs are intended to standardize practice while increasing the safety and efficiency of the work performed. For a training program to be most valuable, the significance of current SOPs developed by the research organization should be researched, evaluated, and incorporated into training programs.

There are many tools used to determine the effectiveness of a training program. The main goal of most training programs is to develop highly qualified employees that can efficiently

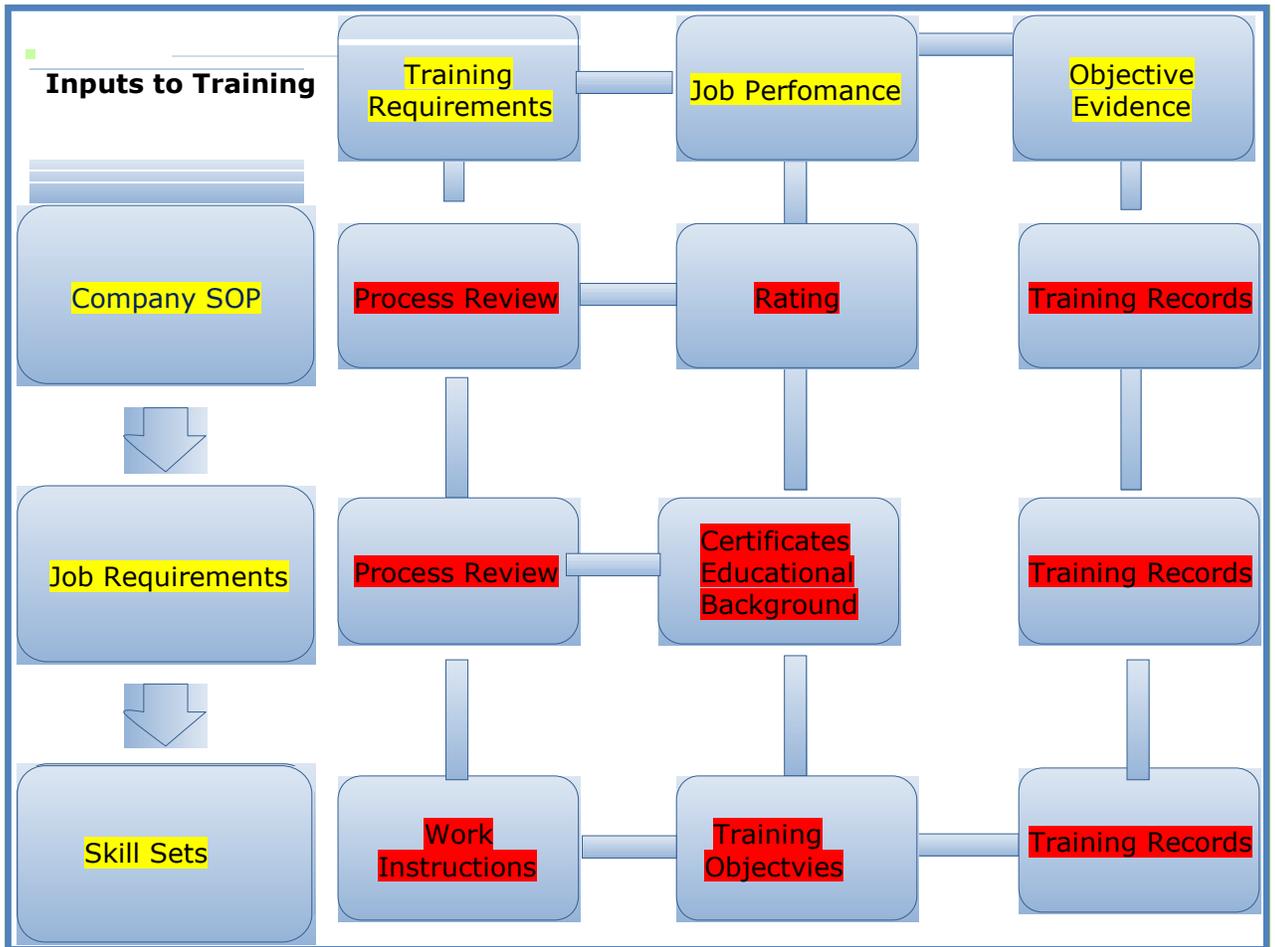
produce quality products or services. One of the most valuable tools utilized on-site to train and measure the progress of research professionals is process mapping (13).

Tools to measure employee competency

Process mapping is created with various input elements in order to measure criteria such as training requirements, training objectives, job performance (includes goals and objectives) that are labeled horizontally with other input elements such as company's SOP, job requirements, and necessary skills sets labeled vertically. With the utilization of a process map, employees and/or managers can record and document progress of an individual employee as an output labeled in the center of the process map. From such a map, employees' on/off site training and effectiveness can be analyzed and studied for future benefits. An example of a process map (Figure 1) for a research professional is illustrated below.

Figure 1. Example of Process Map

Key: Criteria inputs to be measured = yellow, Output employee results of criteria = red.



Process mapping can be an exceptional method for data collection, identifying job duties and responsibilities by clearly defining the work process and describing employee’s specific actions. It offers a systemic view of work history, allowing managers to visualize each employee’s work in the context of the complete workflow and interactions with others rather than only focusing on the work of one person at a time.

Advantages of process maps include synthesis of new ideas for the development of future training programs as well as a system to measure and document current performance level of research professional training. The process map can be modified to reflect specific business activities and to use training as a link to other processes in the quality system. While FDA regulators will not be auditing career development, these activities will most likely pay for themselves in reduced training costs due to turnover. The map provides a way of linking training to the entire quality system of a company. Mapping also highlights gaps and opportunities to improve the quality system (13).

Necessary elements of effective training programs

However, there are additional commercially available training programs to supplement training of research professionals outside of the work place. Abby Dionne, an expert in pharmaceutical sales training, lists criteria that can be followed in order to ensure effectiveness of any research training in commercially available programs (3). These are summarized below.

Step 1: Getting Started

First, the overall goal of the training program should be clearly defined. Goals can be listed through questions and answers about research needs during the trainers' meeting. Long-term and short-term goals for the training sessions should also be addressed. Questions on the expertise of trainers should be considered. A consensus among research professionals is to seek trainers that have clinical research experience more than full-time trainers, who are not readily able to provide cases for application of training (1). Mundane or repetitive training exercises

should be addressed, minimized, and replaced by specific real-life case activities in order to enhance the critical thought process of the trainee.

Step 2: Discoveries and Definition

Step 2 is as an extension of step 1. During discovery and definition, an open dialogue session is conducted so that the training team can identify potential opportunities to engage the trainees. The SOP of research companies for whom the training is intended should be identified to guarantee that the training team knows skills to teach. For example, when a trainer is teaching from experience, he or she should never reveal exact company or individual names in order to protect confidentiality. During training sessions, students or trainees will find it more beneficial to hear the thoughts of experts from various fields of research. Being familiar with overall ideas and schemes of research will enhance the trainees' knowledge and experience. The trainee will learn the significance of their place in the overall process of clinical research. Thus, the trainee will have a better appreciation of roles involved in a clinical trial.

Step3: Design and Development

During the design and developmental phase, thoughts, ideas and verbal communication between the training team is put into visual form. Writing, correcting, and documenting are done. The tactical infrastructure of the training programs is designed.

Step 4: Implementation and Maintenance

During the implementation and maintenance phase, the training program is conducted and then followed by an analysis of the training program's effectiveness. During the post analysis, program's insufficiency should be highlighted through the examining post-surveys that were administered to the students. The trainer should anticipate and be flexible to changes that need to be done in order for the training to be most effective. After the post analysis, expectations of the training programs should be evaluated in order to improve cost, efficiency and effectiveness of future training programs.

Because of the need to identify core research skills for CRCs and CRAs, to find proper off-site training programs available for research companies and to design an effective training model, the specific aims of the study were the following:

Specific Aims

- 1) To define the roles of CRCs and CRAs according to the information reviewed in clinical journals and gathered from MedTrials employee interviews and questionnaires.**

To address this specific aim, Industry journals were reviewed such as: *The Monitor*, *Focus* and *Applied Clinical Trials*. The scope of the search was limited to journals published from January, 2002 to present. A list of all roles and responsibilities of CRCs/CRAs mentioned in the journals was constructed. Then, the roles and the duties listed on the ACRP website were compared and contrasted. Questionnaires and surveys for MedTrials employees were designed and created in order to evaluate current and future trends in positions of CRCs and CRAs. The information from questionnaires, interviews, and journal articles was analyzed, and then a table of the top ten roles of CRCs and CRAs was constructed. Similar roles between the two positions were noted, documented, and summarized in to a table for the top five overlapping roles.

- 2) To design and organize MedTrials' SOP training modules through PowerPoint® presentations and associated quizzes. To design surveys for employee in order to illustrate expectations and measure the effectiveness of the SOP training program.**

To address this specific aim, All SOPs of MedTrials were mapped out and tracked using GroupWise ®. Then using current SOPs, training modules for employees were created.

Existing quizzes were used as a base to design new and revised quizzes for current SOPs. The effectiveness of the training module was enhanced by creating an audio portion of the SOP procedures to give employee learning options.

Post-presentation evaluation survey for the SOP training modules were designed in a multiple-choice format with rating scales. Extra columns were designated in the surveys for the employees to write additional comments or concerns. Surveys were administered to participants after PowerPoint® presentation, self-study review, and the completion of a quiz.

3) To compare and contrast the training program used at MedTrials to commercially available programs in order to suggest proper training tools to train clinical research professionals.

To address this specific aim, training sessions offered to MedTrials Employees on basic and intermediate GCP (Good Clinical Practice) courses were analyzed. MedTrials training programs were then compared and contrasted to commercially available CRCs and CRAs training programs. Subject, time and cost of training programs available to research professionals were analyzed. From such data, a model was proposed to be used as a tool for the training of clinical research professionals.

Significance

Core knowledge assessment and training of clinical research professionals, such as CRCs and CRAs, has yet to be standardized in the clinical research industry. However, there is a general consensus among research professionals that CRCs and CRAs are performing additional duties for which they are not adequately trained. This internship practicum report provides guidelines to build upon the current information about research professionals, which then can be utilized for the professional development of new CRCs and CRAs. Constructing a list of core knowledge and skills for research professionals (e.g., CRCs and CRAs) can assist the design and development of strategic initiatives to build more effective training programs. MedTrials training modules provide a model for industry-standard programs to study and diagnose for effectiveness. Overall, the practicum report provides clinical research organizations and clinical researchers with an appreciation for the need for effective training. SOP training programs developed met the specific needs of the MedTrials employee. Surveys and quizzes were given to measure the effectiveness of such training. From the data gathered, we attempted to clarify some positive and negative methods of training clinical researchers. Because clinical research regulations and training can be unfamiliar to the general public, we hope to interpret and clarify some trends and misconception of the research industry. Because CRAs and CRCs are significant to the approval and success of medical products, their positions should include standardized elements in training on-site and off- site. This practicum report tabulated and reviewed the current standards and compared it to the future demands clinical research.

Materials and Methods

Researching journals for roles of CRCs and CRAs

In order to properly define the role of CRCs and CRAs, clinical research journals located in the library of MedTrials office were searched for appropriate articles. The journals utilized were *Focus*, *The Monitor* and *Applied Clinical Trials*. The search included journals dating from January, 2002 to December, 2008. Research time was properly distributed to cover an adequate number of journals; inclusion of journals was limited to ten. In order to define the roles of CRCs and CRAs, journals were scanned for titles on the cover page, index topics, and key words. Articles with headings and key words such as coordinator, auditor, CRC, CRA, CRO, associates and tools were reviewed as well as any journal discussing the various aspects of the research team and responsibilities of each member involved. Since *The Monitor* is a journal mainly dedicated to the work of CRCs and CRAs, it was searched first, followed by a search of *Focus*, a journal dedicated to current FDA regulations with recommendations to readers of ways to properly follow research practice guidelines. Lastly, *Applied Clinical Trials*, a journal which focuses on defining various research positions and providing resources such as the different types of training programs available to research clinicians, while also reviewing current trends in research, was searched. A listing of all roles of CRAs and CRCs found in the articles were compiled and reorganized for simplicity. This list of roles was supplemented by the data gathered from MedTrials employee interviews and questionnaires which were all recorded onto an Excel® spreadsheet with references noted. The roles were then trimmed and organized in to a

list of the ten most significant roles of CRCs and CRAs. Then a list of overlapping roles was also prepared using all data. A listing of future trends, negatives aspects and future outlooks for the positions of CRA and CRC were also noted; these supplemented the information gathered from employee questionnaires and interviews, which was utilized in the discussion section.

Designing questionnaires and interview questions for participants

Questionnaires and interviews were developed and given to MedTrials employees that had work experience as a CRC and/or CRA during their careers. The questionnaire was limited to 5 questions pertaining to each role so that employee would have an adequate amount of time to answer the questions. The questions included identifying the top five roles of their positions, identifying overlapping roles, evaluation of training programs available, and providing census on future job outlook for CRCs and CRAs. The surveys/interviews were given to 20 employees that had a background as a CRC and/or CRA. Names of participants were excluded from the records to provide unbiased perspectives as well as keep the workers' identities confidential. Topics such as on-site training, roles, and future trends were addressed and asked to MedTrials employees because many had the privilege to have experience with multitude of research positions. An example of the questionnaire is included (Appendix 1). The employees had the option of hand writing or typing their answers. Interviews were recorded onto a recorder, which was then transferred from audio to written version to be included in the results.

Creating SOP training modules

In order to construct on-site-training modules for Med-Trials employees, PowerPoint presentations were designed to cover SOP topics. Eight PowerPoint presentations were designed on the SOP topics: **Protecting Client Confidential Information, Regulatory Review, Escalation Procedures, Research Personnel Training, Monitoring the Informed Consent Process, IND Safety Reporting, Conducting Site Initiation Visits, and Conducting Site Closeout Visits.** The quality assurance department at MedTrials carefully chose these topics because such topics were significant to the enhancement of core skills of all employees. It was not possible to make training programs for all SOP topics because length of time of the internship was a limiting factor.

Each of the SOP presentations included sections such as *Introduction, Self Study Module Overview, Background Information, Definitions and Terminology, Purpose/Scope, Responsibilities, Procedure, Associated Forms/Tools/Templates, References, and Comprehension Check* with a quiz and survey.

The PowerPoint® presentations were created in a manner to efficiently teach core procedures to employee in order for them to effectively do their duties. Supplemental guidance resources were included in the presentation to enhance subject background knowledge and promote the discussions of current topics while also providing websites and articles for references. All aspects of the presentation were created in bullet points to make effective and lucid points. Self-study audio learning modules were constructed in a flowing manner to provide employee with extra options to enhance their learning experience.

Quizzes for each of the eight SOPs were either created and/or edited from previous quiz templates on the topic in order to test the effectiveness of teaching. Most quizzes consisted of 4 questions in a multiple-choice format with greater emphasis on procedural aspects as compared to basic definition testing. Post-presentation surveys were attached in addition to quizzes on PowerPoint presentation slides to be easily accessible for MedTrials employees. Post-presentation surveys served as a feedback tool to compare employee and company expectations of SOP training, so that better methods, if needed, could be created to properly teach the necessary content.

Analyzing off-site training programs for CRCs and CRAs

In order to analyze training programs offered at off-sites within a classroom setting, the Basic GCP and Intermediate GCP Courses offered at the MedTrials site to employees and outside research professionals were analyzed. The courses were chosen because of accessibility and significance of core knowledge included in the presentations. The two days GCP training sessions, course work, presented topics, cost and teaching style were evaluated to understand the effective and less effective methods of teaching research professionals.

Sandra York, a MedTrials employee, conducted the Basic GCP course over two days in June 2008. Copies of all slides were included in a handbook with side margins available to make notes. Topic taught included Introduction to Good Clinical Practice, Good Science, Product Development Overview, Clinical Research Team Roles and Responsibilities, Principles and Process of Informed Consent, Regulatory Documents, Sponsor Visits, Adverse Reporting, and FDA Bioresearch Monitoring Program. Each section also included self-quizzes, in matching or

multiple-choice formats. The lectures were taught in a conference room in an informal manner to five research professionals, including myself. There was adequate time given for questions and answers as well as real life examples on certain topics shared by the instructor in order to highlight significance of GCP in clinical research. The final session concluded with evaluation surveys given to all participants.

Todd Almarez, a MedTrials employee, conducted the intermediate GCP course over two consecutive days in the company training room. Copies of all slides were included in the participant manual with side margins available to make notes. Topics taught were Intermediate Regulatory Review, Understanding a Protocol, Protocol Non-Compliance, Site Performance, Introduction to Data Management, Detecting Fraud and Fabrication, and State Regulations for Clinical Research. The instructor taught in a question-based lecture format where he would introduce a question to the class pertaining to a topic, then follow up with FDA regulation and facts to answer each question. The instructor also highlighted current trends such as electronic CRFs versus written CRFs and the benefits and negatives of both. Several research professionals from all over the country were at the session. The final session concluded with evaluation surveys that were given to all participants.

In order to evaluate the effectiveness of commercially available CRC and CRA training courses, Barnett Education Services course catalog was searched. Beginner CRC and CRA training sessions were reviewed. It was chosen because the topic seemed significantly related to CRC and CRA roles and duties. Course information within the catalog, Barnett Customer Service email and phone numbers were utilized. Roles of CRCs and CRAs and effectiveness of training were analyzed to see if the training would enhance onsite training and to what level of

research professional experience would be needed for the sessions to be most beneficial. With regards to MedTrials' GCP Course and Barnett Educational Services Training Course, topics such as cost, duration of session, significance, and teaching style were evaluated, and then listed onto a table for side-by-side comparison.

Results

Roles of CRCs and CRAs

In formulating a list of roles of CRAs and CRCs, an Excel Worksheet was utilized that included references of journals and interviews. A list of 30 roles for CRAs and CRCs was generated from the review of 6 research journals and 1 ACRP Certification Guide for research professionals. Even though more than 15 journals were searched, less than half had relevant information about the roles of CRAs and CRCs. Much of the information about the different roles of CRAs and CRCs was gathered from the 2 interviews (Appendix 8 & 9) and 10 Questionnaires (Appendix 6 & 7) given to participants from Med Trials.

CRAs tasks found from the interviews and journals paralleled the recommendation made by mostly GCP guidelines summarized by the FDA. CRAs have roles such as protocol trainers, source document verifiers, site auditors, research consultants, problem anticipators, and liaisons between site and sponsor; MedTrials employees in their interviews listed such responsibilities at multitude of sites at a given time. Table 1, a list of top ten roles of CRAs, was created from a list of 25 different roles found about CRAs from review of the literature and interviews..

The data showed that CRCs tasks mainly involved patient safety and the integrity of data gathered. CRCs have roles such as protocol experts, patient protectors, effective communicators of informed consent to subjects, and managers of their sites. Previous unknown roles of CRC found include constructing creative methods to enroll subjects into clinical trials and acting as first line of defense to adverse events. Table 2, a list of top ten roles of CRCs, was created from a

list of 32 different roles found about CRCs through the participant interviews and research articles.

Table 3 summarizes the overlapping roles of CRAs and CRCs, which include patient safety, protocol expert, enrolling subjects, ensuring GCP, and reporting of protocol deviations. A supplemented role that was not included in the top five list but could have been added was being an auditor of source data, which was mentioned by participants as necessary tools that CRCs can utilize as well CRAs who regularly perform such function.

Creating SOP training modules

Eight PowerPoint presentations created on the topics **Protecting Client Confidential Information, Regulatory Review, Escalation Procedures, Research Personnel Training, Monitoring the Informed Consent Process, IND Safety Reporting, Conducting Site Initiation Visits, and Conducting Site Closeout Visits**, only the presentation **Escalation Procedures** is illustrated in the practicum report (Appendix 2). The presentations were organized with sections that include topic introduction, presentation overview, background information, definition of key words, the purpose of training, the responsibilities of the different departments, the forms to fill out, references, and a comprehension check that included a quiz and survey. A typical quiz had 3 to 4 questions, which mainly asked employees about the roles of different department and the procedure to follow for the specific SOP. Example of the SOP quiz (Appendix 4) on **Escalation Procedures** is included in the report

The post-presentation survey created was generic for all SOPs and included scales for employees to rate objective, organization, length and effectiveness of the presentation. It also included a question that asked participants to give their opinions of topics, which may have not

been included but should be discussed in future SOP topics. An example of the survey is included in the report (Appendix 5).

The audio presentation option was included in some of the SOP presentations. It was constructed in conversational manner, which allowed employees to listen to the presentation without actually looking at the slides. Both the PowerPoint® presentation and audio presentation covered the same topics and depth but audio presentation was given in flowing manner. An example of the audio transcript of the SOP topic **Escalation Procedures** is included in the report (Appendix 3).

Comparing off-site training programs

A table comparing MedTrials GCP course and Barnett Educational Service's Beginner CRC/CRA training course was constructed and shown in Table 4. The topics included in the table were cost duration, offered times of course, significance to student, location and teaching style of trainers. Barnett Educational Services offered same duration of training, similar cost but more times and locations to attend with different teaching styles. They offered multiple lecturers and one on one situational reviews of topics, while MedTrials offered more group discussions and exercises.

Table 1.

Top 10 Roles of a CRA

CRA Roles	Number of References
Patient Safety Monitoring	3
Protocol Training at Site	3
Source Data Verification	2
Ensure GCP	2
Protocol Submissions	2
Communicating with Site and Sponsor	2
Site Overseeing/ Management	2
Regulatory Document Management	2
“Expert” on Clinical Trials	2
Proactive/ Anticipating Problems during the Study	2

Table 2.

Top 10 Roles of a CRC

CRC Roles	Number of References
Patient Safety	5
Ensuring Regulatory Compliances	3
Collecting Valid Data	3
Conducting and Explaining Informed Consent	3
Completes Case Report Forms	2
Enrolling Subjects	2
Protocol Expert	2
Gather Information During Adverse Event	2
Coordinating CRA Site Visits	2
Facilitates Communications IRB, Sponsors, and CRO	2

Table 3.

Top Roles That May Overlap Between CRAs and CRCs

Overlapping Roles	Number of References
Patient Safety	8
Protocol Expert	4
Enrolling Subjects	2
Ensuring GCP at site	2
Reporting Protocol Deviations	2

Table 4.

Comparing MedTrials GCP training to other Commercially Available Training Programs

Topic	GCP Training	Other Commercial Training
Name:	Basic/Intermediate GCP Training	Beginner CRC & CRA Training
Company:	MedTrials	Barnett Educational Services
Cost:	\$1500.00	\$1695.00
Duration:	2 days (8 am- 5pm)	2 days (8 am- 5pm)

Offered Time: 4 times a year

10 times a year

Significance: in-depth review of GCP

Ethics in Clinical Research

Historical and Global Regulatory Perspective

provides in depth survey of roles

of CRC & CRA, mechanic of FDA

audit, strategy on recruitment,

adverse event reporting

Location: Dallas, TX

San Diego, Philadelphia, Orlando

Chicago,

Teaching Style: Interactive Exercises, Group

Discussion, Creating Posters,

End of Chapter Quizzes,

Cases, One Lecturer

Adverse event exercises, Jeopardy

Game, Lecture Format, Situational

Reviews, Multiple Lectures

Discussion

The main objective of the report was to clarify roles of CRCs and CRAs, list possible overlapping roles among the positions, create effective SOP training modules for MedTrials' employees with included quizzes and surveys, and compare and contrast off-site training vendor in the field of clinical research. The data was gathered from one-on-one interviews, participant questionnaires, searching journal articles for clarification of CRC and CRA roles, creating training presentations, and information gathered about off-site training via research websites and phone conversations.

Developing the roles of CRCs and CRAs

In attempting to clarify the roles of current CRCs and CRAs, it became clear that both positions require an individual who must be able to multi-task because of the flexibility needed to perform their work properly. Although the PIs have historically held the leadership position at clinical research site and as main directors of the study, CRC roles at times may contribute more to the progress of the study. While trying to assemble a list of top ten roles of the CRC from employee interviews, questionnaires and information gathered from clinical research articles, a multitude of roles was discovered which were astonishing. No one resource searched provided a clear-cut duty of a typical CRC, but necessary skills consistently mentioned were good communication and protocol and regulation expert. Some CRCs had worked on single studies and dedicated a majority of their time on study visits of the subjects and management of the clinical trial with an experienced PI, who offered CRCs greater assistance in gathering data and

ensuring patient safety. In contrast, other unfortunate CRCs were given unreasonable workloads on multiple studies with inadequate protocol training that included overwhelming additional tasks such financial budgeting and handling laboratory specimens. Thus, such evidence of vast responsibilities provides possible reasons for the high turnover rate of CRCs measured in recent years.

When entering a study, a new CRC should expect to work on all aspects of studies. To overcome such challenges, a new CRC should be ready to require further assistance in their work. Before entering a new study, a CRC should work with the PI to estimate their individual workload. It is in workloads that current CRCs cite as a reason for work anxiety that leads to the increase pressure of their positions. In the participant interviews conducted, many MedTrials employees, whom were previous CRC, had inconsistent perceptions of their job responsibilities prior to the start of a Clinical Trial. Most CRCs displayed enthusiasm in the ability to help subjects but were unclear regarding their workload prior to the beginning of study.

In order to decrease the turnover rate of CRCs during a study, Sponsors and PI should increase the promotional opportunities and occasions for positive recognition of CRC contributions. Instead of burdening the CRC with all responsibility of trials from the start of employment, additional tasks should be added in the later stage of professional development. Sponsors and PI should also be more aware of the complexity of the protocol of studies. They should formulate reasonable expectations for CRC to accomplish in order to decrease the current workload discrepancy felt by CRCs.

Roles of the CRA

In trying to compile the top ten roles of CRAs, there was an obvious trend that most CRAs came to their position from working as seasoned CRCs. Even though the roles of CRAs are more defined compared to those of CRCs, the CRAs take on much responsibility that overlap with those of CRCs, such as Patient Safety. Most CRAs consider themselves as experts of the clinical trial process. CRAs have the ability to participate and make strong contribution at any stages of clinical trials, though most prefer to monitor the trial from the beginning. MedTrials employees, known for being experienced in the clinical research process, frequently have the opportunity to replace other CRO and/or audit companies and significant contribution to the advancement of clinical trials.

Most CRAs are responsible for auditing multiple studies simultaneously. Their workload can be reasonable at times but they can experience an overload at other times. Each new day for the CRA may provide new adventure, unique challenges, and the need for relevant guidance by their clinical sites. Most CRAs find their jobs very rewarding because of the direct teaching and mentoring opportunities offered to them during their work. Experienced CRAs know which of their sites will need more guidance and positive encouragement and which sites are able to work more independently.

Effective CRAs consider the ability to anticipate problems and hurdles of clinical trial just as important as properly solving unintended issues once it arises. For example, while performing an internal audit of a clinical trial's regulatory documents, I was guided by several knowledgeable CRAs, who knew the sites and their PI more personally, on which sites to anticipate problems and audit more carefully. Employees at MedTrials create monitor visiting

reports to record and store after each site visit. They actively monitor the informed consent process, protocol deviations, case report form with source documents, storing of investigational products as well closing of all studies, which is a duty performed in collaboration with the coordinators. The great amount of detail verification may seem overwhelming to a new CRA, but an experienced CRA knows the practicality of following up on all discrepancies. The most important role shared by CRAs and CRC is patient safety. Not clarifying discrepancies, such as drug dosage, can place a subject in danger; a good CRC or CRA will be the initial individuals to notice such things.

New CRAs at MedTrials can expect to receive at least one month of formal training at sites before they start to monitor sites independently. Much of the requirement to becoming an effective CRA involves initially knowing federal regulation and good clinical practices. The start of their duties in a study can be an overwhelming process but if they are working with an experienced CRA, the transition can be made easier. A CRA is similar to a detective when working on a case; they need to be able to ask the right questions of coordinators and PIs. They have to establish good communication channels with the study sites. Their knowledge and monitoring skills are critical to the success or failure of a study. Every CRA develops their unique method for motivating sites to follow regulations and rules, but the cornerstone of success is open communication. The position of CRA can be branched to other overlapping positions, such as a in-house CRA and/or project manager. Project managers are usually experienced CRAs that act as mentors to CRAs, while in-house CRAs work at the organizational aspects of CRA duties. In-house CRAs handle the scheduling of site visits and storing of regulatory documents and usually travel less than conventional CRAs.

Developing training presentations

While designing training presentations of MedTrials SOP for employees, the main challenge was to be creative and effective. With the progression of technology in recent years, new research professionals expect more options in the learning process. Trainers have to find methods to bring relevance and entertaining ways to illustrate all aspects of their presentations. Designing SOP training modules was a team effort that included employee feedbacks, quality assurance collaboration and assistance of the information technology department. The eight PowerPoint presentations created for the practicum included audio options, background discussion, quizzes and surveys in addition to the traditional lecture slides. However, the training product still has not reached its full potential because effective training is an evolving process. Only after months of utilizing the presentations and measuring feedbacks from the employees can final formats of the presentations begin to develop. The goals of an effective training presentation include employee accessibility, reinforcement of knowledge, practical case scenarios, and proper use of time. The quizzes, even though brief were utilized by employees in order to demonstrate their ability and measure their knowledge of key procedural aspects. Length of time, which can be overlooked during training, is pivotal to teaching the core messages of a presentation. The employee must be able to trust that their time and efforts are utilized during the training to carefully learn the aspects that will bring relevance and enhancement to their work, and it will not just be a way to regurgitate facts that can easily be searched via the Internet.

Comparing off-site training programs

When comparing training programs offered by MedTrials and other commercially available programs, the goal was to provide CRAs and CRCs good perspectives and expectations on training programs offered. Most training programs will provide the continuing education credits needed by research professionals each year, but training programs can provide extra benefits as well. Good training programs intended for research professionals will express and discuss the latest trends and regulation in clinical research deeply necessary to be known by research professional. Because clinical research regulation differentiate on details from state to state or even year to year, it is beneficial for research organizations to encourage their employees to attend necessary training programs to comprehend new information. The evaluation of training programs offered by Barnett Educational Services and MedTrials revealed that there were active learning methods in both programs that offered participants multiple options to learn through interactive techniques. Training methods offered presently still mostly use the lecture-format as the foundation of teaching but many have come to integrate technological and group interactions as a way to connect with the younger generation of professionals that have grown up with the internet. The best trainers offer collaborative options to the student where they can actively perform tasks themselves. This was a concern cited on the interviews and questionnaires by some MedTrials Employees as one of the major flaws of some research training programs. Even when teaching the history of GCP and regulations, instructors have to prove practicality of knowing such information. The instructor, while teaching the intermediate GCP course, encouraged our student group to produce different examples of daily activities where the topic discussed could bring relevance. Instead of taking the classical role of a teacher, who reports an overhaul of tedious facts to his students, he facilitated the active participation of student by

learning from each other through tales of research experience. This proved to be beneficial because everybody seemed to have a role in the learning process.

In the end however, it is not just the research professionals themselves that decide if training programs are cost and time effective; Sponsor, managers, and/or research companies also play pivotal roles in making the decision to encompass additional training options. A company must research and evaluate the effectiveness of training program based on their current needs as a company to continue to grow. MedTrials employees pride themselves in their experience and their employees' ability to adapt and produce success in the changing environment of clinical research. For them continuing education is a necessity to achieve their goals. They actively encourage their employees to not only attend training sessions but also integrate their knowledge and skills by becoming trainers themselves.

Summary and Conclusions

The goal of the practicum report was to elucidate the roles of CRCs and CRAs, the importance of acquiring core research skills, and the various types of training programs available to them. CRCs are consistently involved in numerous roles at study sites and at times may sense an overbearing amount of responsibilities, while CRAs act as consultants to sites and sponsors, are experts on clinical trials, and mentor the learning process of researchers. The growth of the CRA job market seems to be increasing due to high job satisfaction, high salary, and personal connection offered in their position. The high turnover rate of CRCs illustrates the fact that the CRC's work load and job satisfaction needs to be reevaluated by sponsors and site managerial positions. However, it is clear that both positions require core training in good communication, leadership development and research knowledge for successful clinical trials. Research trainers need to adjust to the learning styles of the younger generation of research professionals in order to bring effective teaching methods to their programs. Having a thorough knowledge and experience of GCP and Federal Regulations is the foundation to becoming great CRCs and CRAs. MedTrials' philosophy is to produce excellent products and services through effective employee training and teaching. Ensuring safety is the greatest goal of research professionals even more significant than success of research products. The only way to achieve this objective is to thoroughly train and teach research professionals core clinical skills. SOP training provides on-site outlets to practice and implement new teaching methods to enhance the learning experience of participants. While deciding on proper off-site training vendors for research professionals, companies must carefully evaluate the different aspects of training programs for benefits and drawbacks such as cost, duration, and significance to company progress.

Chapter III

Internship Experience

MedTrials is a contract research organization that is organized into different departments such as Business Operations, Clinical Operations, Data Management, Biostatistics, Information Technology, Training and Quality Assurance. During my internship, I organized and evaluated paper and electronic copies of MedTrials' SOPs in order to assure that they meet guidelines such as correct version, properly written, dated and signed. I designed a map of SOP-related documents and forms to create a reference tool that employees can utilize to better understand their job duties and responsibilities.

Training modules were designed and constructed in PowerPoint programs with quizzes attached to help employees learn and measure their understanding. Surveys were given to MedTrials employees before and after training sessions to address the training programs' expectations and concerns.

While working with individual CRAs on monitoring their projects, I learned the latest skills and trends in auditing required to be an effective research professional. The knowledge gained was utilized to construct the final thesis report on the core necessary skills of current CRCs and CRAs. I assisted with internal audits in order to better understand the regulatory and contractual requirements in managing clinical trials. General duties of mine provided a depth of knowledge about Clinical Research Management; this included assisting with the maintenance and compliance review of regulatory files, training materials and clinical trial management documentation.

Journal Summary

This journal represents my weekly activities at MedTrials Inc. I have chosen to include all activities from attending GCP course to auditing regulatory documents. I talk about my interaction with MedTrials Employees. I have included a detailed recollection of my time as an intern and showed my progression in learning. The journal is found in Appendix B.

3) List your last commercially available CRA training course taken?

a) Effectiveness of Training (1-5, 5 being most effective) and Why?

___/5 ranking because_____

4) How long was your onsite CRA training before work was performed independently?

_____ months _____ years

5) Was there any time during your position as CRA that you felt you were doing someone else's work. If so, describe the task and who should have been responsible otherwise?

CRC

6) Top five roles of CRCs (in your opinion).

1)

2)

3)

4)

5)

7) Role(s) that may overlap with other clinical research professionals (in your opinion).

8) List your last commercially available CRC training course taken?

a) Effectiveness of the training (1-5, 5 being most effective) and Why?

___/5 ranking because _____

9) How long was your onsite CRC training before work was performed independently?

_____ months _____ years

10) Was there any time during your position as CRC that you felt you were doing someone else's work. If so, describe the task and who should have been responsible otherwise?

*)Where do you see the future responsibilities of CRAs and CRC going? Do you think their roles will expand, constrict or stay the same? If change, then what kind of change do you anticipate?

Appendix 2. This is (one of eight) a Power-Point Presentation created for SOP training. This presentation specifically was about Escalation Procedures.



Self Study Module Introduction

MedTrials
Helping the World's Leaders of Global Research

- This self-study module covers important information and highlights of the SOP. Staff members are expected to review the entire SOP carefully and seek clarification from management or QA representative if needed.

Click here to link and review the SOP:
****_***

- All current versions of approved SOPs/WPGs may be accessed in the GroupWise QSM find folder [see screen shot at right]

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Self Study Module Overview

MedTrials
Helping the World's Leaders of Global Research

- Background Information
- Definitions/Terminology
- Purpose/Scope
- Responsibilities
- Procedure
- References
- Associated Forms/Tools/Templates
- Comprehension Check

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SOP_**_*** Background Information**

MedTrials
Helping the World's Leaders of Global Research

- The benefits to company of having research personnel participate in problem reporting system are substantial and obvious.
- Conversely, failure to participate in a reporting system can result in dangers remaining unknown and potentially harming client, research personnel, and/or participating subject.
- Currently in the U.S. compared to other countries, there is under-reporting of adverse events and/or non compliance.
- Reason for under-reporting include lack of awareness, fear of legal liability, and uncertainty of effects.

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SOP_**_*** Definitions and Terminology**

MedTrials
Helping the World's Leaders of Global Research

- Research (Scientific) Misconduct:** Fabrication, falsification, plagiarism, and other practices that seriously deviate from those which are commonly accepted in research industry.
- Research Noncompliance:** Failure to follow company standards and/or federal regulations.

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SOP_**_*** Purpose/Scope**

MedTrials
Helping the World's Leaders of Global Research

- To define procedure to escalate issues of concern to bring attention to *****
- ***** emphasizes the company's commitment to high quality and integrity clinical research and illustrates a strong commitment to legal and ethical standards of conduct.
- ***** is responsible to report acts of non compliance or issues that may impact the company to management.

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SOP-****_***

Responsibilities

MedTrials
Aligning the Art & Science of Clinical Research

- Project Managers are responsible for *****
- Department Managers are responsible for *****
- QA management is responsible for *****
- All employees should report violation *****

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SOP-****_***

Procedure

MedTrials
Aligning the Art & Science of Clinical Research

Insert VIDEO Link

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SOP-****_***

Procedure

MedTrials
Aligning the Art & Science of Clinical Research

- All personal should report*****
- Reporting should be followed through *****
- Project Managers will review and report *****
- Department managers will initiate *****
- QA management will ensure *****
- All issues will be reviewed *****

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SOP-****_***

Associated Forms/Tools/Templates

MedTrials
Aligning the Art & Science of Clinical Research

- MT-QA Doc # *****
- SOP-****_*****
- MT-QA Doc-****_*****

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SOP-****_***

References

MedTrials
Aligning the Art & Science of Clinical Research

- Electronic Records: Electronic Signatures (21 CFR Part 311)
- Protection of Human Subjects (Informed Consent) (21 CFR Part 312)
- Financial Disclosure by Clinical Investigators (21 CFR Part 312.63)
- Institutional Review Boards (21 CFR Part 312.61)
- Investigational New Drug Application (21 CFR Part 312)
- Foreign Clinical Trials not conducted under an IND (21 CFR Part 312.120)
- Forms 1571 (Investigational New Drug Application) and 1572 (Statement of Investigator)
- Applications for FDA Approval to Market a New Drug (21 CFR Part 314)
- Availability and Biobivalence Requirements (21 CFR Part 320)
- Applications for FDA Approval of a Biologic License (21 CFR Part 301)
- Investigational Device Exemptions (21 CFR Part 812)
- Premarket Approval of Medical Devices (21 CFR Part 814)
- Information Sheets: <http://www.fda.gov/oc/ohrt/rtist/>
- ICH E6 GCP Guidance: <http://www.ich.org/LOB/media/MEDIA422.pdf>
- http://www.fda.gov/oc/ohrt/rtist/rtist_report_C51.pdf (adverse event reporting in U.S.)

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SOP-****_***

Comprehension Check

MedTrials
Aligning the Art & Science of Clinical Research

Quiz- Escalation Procedures

Survey

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Appendix 3. An audio transcript of SOP training on Escalation Procedures.

SOP-****-****

Version 1

Title: Escalation Procedures

Self Study Module

Unit 1: Introduction

This is the self-training module for SOP ****-****, entitled Escalation Procedure. This self-study module is designed for you to complete on your own, either self-paced or for review. *Escalation Procedures* includes the reporting of noncompliance, serious noncompliance, research noncompliance and/or misconduct to management as a significant issue.

Currently in the U.S. compared to other countries, there is under-reporting of adverse events and/or non-compliance. Reason for under-reporting can include lack of awareness, fear of legal liability, and uncertainty of effects. The key to overcoming these hurdles is to realize and understand that ethical standard and reporting is need to protect patient, sponsor and all research professionals involved.

MedTrials Quality Management System(QMS) emphasizes the company's commitment to high quality and integrity in clinical research. Thus, all personal should comply with the ethical standard dealing with reporting any misconduct involving the company.

Objectives of this Module:

After you complete this module, you will be able to do the following:

- Properly report non-compliance issues to correct management department
- Know the process to review performance and progression
- Able to initiate corrective and preventive action for noncompliance in accordance with MedTrials QMS
- Collaborate with Project Manager and other employees to design a plan which will ensure proper investigation of all serious noncompliance issues
- Know responsibility of all company employees during non-compliance events

Key definitions you should know

- **Continuing Noncompliance** is the systematic and habitual disregard of company standards and procedures and/or applicable federal, state and local laws and/or ordinances as they relate to regulated activities
- **Research (Scientific) Misconduct** is fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the research industry for proposing, performing or reviewing research, or reporting research results. Misconduct does not include honest error or honest difference in interpretations or judgments of data.
- **Research Noncompliance** is the failure to follow company standards and procedure and/or applicable federal, state, and local laws as they relate to regulated activities.
- **Serious Noncompliance** is all noncompliance substantially affecting human research subject rights and/or welfare or impacting upon the risks or benefits.

Scope and Responsibilities

As a research professional you have to be aware of delegation of responsibilities during non-compliance. If a member of the employee team is unaware of their responsibility you have to help and encourage them to learn. If you have question regarding compliance, please refer to the project manager/lead.

It is the duty of [REDACTED].

[REDACTED] responsible for [REDACTED].

[REDACTED] are responsible for notifying [REDACTED].

[REDACTED] is responsible for notifying the [REDACTED].

- ✓ Effective compliance can only be achieved through a collaborative approach to clinical trial management and a commitment to ongoing, good communication.

Procedure you should follow in the event of non-compliance issue

5.1 [REDACTED]
[REDACTED]
[REDACTED]

5.2 [Redacted]
[Redacted]

Project Managers should:

5.3 [Redacted]

5.4 & 5.5: [Redacted]

Department managers will:

5.6 [Redacted]

5.7 [Redacted]

QA Management will:

5.8 [Redacted]
[Redacted]

5.9 [Redacted]
[Redacted]

5.10 [Redacted]

5.11 [Redacted]
[Redacted]

The Executive Committee will:

5.12 [Redacted]
[Redacted]

5.13 [Redacted]
[Redacted]
[Redacted]

5.14 [Redacted]

Summary of Procedures

Direction of Reporting

Employee → PM → DM → QAM → Executive Committee

PM+DM+QAM= Collaborates to ensure proper investigation

DM= [REDACTED]

QAM= [REDACTED]

PM= [REDACTED]

Employee= [REDACTED]

Executive Committee= [REDACTED]

Appendix 4. Quiz created for (1 of 8) SOP training module on Escalation Procedure. Answers are highlighted in yellow.

MT SOP Training Quiz

SOP- [REDACTED]: Escalation Procedures

1. Name

Please write first **and** last name

2. Project Managers have to report acts of [REDACTED]
[REDACTED]

Client

Quality Assurance

Department Manager

All of the above

3. Department Managers will solely [REDACTED]
[REDACTED]

True

False

4. Who will ensure that [REDACTED]
[REDACTED]?

All employees

COO

CEO

Quality Management

Appendix 5. Post presentation survey for all SOP training modules.

End of Presentation Survey

Name (optional)

Title of SOP: Escalation Procedures

Date

Please evaluate the following statements on a scale of 1(poor) to 5(Excellent)

Subject:

Main objectives met.....	1	2	3	4	5
Presentation met my expectations.....	1	2	3	4	5
The material length was appropriate.....	1	2	3	4	5
Quiz questions were appropriate.....	1	2	3	4	5
The presentation was organized.....	1	2	3	4	5
The presentation was effective.....	1	2	3	4	5
Extra Resources were made available.....	1	2	3	4	5

What topics would you like to see included in this SOP presentation?

What other effective training methods can be used to present this SOP?

Appendix 6. One of ten questionnaires created that was filled out by a CRA.

CRA/CRC Training Survey

Educational Background: Associates Bachelors Masters Doctorate
Professional Licensure/ Certification: LPN RN CCRA MD Other_____

Industry Experience: <2 years 2-3 years 4-8 years >8 years

Worked as: CRA (Questions 1-5) CRC(Questions 6-10) Both(All)

FOR CRA

1) Top five roles of CRAs (in your opinion).

- 1) Working for the protection of subjects enrolled in clinical trials
- 2) Working to ensure that the study is being conducted ethically
- 3) Working to provide accurate data for success of product
- 4) Being a good communicator and people person
- 5)

2) Role(s) that may overlap with other clinical research professionals (in your opinion).

I think that the roles of the CRA often overlap with a CRC. Many of the task that are undertaken at a specific monitoring visit often are task that the coordinator might have already done. Assessment of Adverse events and proper review of the medical record are 2 examples which are conducted by 2 individuals.

3) List your last commercially available CRA training course taken?

Advanced GCP

a) Effectiveness of Training (1-5, 5 being most effective) and Why?

4/5 ranking because the course was a re-enforcing of skills that I have already been taught. The new curriculum was more hands on and application then just memorizing dates and specific rules. A hands on approach is the best way for me to learn.

- 4) How long was your onsite CRA training before you started to work independently of a trainer?

_____4.5_____ Months _____ years

- 5) Was there any time during your position as a CRA that you felt you were doing someone else's work. If so, describe the task and who should have been responsible otherwise? I often feel that I'm doing the job of the CRC, but that is due more to the fact that the CRC is not doing his/ her job. When you arrive for a monitoring visit and nothing has been completed, you go through the steps of review for the subject's medical record to ensure that subject health is within range for his/her specific ailment. Often you aid the coordinator by pointing to data that needs to be completed and are reported to appropriate persons.

FOR CRC

- 6) Top five roles of CRCs (in your opinion).

- 1)
- 2)
- 3)
- 4)
- 5)

- 7) Role(s) that may overlap with other clinical research professionals (in your opinion).

- 8) List your last commercially available CRC training course taken?

Appendix 7. One of ten questionnaires specifically filled out by a person, who has been a CRA and CRC.

CRA/CRC Training Survey

Educational Background: Associates Bachelors Masters Doctoro
Professional Licensure/ Certification: LPN RN CCRA MD Other___
Industry Experience: <2 years 2-3 years 4-8 years >8 years
Worked as: CRA (Questions 1-5) CRC(Questions 6-10) Botl

FOR CRA

1) Top five roles of CRAs (in your opinion).

- 1) site management oversight – to include training requirements for IRB and protocols
- 2) ensuring regulatory compliance for GCP, ICH, and institutional standards
- 3) Safe guarding patient safety and well-being
- 4) Training to protocol and explaining the reasons behind the procedures
- 5) Regulatory Document Management – keep current and house originals

2) Role(s) that may overlap with other clinical research professionals (in your opinion).

?

3) List your last commercially available CRA training course taken?

ADVANCED GCP conducted by MedTrials

a) Effectiveness of Training (1-5, 5 being most effective) and Why?

...5_/5 ranking because this course explained both the FDA – GCP guidelines as well as the ICH guideline pointing out discrepancies – which is extremely important in the global research industry of today.

- 4) How long was your onsite CRA training before you started to work independently of a trainer?

_____ 1 _____ Months _____ years

- 5) Was there any time during your position as a CRA that you felt you were doing someone else's work. If so, describe the task and who should have been responsible otherwise?

FOR CRC

- 6) Top five roles of CRCs (in your opinion).

- 1) Informing the patient of their rights and responsibilities
- 2) Protecting the patient – avoiding excessive wait times, long procedure days,
- 3) Collecting valid data reporting it to the appropriate authorities
- 4) Inter-Rater reliability – we used subjective questionnaires and it was imperative that they all were conducted in the same manner
- 5) Good relationship with the PI, other research staff, and your patients

- 7) Role(s) that may overlap with other clinical research professionals (in your opinion).

?

- 8) List your last commercially available CRC training course taken?

Basic GCP

- a) Effectiveness of the training (1-5, 5 being most effective) and Why?

5_/5 ranking because introduction into the rigorous world of research

9) How long was your onsite CRC training before you worked independently of a trainer?

_____1_____ Months _____ years

10) Was there any time during your position as a CRC that you felt you were doing someone else's work. If so, describe the task and who should have been responsible otherwise?

No

*) Where do you see the future responsibilities of CRAs and CRC going? Do you think CRAs roles will expand, constrict or stay the same? If change, then what kind of change do you anticipate?

I believe the CRA and CRC roles will expand – as our economy gets tighter while our research continues to expand across the globe the level of responsibilities of all research personnel will escalate.

Appendix 8. One of two interviews conducted by participants. This interview was with Med Trials Employee who was a CRC

How long did you work as a CRC?

3.5 years

Where were the sites located?

One was in Florida for 1.5 year and the other was in Texas for 2 years.

What were some of your responsibilities as CRC?

I pretty much did little bit of everything from the beginning of the trail to the end of the trial. I oversaw much of regulatory paperwork and guidelines, communicated with patients about informed consent, filled out CRF, help develop budgets, and communicate with the IRB for proper approval

What was your most common mistake when you started?

Not having the depth on knowledge about regulation, such as importance of getting PI signature and dates on all important documents. This lack of knowledge is seen in many people that start as health professional then move to research.

Please rate your workload from 1 to 10 as a CRC?

It was 9/10 because of high turnover rate other CRC at site, which meant more workload.

How much training is necessary to become an independent CRC and what kind is important?

I think school training has become very significant in the past years, but currently the best form of training is offered at sites. However, the profession definitely needs standards such as certification exams.

What was your on-site training like?

Well I started to work independently from day one since; the PI that I was working with was also new to research. It became a very tough job, but I came out with much knowledge and few scars. It's more optimal to start off working next to an experience coordinator at bigger sites.

Appendix 9. Two of two interviews conducted. This was an interview with Med Trials Employee who is a In-house CRA.

What is your educational background?

Well I have a bachelor degree from UTD, I have worked as coordinator of psychology study for 1 year and am now working as in-house CRA.

What are some of your responsibilities?

Site management oversight – to include training requirements for IRB and protocols, ensuring regulatory compliance for GCP, ICH, and institutional standards, Safeguarding patient safety and well-being, and Training to protocol and explaining the reasons behind the procedures

What is the difference between In-house CRA and a regular CRA in your opinion?

The two involve different amounts of travel. CRA travels up to 80% of their time, while I (in-house CRA) am usually working from the office. I manage many more sites than a regular CRA. I am also more involved with different project managers on the planning aspects of different studies.

What is the biggest hurdle of being a new In-house CRA?

I think it's about making adequate time management. I have to be able to organize dates and times of different study activities to ensure that everything gets processed in time. I have to be able to communicate with managers on the problems and progression of studies. We also have to manage all of the study files that are sent from the sites to our offices to keep and hold.

How long was your training?

I received 2 weeks of formal training with a in-house CRA. After which I started to work independently.

What do you think is the future job-outlook for an In-house CRA?

I think the position of in-house CRA is in pretty high demand because of the increasing research projects that are in process. Companies need people to be able to organize and do different work to support regular CRAs. There are also different ways to move up to a higher position such as a project manager or a project lead.

APPENDIX B

Asif Ali

MedTrials

Intern/CRM

Internship Practicum Daily Journal

6/2/08

- Researched MedTrials Website for relevant information about company
 - MedTrials offers Monitoring, Auditing, Consulting, Training, Data Management, Project Management, Statistical Analysis

6/3/08

- Read Regulatory Affairs Journal, learned about FDA
 - FDA considers new research laws on certain criteria such as economic impact of laws, environmental impact
 - In National versus State Laws, if safety is concern then National Laws take precedence

6/4/08

- Learned about compliance reporting in the Regulatory Affairs journal Focus
- Example given of device
 - 1) Report incidence even if small
 - 2) Make photocopy of device for proof
 - 3) Even if no harm is done to patient, look for future adverse events, report all unintended events of the device
 - 4) Do a MDR (Medical Device Report) w/ in 30 days of incidents

6/5/08

- Learned about training methods in the journal Focus
- Training:
 - 1) is very important to ensure quality of research
 - 2) is best when 3d models are used
 - 3) have students teach each other
 - 4) Try to teach to all senses (hearing, doing, seeing, etc)
 - 5) Must be flexible

6/6/08

- Researched ways to avoid non-compliance in Focus
 - How to avoid Non-Compliance
 - 1) write all procedures and policies in clear manner

- 2) appoint a compliance committee
- 3) conduct effective training and education
- 4) communicate
- 5) have GMP (good manufacturing practices), which was historically seen as money waster but is now considered important for competitive companies

6/9/08

- Orientation
 - 1) Introduction with company overview, Office Manager via teleconference.
 - 2) Met staff, set up office work space, learned about copiers, fax, phones
 - 3) Quality Management System and Training
 - 4) Learned about computer login and GroupWise training with Jeremy Weaver

6/10/08

- Attended Beginning GCP Training day 1
- Introduction to GCP Training by MedTrials Instructor
 - 1) Purity, Safety, Effectiveness
 - 2) Belmont Report, Nuremberg Code
 - 3) Medical Device safety slower process
- Goals of Good Science
 - 1) Must have Checks and Balances between the different positions
 - 2) Have right question, of right person, at right time
 - 3) Randomize with appropriate methods
 - 4) Try not to break blind
 - 5) Follow protocol exactly
- Product Development
 - 1) Pre-Clinical (toxicology, Pharmacology) on Animals
 - 2) IND (form 1571) and Drug Development, Reviewed by CDER of FDA for both prescription and over-the-counter
 - 3) IND in effect 30 days after, updated annually
 - 4) Phase 1(Safety), Phase 2(Safety, effectiveness) Phase 3(long term benefit-risk assessment)
 - 5) NDA then phase 4 (Post Market Studies)

6/11/08

- Went to Beginning GCP training day 2, and received certification for attendance
- Roles and Responsibilities
 - 1) CRO (Contract Research Organization, Med Trials) is liaison between sponsor and site but also deals with the FDA
 - 2) FDA enforces law, had many subdivisions, provides guideline under CFR

- 3) ICH concerns with issues on international guidelines, Regulatory authority over Japan, U.S., European Union, and can be interpreted as being more specific than US regulations
- 4) CRA (Clinical Research Associate) monitors ongoing investigation process
- 5) Roles and responsibility can be transferred but has to be writing. However, PI is sole responsible of the investigation.
- 6) Clinical Research Coordinators assist PI, organizes, talks to sponsor, and usually does most work.
- 7) IRB (ethical review board) given power by FDA, can be hired, and has to have certain types of members (21 CFR 56)
- Informed Consent Process, where most mistakes happens. PI is responsible for it.
- Regulatory Documents, must keep records, all FDA forms, PI's CV, Shipping Records
- Monitoring Expectations
 - 1) Pre-study-Evaluating PI
 - 2) Initiation w/ protocols, and informed consent forms done.
 - 3) Monitoring- Ask and answer queries.
 - 4) Close-Out data collect, verified, product reconciled, final reports
- AE reporting and monitoring programs

6/12/08

- Did QA work for MedTrials
 - 1) Inspected SOP in GroupWise to make sure staff had current version & not old version
 - 2) Made sure SOP matched with Document#, title, version #, effective date

6/13/08

- Assembled new SOPs
- Placed SOPs in to folder
- Went to in-service presentation on Pharmacovigilance presentation
 - 1) It is post marketing surveillance on drugs filed under 314
 - 2) Can be biased, imprecise, limited but is still very important
 - 3) ADR is adverse event during post marketing

6/16/2008

- Standardized and updated SOP files
- Verified information was correct in SOP chronology files
- Read "The Monitor" December 2006 edition

6/17/2008

- Standardized and updated WPG files

- Verified information was correct in WPG
- Started Microsoft Excel Spreadsheet for Project” Contracting SOP and Training Log for Employee”

6/18/2008

- Standardized and updated in chronology files
- Verified information was correct in the forms
- Worked on spreadsheet for project and found some errors

6/19/2008

- SOP file administration
- Verified information was correct in the forms
- Worked on spreadsheet for Project/ found some errors

6/20/2008

- Put all folders in order
- Made sure information was correct and current
- Finished Spread sheet for Project

6/23/2008

- Worked on proposal
- Read The Monitor, Investigator’s Role
- Made new folders for unlabeled SOPs

6/24/2008

- Worked on new SOP folders
- Relabeled few SOP folders
- Went through to make sure that SOPs had proper signature

6/25/2008

- Worked on new SOP folders
- Relabeled few SOP folders
- Went through to make sure that SOPs had proper signature

6/26/2008

- Worked on spreadsheet for SOP Project and found some errors
- Relabeled few SOP folders
- Made sure SOP in QSM folders were properly titled

6/27/2008

- Developed on all SOP Tracker

6/30/2008

- Worked on Tracker

7/1/2008

- Finished Tracker
- Made notes of mistakes and errors
- Internship update meeting

7/2/2008

- Worked on SOP project

7/3/2008

- Organized new SOPs
- Worked on SOP project

7/7/2008

- Worked on SOP project
- Received Training on Internal Audit Report

7/8/2008

- Started working on SOP training specific for client
- Typed and verified SOP checklist document for client

7/9/2008

- Read SOP specific for client

7/10/2008

- Completed SOP Quizzes for client
- Helped organize files for client

7/11/2008

- Assisted with logging and tracking SOP and quizzes completed by MedTrials Employees

7/14/2008

- Meeting with clinical project team to discuss new project on auditing
 - Will perform internal audit of client files because MedTrials has been given responsibility for maintaining original study files
 - Received training for internal audit

7/15/2008

- internal audit of one site
 - Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site

7/16/2008

- internal Audit of one site
 - Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site
 - Checked for Signatures, Dates, Expiration Dates

7/17/2008

- Internal Audit of one Site
 - Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site
 - Checked for Signatures, Dates, Expiration Dates

7/18/2008

- Internal audit of a site
 - Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site
 - Checked for Signatures, Dates, Expiration Dates

7/21-8/1/2008

- Internal audit of a site
 - Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site
 - Checked for Signatures, Dates, Expiration Dates

08/4/2008

Developed PowerPoint training presentation on **Protecting Client Confidential Information**

- Made background information, definitions, procedures, responsibility, quiz, purpose scope

8/5/2008

Developed PowerPoint training presentation on **Regulatory Review**

- Made background information, definitions, procedures, responsibility, quiz, purpose scope

8/6/2008

Developed PowerPoint training presentation on **Escalation Procedures**

- Made background information, definitions, procedures, responsibility, quiz, purpose scope

8/7/2008

Developed PowerPoint training presentation on **Research Personnel Training**

- Made background information, definitions, procedures, responsibility, quiz, purpose scope

08/8/2008

Developed PowerPoint training presentation on **Monitoring the Informed Consent Process**

- Made background information, definitions, procedures, responsibility, quiz, purpose scope

08/11/2008

Developed PowerPoint training presentation on **IND Safety Reporting**

- Made background information, definitions, procedures, responsibility, quiz, purpose scope

8/12/2008

Developed PowerPoint training presentation on **Conducting Site Initiation Visits**

- Made background information, definitions, procedures, responsibility, quiz, purpose scope

8/13/2008

Developed PowerPoint training presentation on **Conducting Site Closeout Visits**

- Made background information, definitions, procedures, responsibility, quiz, purpose scope

8/14/2008

- Meeting to discuss Internal File Audit Update
- Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site
- Checked for Signatures, Dates, Expiration Dates

8/15/2008

- Absent/ Sick

8/18- 8/22

- Internal audit of site
- Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site
- Checked for Signatures, Dates, Expiration Dates
- Listen to Presentation by Robin from Media, Pennsylvania on Informed Consent Process

8/25/2008

- Meeting with Project Team-
 - Decide to finish up files audit by December

8/26/2008

- Excused Absence

8/27-8/29 2008

- Internal Audit of a site
- Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site
- Checked for Signatures, Dates, Expiration Dates

9/02/2008

- Internal Audit of a site,
 - Started to Check Gap in Expiration Dates and Follow up and inform monitor to get the required information

9/03- 9/04 2008

- Worked on PowerPoint presentations w/ editing and finding more back ground information, read Monitor and Focus

9/05/2008

- Internal audit of a site, Checked IRB Approval, 1572 Forms, Monitor Visiting Report, Protocol Approval, Informed Consent Approval, Financial Disclosure, Statement of Investigator, PI and Sub Pi CV, Lab Certificate, Lab Normal

9/08/2008

- Internal Audit of a site, Checked IRB Approval, 1572 Forms, Monitor Visiting Report, Protocol Approval, Informed Consent Approval, Financial Disclosure, Statement of Investigator, PI and Sub Pi CV, Lab Certificate, Lab Normal

9/09/2008

- Data Management Lock Down for Site, Performed Quality Control on Database vs CRF(Case Report Form)
- 100% of All Safety and Efficacy for 32 patients

Guidelines

- Performed on all subjects after review is completed and DCFs are applied
- DM/CDC to identify the safety and efficacy parameters as outlined by DMP
- DM/CDC to highlight the S&E fields on the study annotated CRF for the programmer
- Programmer to develop an S&E profile, as appropriate

Validate

- Circle, Sign and Date all mistakes

9/10/2008

- Data Management Lock Down for Site, Performed Quality Control on Database vs CRF(Case Report Form)
- 100% of All Safety and Efficacy for 32 patients

Guidelines

- Performed on all subjects after review is completed and DCFs are applied
- DM/CDC to identify the safety and efficacy parameters as outlined by DMP
- DM/CDC to highlight the S&E fields on the study annotated CRF for the programmer
- Programmer to develop an S& E pt profile, as appropriate

Validate

Circle, Sign and Date all mistakes

9/11/2008

- Internal Audit of a site, Checked IRB Approval, 1572 Forms, Monitor Visiting Report, Protocol Approval, Informed Consent Approval, Financial Disclosure, Statement of Investigator, PI and Sub Pi CV, Lab Certificate, Lab Normal

7-8:30 pm

- Attended a teleconferenced CC meeting with physician neurology specialists to analyze proper causality of adverse events in a clinical device trial. Also present were MedTrials employees.

9/12/2008

- Internal Audit of a site, Checked IRB Approval, 1572 Forms, Monitor Visiting Report, Protocol Approval, Informed Consent Approval, Financial Disclosure, Statement of Investigator, PI and Sub PI CV, Lab Certificate, Lab Normal

9/15/2008

Internal Audit of a site, Checked IRB Approval, 1572 Forms, Monitor Visiting Report, Protocol Approval, Informed Consent Approval, Financial Disclosure, Statement of Investigator, PI and Sub PI CV, Lab Certificate, Lab Normal

9/16/2008

Attended Intermediate GCP training course, will use as reference in practicum report.

Instructor=MedTrials Employee

- Session 1: Intermediate Regulatory review
- Session 2: Understanding a Protocol
- Session 3: Protocol Non-Compliance
- Session 4: Site Performance Metrics

9/17/2008

Attended Intermediate GCP training course, will use as reference in practicum report.

Instructor=MedTrials Employee

- Session 5: Introduction to Data Management

- Session 6: Detecting Fraud and Fabrication
- Session 7: State Regulation for Clinical Research
 - Read Warning Letters from FDA website, read guidance documents from FDA website,
 - Received certification for completion of course.

9/18/2008

- Internal Audit of a site, Checked IRB Approval, 1572 Forms, Monitor Visiting Report, Protocol Approval, Informed Consent Approval, Financial Disclosure, Statement of Investigator, PI and Sub PI CV, Lab Certificate, Lab Normal

9/19/2008

- Internal Audit of a site, Checked IRB Approval, 1572 Forms, Monitor Visiting Report, Protocol Approval, Informed Consent Approval, Financial Disclosure, Statement of Investigator, PI and Sub PI CV, Lab Certificate, Lab Normal

9/21-22/2008

- Internal Files Audit
- Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site
- Checked for Signatures, Dates, Expiration Dates

10/6-10/24

- Internal Files Audit
- Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site
- Checked for Signatures, Dates, Expiration Dates
- Internal Audit of a site, Checked IRB Approval, 1572 Forms, Monitor Visiting Report, Protocol Approval, Informed Consent Approval, Financial Disclosure, Statement of Investigator, PI and Sub Pi CV, Lab Certificate, Lab Normal
- Read Journal articles on the roles and training of CRCs and CRAs

11/3- 11/4

- Worked on designing script and audio training for SOP Escalation Procedures and Regulatory Review
- Presented in a manner where all section had a flow

11/5/08

- Internal Audit a Site w/ Katie
 - Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site
- Checked for Signatures, Dates, Expiration Dates

11/15-12/12

- Finished Internal Audit of 70 sites
- Checked IRB Roster, Protocol Signatures, Monitor Reporting and Visit, Approval Letters, Confidentiality Agreements, CVs, Licenses, Financial Disclosures, Lab Normals of One Site
- Checked for Signatures, Dates, Expiration Dates
- Also added recent site regulatory document to files, update all files, organized all files, organized central file room

References

- 1) Brown-Tuttle, Meredith. "Regulatory Training: Tips and Tools." Regulatory Affairs Focus 12 (2007): 41-42.
- 2)"Career Description." Healthcare.Gatewaycc.Edu. GateWay Community College. 1 July 2008
<<http://healthcare.gatewaycc.edu/Programs/ClinicalResearchCoordinator/>>.
- 3) Dionne, Abby. "Partnering Successfully with Vendors." American Pharmaceutical Outsourcing 1 (2007): 26-30.
- 4) Fedor, Carol. "Clinical Research Coordinators Forum." ACRP. 2 Feb. 2004. University Hospitals of Cleveland. 1 July 2008
<<http://www.acrpnnet.org/GetInfoFor/Forums/CRC.aspx>>.
- 5) Gerstner, Louis V. "Importance of Clinical Trials." Pediatric Cancer Care. Memorial Sloan-Kettering Cancer Center. 1 July 2008 <<http://www.mskcc.org/mskcc/html/2873.cfm>>.
- 6) Basic GCP. Ms. 1. Basic GCP Training Guide, Dallas,TX. 1998
- 7) Pierre, Christine. "Behind Every Great Principal Investigator..." The Monitor 21 (2007): 9-10.
- 8) Raymond, Stephen. "CDISC Clinical Research Glossary." Applied Clinical Trials 16 (2007): 12+.
- 9) "The Importance of Education and Training in the Clinical Research Industry." Clinical Research Consulting. CLINICAL RESEARCH CONSULTING. 1 July 2008
<<http://www.eclinicalresearchconsulting.com/importance.php>>.

- 10) Twyman, Richard. "A Brief History of Clinical Trials." The Human Genome. 22 Sept. 2004.
1 July 2008 <http://genome.wellcome.ac.uk/doc_WTD020948.html>.
- 11) Newman, Robin. "Responding to the Challenge for Change." The Monitor 20 (2006): 6-6.
- 12) Lanter, Jennifer. "Complexities of Starting an Industry-Sponsored Clinical Study." The Monitor 20 (2006): 25-28.
- 13) Nusser, Kathy. "Tools for Determining an Effective Training System." Focus Sept. 2002: 26-30.
- 14) Ensuring Drugs are Safe and Effective. Rep.No. Center for Drug Evaluation and Research, FDA. 4th ed. Rockville, MD: FDA, 2005. 18-21.
- 15) <http://www3.niaid.nih.gov/research/resources/DAIDSCLinRsrch/>