Abstract

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Purpose: To identify performance metrics for use in clinical trial management, identify different levels of understanding of and experience with performance metrics among clinical research professional, and to establish performance metrics within the clinical research organization MedTrials, Inc.

Hypothesis: There is a significant gap in knowledge and disconnect between clinical research professionals regarding performance metrics and how and when to use them.

Design: A survey was designed to test the understanding and knowledge of clinical research professionals regarding performance metrics. This study survey was also designed to gather opinions of clinical research professionals regarding the usefulness of performance metrics and when and where to appropriately use performance metrics.

Results: There is a deficiency in the understanding of performance metrics among clinical research professionals, as well as some disconnect regarding how to appropriately use performance metrics.

ESTABLISHING METRICS FOR EVALUATING PERFORMANCE AND QUALITY IN CLINICAL TRIAL MANAGEMENT

INTERNSHIP PRACTICUM REPORT

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By

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Introduction

Clinical Research

Advances in medicine and therapeutic treatments have grown at a substantial rate since the end of World War II, resulting in ground-breaking treatments such as coronary bypass, a vaccine for polio, organ transplantation and many antibiotics that are crucial to our survival today (Varmus, 1997). Medical technologies that have dramatically increased our survivability as a species have been made possible, in part, by clinical research. According to the United States Department of Health and Human Services (HSS), clinical research is defined as research conducted with human subjects with whom an investigator directly interacts (Research Involving Human Subjects, 2012). Clinical research includes the investigation of mechanisms of human disease, therapeutic interventions or the development of new technologies (Research Involving Human Subjects, 2012). The execution of clinical research is typically done so via clinical trials and is conducted in either one of four different phases referred to as phase I, phase II, phase III and phase IV. Phase I trials are conducted to test a new intervention in a relatively small group of subjects, usually less than 80 people. This phase helps evaluate and determine the safety of a new intervention. Phase II trials study interventions with a group of several hundred subjects, to not only further evaluate safety, but efficacy as well. Phase III trials involve several hundred to several thousand subjects when comparing the investigational intervention to other standard or experimental interventions, all while monitoring adverse effects and determining how the intervention can be safely used. Phase IV trials, also referred to as post-market studies, evaluate and monitor the effectiveness of an approved intervention in the general population while

collecting information on any adverse effects the intervention may have caused (Research Involving Human Subjects, 2012). In addition to the investigation of drugs, medical devices are also thoroughly researched to determine effectiveness. Unlike drugs, medical devices are broken down into classifications based on the risk they pose to patients. For example, if a device poses a high level of risk, then it will gain a higher classification and require a more strict investigational process (FDA, 2009). The opposite is true for a device that poses little or no risk to patients (FDA, 2009). Lastly, biologics are also subjected to clinical research and can include vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues and recombinant therapeutic proteins (FDA, Vaccines, Blood and Biologics, 2012). During clinical research, whether investigating drugs, devices or biologics, all parties involved are bound by strict regulatory laws and guidelines enforced by governmental agencies around the world, mostly in an effort to protect the welfare and ensure the safety of human subjects. Clinical research can be overwhelmingly complex; but managing the processes of clinical research or a clinical trial itself can be equally or more challenging.

When managing a clinical trial, there is a large quantity of information to coordinate simultaneously, and how this information is managed can determine the success of a trial. This critical information includes but is not limited to patient/subject data, investigative site data, investigational product records, trial budget information, applicable regulatory mandates and guidelines and investigator and staff credentials. With typically millions of dollars invested in an investigational product, an abundance of data to be managed, and the numerous facets of a clinical trial, it becomes imperative that errors are minimized and performance is optimized. However, optimizing performance means little when performance benchmarks have not been

established and as a result, quantifying the performance of any activity or process during a clinical trial makes way for the ability to define or grade levels of performance.

Metrics

The quantification of performance or quality of work within a business activity or process can be accomplished by introducing the use of metrics, which are defined as standards of measurement by which efficiency, performance, progress, or quality of a plan, process or product can be assessed (Business Dictionary). During the management of a clinical trial, it is vital to the success of the trial to measure and track its progress and activities. Without the use of metrics, it is unknown whether set goals are being met or exceeded throughout the duration of a trial. In addition to identifying success or failure, metrics provide a reference point which allows for identification of process-improvement or lack thereof. For example, through years of measuring vital signs of healthy individuals, the medical field has established an ideal reference point for healthy vital signs. As a result, a healthcare provider can measure a patient's vital signs and immediately know the health status of that patient based on the degree of deviation from the reference point deemed healthy. While gathering valuable information from measurements is important, too much information may not be useful. A common pitfall for companies is to over-measure by using a large number of metrics simply because they can (Nelson, 2008). In this case, more is not better because time, money and personnel are required to manage and analyze performance measures and can become a significant cost in a clinical trial. A good example of over measuring would be if a patient goes to their physician for high plasma cholesterol, and the doctor conducts all known blood tests, includes a computerized tomography scan, X-ray and screens for all diseases; the process would be time consuming, costly and simply impractical. In many cases, there may be only a small number of key factors that are useful to measure in a

given situation or circumstance; these can be considered performance metrics that are vital, or key performance indicators (KPIs) (Dorricott, 2012). KPIs have been used in many different organizations for decades but are relatively novel in the industry of clinical research; it is not that companies specializing in clinical research have not been measuring their performance, it is that performance has not been measured effectively, efficiently and to consensus such that optimal process and quality improvement may ensue.

Internship Subject

Problem

In clinical research, there is a multitude of data and information to be assessed, evaluated and stored ranging from study endpoints to the factors relating to study management. Much of this information is critical to the success of a clinical trial and often invaluable to the parties involved. While some of this data is an indicator of a subject's health or the efficacy, safety and tolerability of an investigational product, other pieces of data can be indicative of performance and quality of work done by a clinical research organization (CRO), an investigative site and even a sponsor. Most often a sponsor, usually a biotechnology or pharmaceutical company, hires a CRO to monitor and oversee investigative sites and the processes involved when conducting clinical research. Often the sponsor is paying close attention to the performance of a CRO and research site and the quality of work that is produced. This attention creates a demand for performance metrics, or more specifically KPIs, by the sponsor in an effort to ensure goals and milestones are being met and a certain level of quality is being maintained by the CRO. In addition to promoting quality and performance, metrics can be useful tools when trying to illustrate the level of client satisfaction. If a CRO wishes to maintain a productive and long-

standing business relationship with a sponsor company, it is beneficial to always know whether their customer's expectations are being met. Maintaining a positive relationship with a sponsor company can be accomplished by the use of metrics assessing the sponsor company's level of satisfaction which can provide actionable results. In a 2008 survey of biotechnology and pharmaceutical organizations, 87% reported that the demand for performance metrics was either "growing" or "rapidly growing" (Metrics Champion Consortium, 2008). Of the 87%, less than 20% reported that they collected, reviewed or used performance metrics with their service providers (Sullivan & Wool, 2012). Nearly 33% of sponsors reported that they collected performance metrics but never took action with their service providers. Another 16% of sponsor companies reported collecting performance metrics but never reviewing them (Sullivan & Wool, 2012). This data indicates a desire and demand for formal measurement of performance and quality between sponsors, CROs and other service providers while highlighting a significant deficiency of an industry-wide understanding of performance metrics, and when and how to effectively and efficiently use them. As a result, the establishment of metrics, or more specifically KPIs, for use in evaluating performance and quality is valuable in clinical trial management, because it provides feedback on critical-processes which renders opportunity for improvement.

Background and Literature Review

Traditional methods of measuring performance within an organization have been rooted in retrospective analysis (Bourne *et al.*, 2000). This form of performance measurement has been criticized for lacking strategic focus (Skinner, 1974) and not being externally focused (Kaplan and Norton 1992) leading to minimal improvement in company-wide performance. In addition, these traditional methods were mostly financially biased and measured performance based more

on a company's net gain rather than measuring foundational and process-based attributes (Hayes and Abernathy, 1980). In light of the shortcomings of these traditional methods, business performance and development experts have been creating new ways to measure not only the financials of a company, but performance and overall quality the company produces. New standards and criteria have evolved to include the need for measures that relate directly to an organization's mission and objectives. This evolution may reflect not only customer needs and internal goals, but an organization's external competitive environment. Today, the two most common terms used for business performance measurement are metrics and key performance indicators (KPIs). In order to successfully design metrics and KPIs for a business, it is important to understand how one relates to the other.

The overarching term for a single measurement is referred to as a metric. A metric is the holder of information and can be used to define the calculation for a KPI. (IBM, 2008) Examples of metrics are: time taken to complete a monitor visit report (MVR), number of products shipped or the occurrence of a protocol deviation. KPIs are the measurements deemed significant and are used to track performance versus a set business objective. (IBM, 2008) KPIs can include one or multiple metrics. For example, mentioned above is a metric that measures the time it takes to complete an MVR; using that example, a KPI can represent the measurement of the time it takes to complete one MVR or a KPI can represent the measurement of the mean time it takes to complete MVRs over the course of an entire study. The design of a KPI depends largely on the business objectives and strategic goals that have established

Metrics and KPIs have been commonplace in the business practices of large industries and maintain a degree of fluidity due to their inherent nature of promoting improvement and change within organizations. One industry where there is a lack of understanding, consensus and

utilization of metrics and KPIs is that of clinical research. When the Metrics Champion Consortium (MCC) conducted a survey of sponsors in 2007, they found that almost all survey respondents reported having an increased demand for performance metrics and only 9% have well defined metrics in place (Sullivan, 2011). Likewise, when CROs were surveyed, more than 80% responded that sponsor demands for performance metrics are growing rapidly, but none reported sponsors ever requesting or reviewing performance metrics. (Sullivan, 2011) However, there has been a recent initiative by advocates of performance metrics such as Linda Sullivan, VP of Operations for MCC, to help establish a uniform understanding and use of performance metrics in the clinical research community. MCC is a not-for-profit organization that is comprised of pharmaceutical, biotechnology and service provider organizations. The mission of MCC is to help develop and implement standardized performance metrics with the intent of improving the efficiency and effectiveness of managing and tracking resources needed to successfully run clinical trials (Sullivan L. , 2011). Another advocate of the standardization and efficient use of performance metrics in clinical research is Keith Dorricott, the director of operations management, process improvement, and metrics at INC Research in the United Kingdom. Mr. Dorricott believes the result and key purpose of measurement in clinical trial management is to reduce the time to conduct clinical trials, to maximize the success of applications of new drugs to regulatory authorities and for a CRO to be able to demonstrate oversight for the trials in its control to ensure timely, accurate and actionable data (Dorricott, 2012). While there is substantial history and literature on performance metrics in standard business models, there lacks an abundance of such in the field of clinical research. As a result, the clinical research industry is still on the frontier of standardized performance metrics and KPIs. The overall goal of this practicum project was to continue the exploration of that frontier

with the aim of establishing metrics and KPIs useful both to the sponsor, the investigative site and the CRO, MedTrials, Inc.

Specific Aims

1. **To identify metrics useful for performance and quality evaluation in clinical trial management.**

   Once all data was collected from the administered survey, the responses from the qualified subjects was used to identify metrics that may be valuable when used to measure performance and quality in various areas of clinical research. Subject responses were used to correlate various data points such as the length of a subject's clinical research experience, the area of a subject's clinical research experience and the responses they provide regarding the metrics detailed in the study survey.

2. **To identify different levels of knowledge among clinical research professionals regarding metrics in clinical trial management.**

   This aim will help assess the respondent's understanding of performance metrics compared to the understanding of other survey respondents. The responses were used to potentially correlate the level of understanding with various pieces of data such as length of experience in clinical research, the position held in clinical research, and work experience at an investigational site, CRO and/or sponsor.

3. **To establish metrics for performance and quality evaluation in clinical trial management.**

   Performance metrics will be chosen based, in part, on respondent data and then introduced to executive and operational management as well as various employees at MedTrials, Inc. Critical performance metrics will be identified and established for use in select company processes as well as in future projects.

Significance

The measurement of specific information in order to evaluate performance can provide crucial feedback at any level of an organization or company. Metrics, based on strategic business objectives, have been utilized in mainstream business since the redevelopment of business measurements in the mid twentieth century (Bourne *et al.*, 2000). With the implementation of standardized performance metrics, the opportunity for process improvement increases internally at the CRO and between the CRO and its clients and investigative sites. Better performance and processes create the potential to save money, time and other valuable resources. This practicum project focused on standardization of the measurements and use of performance metrics within the CRO. The chosen metrics will be organized such that the metrics are easily communicated and uniformly comprehended throughout the company and beyond. Finally, the chosen metrics will be utilized to assess, evaluate and grade performance and quality of various aspects of the CRO, including but not limited to operations and client relations. This system of performance evaluation promotes continuous growth and development of employees, departments and the company as a whole, ultimately leading to increased productivity and service excellence.

Materials and Methods

Overview

During this project, metrics were designed by partitioning the framework of a trial into its basic components and assessing the information needs of each component. Based on how frequently a piece of information is used or how important a piece of information is, a metric was created for that piece of information. The metrics were also influenced by stakeholder demands and internal needs. Next, a list of metrics was compiled and organized so they can be used easily and appropriately. A multiple choice survey was created through SurveyMonkey® to measure the respondent's understanding of metrics and the respondents perception of value the metrics provide within the context of clinical trial management. The information gathered from this survey is being used to help promote the establishment of formal performance metrics for future use.

Gathering Data: Specifics

An email was sent to employees and affiliates of MedTrials, Inc. as well as research professionals affiliated with the North Texas chapter of ACRP. The email described the study and the study survey and offered the potential respondent the option to take part in the survey or to not take part in the survey. If the email recipient chose to participate in the survey, they clicked on the survey link which directed them to the introduction page of the survey. The introduction page described confidentiality, risk/benefits, leaving the study, security, questions/concerns, principal investigator, co-investigator and student investigator elements. The email recipient then responded to the prompt: "If you agree to participate in the survey, select 'I agree'. If you do not agree to participate in the survey, select 'I do not agree'. After your selection, click the 'Next' button". If the email recipient agreed to participate in the survey, they clicked "I agree" followed by the

"Next" button and the survey continued. If the participant did not agree to participate in the survey, they clicked "I do not agree" followed by the "Next" button and the survey window was terminated. The individual that agreed to participate in the survey became a participant and continued with the survey as prompted (the survey was approximately 30 minutes in duration). Once the participant reached the last page of the survey, they were presented with the option of participating in a random drawing for a twenty dollar gift card. If the participant was to take part in the drawing, they clicked the "Click Here" link which caused an email window to appear with the student investigator's email address pre-filled in the email. The participant then added their name to the email template and clicked send to enter into the drawing. The participant's name was in no way associated with their survey responses. Once the survey was closed to potential participants (three weeks following the day the email was sent to them), the data was collected and analyzed for general response measures and potential correlations between data points. All of the participants that entered their names into the drawing for the twenty dollar gift card had their name typed onto a one inch by three inch piece of paper that was folded in half such that the one-inch sides proximate. The pieces of paper were then placed in an opaque four-quart bowl and were mixed in the bowl by hand. Then one piece of paper was blindly drawn by a MedTrials, Inc. employee that was not involved in the design of the study and was also not a participant in the study. The participant whose name was drawn was contacted the week of October 22, 2012 and received the twenty dollar gift card.

Once the survey was closed to potential participants, the data was collected and analyzed for general response measures and potential correlations between data points. A data safety monitoring committee was not appropriate for this study. The data was stored on an Excel spreadsheet on the hard drive of the student investigator's internship computer at MedTrials, Inc. and on the hard drive

of the student investigator's personal computer. Access to both of the aforementioned computers was password secured. The student investigator and the student investigator's internship mentors had access to the data via the student investigator. The survey was delivered via the internet; as a result, the study was conducted via the internet at various locations which was dependent upon the location of the participant. The survey was available to complete up to October 21, 2012. The data was analyzed and reported on October 23, 2012. The sample size was 20 subjects. The subjects were selected based on their affiliation with MedTrials, Inc. and/or the North Texas chapter of ACRP.

Inclusion Criteria

- 18 years of age or older
- Currently involved in any aspect of clinical research
- Affiliated with MedTrials, Inc. and/or the North Texas chapter of ACRP

Exclusion Criteria

- Under the age of 18 years
- Not involved in any aspect of clinical research
- Not affiliated in any way with MedTrials, Inc. and/or the North Texas chapter of ACRP,

SurveyMonkey

SurveyMonkey is a widely used survey tool that is PCI-DSS compliant. The SurveyMonkey data center is located in a SOC 2 Type II audited facility and is staffed and surveilled twenty-four hours a day/seven days a week.

CHAPTER 2

Results

The survey consisted of fifty-five (55) questions (excluding the agreement to participate in the survey or not) and was open to potential respondents from September 24, 2012 to October 15, 2012. There were twenty (20) total respondents. The survey was designed to gather general information on the respondents background as it related to clinical research, to assess the participants experience with and understanding of performance metrics and to gather the participants opinions on how and if select performance metrics should be used.

Background Information

General background information was collected from the respondents and is depicted in Table1, Table 2 and Table 3. Ninety percent (90%) of the respondents said to have more than five years of experience in the clinical research. When asked to describe their current position at their place of work, 45% of the respondents categorized themselves as being staff, 35% as management and 20% said they held executive management positions. Within the survey, areas of clinical research experience were broken down into three areas: experience as a clinical research coordinator (CRC), experience working at a CRO and experience working at a sponsor company. At some

point in their career, 60% of respondents said they have worked as a CRC, 95% said they have worked at a CRO and 40% said they have worked for a sponsor company.

Table . 1 Length of work experience in the clinical research industry

Question 2: Length of work experience			
	< 2 Years	**2 - 5 Years**	**> 5 Years**
Length of work experience in the clinical research industry	5%	5%	90%

Table 2. Description of current work position

Question 3: Description of current work position/role			
	Staff	**Management**	**Executive Management**
Description of current work position	45%	35%	20%

Table 3. Respondents work experience

Question 4, 5 and 6: Clinical research work experience	
Work Experience	
CRC only	0%
CRO only	35%
Sponsor only	5%
CRC+CRO	25%
CRC+Sponsor	0%
CRO+Sponsor	20%
CRC+CRO+Sponsor	15%

This table shows respondents that have, in their clinical research experience, either worked only as a CRC, only at a CRO, only at a Sponsor, as a CRC and at a CRO, as a CRC and at a Sponsor, at a CRO and at a Sponsor or as a CRC and at a CRO and at a Sponsor. (**CRC**= Clinical Research Coordinator. **CRO**=Clinical Research Organization)

Performance Metrics: Understanding

Five questions were asked to gauge the respondents' understanding of performance metrics, mostly as they relate to the management of clinical research. The responses to these questions are displayed in Table 4. While 90% of respondents admitted to having read about performance metrics, 65% were able to correctly answer questions asking for the best description of performance metrics. However, when respondents were asked questions that tested their knowledge on the appropriate use of performance metrics in clinical research, 90% answered correctly.

Table 4. Results from questions used to test respondent understanding of performance metrics

Questions 7-11: Understanding of Performance Metrics (PM)

	Yes	No	Unsure
Has read about PM	85%	5%	10%
Identified the correct description/definition of PM	65%	35%	N/A
Correctly identified PM for investigational site use	90%	10%	N/A
Correctly identified PM for CRO use	100%	0%	N/A

(**PM**=Performance Metrics. **N/A**=Not Applicable)

Performance Metrics: Experience

Table 5 shows the responses to questions used to gauge the respondents' past experience with performance metrics. Sixty percent (60%) percent of respondents claimed to have been involved in reporting study performance metrics and 55% said they know which performance metrics are considered KPIs in their current projects. When respondents were asked if they have ever reviewed

performance metrics for an ongoing clinical trial/project, 60% answered yes. However, when asked if they reviewed performance metrics after clinical trial/project had been completed, only 30% answered yes.

Table 5. Results from questions used to assess respondent experience with performance metrics

Question 12-15: Experience with Performance Metrics (PM)

	Yes	No	Unsure
Involved in reporting PM	60%	35%	5%
Know which PM are KPI for current projects	55%	15%	30%
Has reviewed PM for an ongoing project	60%	35%	5%
Has reviewed PM once a project has been completed	30%	60%	10%

(**PM**=Performance Metrics. **KPI**=Key Performance Indicators.)

Performance Metrics: Opinions

The remaining questions in the survey were used to assess the respondent's opinion on how performance metrics should be used. The first question asked if it is useful to receive quantitative feedback regarding the status of a project; of the 90% that answered "yes" to this question, 44% said they would like quantitative feedback on a project status monthly while 50% said they would like quantitative feedback quarterly (Table 6). When respondents were asked if it is useful to receive performance metrics relating to their work, 94% answered "yes"; of those answering "yes", 65% said they would like those metrics reported quarterly and 24% said they would prefer those metrics be reported monthly (Table 6).

Table 6. Results from questions 16-19 on use of performance metrics.

Question 16-19: Opinions on use of Performance Metrics (PM)

Would it be useful to have….	Yes		No	Unsure
PM regarding project status?	90%	**Monthly:** 44% **Quarterly:** 50% **Semiannually:** 6%	5%	5%
PM relating to your work?	95%	**Monthly:** 21% **Quarterly:** 68% **Semiannually:** 11%	5%	0%

Responses to frequency of use (Monthly/Quarterly/Semiannually) were only provided by respondents who answered yes to performance metrics use regarding project status and/or use of performance metrics relating to respondent work. (**PM**=Performance Metrics)

Question 20 of the survey listed 19 performance metrics aimed at measuring performance during clinical trials. For each performance metric listed, the respondent was to indicate whether each measure should be considered a site, CRO/sponsor or a site and CRO/sponsor performance metrics (results displayed in Table 11). The five performance metrics that gained the most agreement among respondents are as follows: average cost of monitoring visits per site, 94% CRO/sponsor metric; number of protocol amendments, 89% CRO/sponsor metric; percent initiated sites, 89% CRO/sponsor metric; percent compliance for MVR submission, 89% CRO/sponsor metric; percent planned monitoring visits completed, 89% CRO/sponsor metric. Conversely, the performance metrics that gained the least agreement among respondents are as follows: average days outstanding for invoice submission, 33% site metric, 33% CRO/sponsor metric; percent compliance for regulatory document submission, 44% site and CRO/sponsor metric; average days outstanding for query resolution, 50% site metric; average time to first

subject enrolled post initiation, 50% site metric and 50% site and CRO/sponsor metric. A majority of the answers to question 20 varied significantly among respondents.

Survey question 21 listed 18 different instances in clinical research where performance metrics may potentially be used. The respondent was asked, for each instance, if performance metrics should or should not be used (results displayed in Table 12). The top four choices among all respondents was workload management/resource allocation, feedback to project team, project planning and feedback to CRAs (individually) where 100% of respondents agreed that performance metrics should be used. For the remaining choices, at least 72% of respondents agreed performance metrics should be used, with the exception of using performance metrics for marketing claims. Only 39% agreed that performance metrics should be used for marketing claims, 50% disagreed and 11% were unsure.

Filtered Responses: Current Work Position

Responses were filtered based on the respondent's current position at their place of work. The filter that was applied categorized the respondents as being either at the staff, management or executive management level. These filters will be referred to as the staff filter, the management filter and the executive management filter. All survey questions were analyzed using these filters, however, only questions 19 and 20 are being reported. As shown in Table 7, the comparison of each filter depicts discrepancies between responses on assigning measures as a site metric, a CRO/sponsor metric or a site and CRO/sponsor metric. All responses to this question were relatively similar with the exception of the following measures: "Average days outstanding for query resolution", "Number of protocol deviations", "Expedited safety report compliance rate", "Percent compliance for regulatory document submission" and "Screen failure

rates". The work position filters were also applied to how performance metrics should be used in unique instances in clinical trial management (Tables 8). The responses across current position categories were almost all the same for each instance. The responses to "Marketing claims" showed the most variability across position categories followed by "Site selection (based on past performance track-record)", "Site ranking", "Site qualification", "Project status reporting" and "Proposal development".

Questions 19 and 20 were again analyzed using a different respondent filter. As shown in Table 9 and Table 10, responses were filtered based on the respondent's work experience in the clinical research industry. Since over 90% of the respondents have worked or currently work at a CRO, respondents were categorized based on an absence of experience: those who have never worked as a CRC and those who have never worked directly for a sponsor company. In other words, responses to questions 19 and 20 were analyzed for those who have worked at a CRO and as a CRC and for those who have worked at a CRO and directly for a sponsor. When this filter was applied to question 20 (Table 9), the responses varied so greatly between those without sponsor experience and those without experience as a CRC, that responses with the greatest disparity were identified. Measures with the greatest contrast in response type are the following: "Average days outstanding for query resolution", "Average cost of monitoring visits per site", "Enrollment rate", "Percent initiated sites", "Number of protocol deviations", "Number of queries", "Percent compliance for MVR submission" and "Percent planned monitoring visits completed." Quite the opposite was true when the same filters were applied to question 21 (Table 10), the assessment of instances when performance metrics should be used. Almost all responses were the same between those who have never worked as a CRC and those who have never worked directly for a sponsor company except for using performance metrics for marketing

claims; 75% of those with no CRC experience said no to the use of performance metrics for marketing claims while 60% with no sponsor experience also said no. Unfiltered responses for questions 20 and 21 are displayed in Table 11 and Table 12, respectively.

Table 7.

Question 20. Assigning Performance Metrics: Current Work Position Filter				
Performance Metric	**Position**	**Site**	**CRO/Sponsor**	**Site and CRO/Sponsor**
Average days outstanding for query resolution	Staff	56%	11%	33%
	Management	43%	0%	57%
	Executive Management	25%	0%	75%
Expedited safety report compliance	Staff	11%	22%	67%
	Management	43%	14%	43%
	Executive Management	0%	50%	50%
Number of protocol deviations	Staff	67%	0%	33%
	Management	43%	0%	57%
	Executive Management	25%	0%	75%
Percent compliance for regulatory document submission	Staff	11%	33%	56%
	Management	43%	14%	43%
	Executive Management	50%	0%	50%
Screen failure rate	Staff	78%	0%	22%
	Management	29%	0%	71%
	Executive Management	50%	0%	50%

Once filtered for current work position (staff, management and executive management), the five largest discrepancies in response-type when asked to assign performance metrics as either at the site, CRO/sponsor or site and CRO/sponsor level, were identified.

Table 8.

Question 21. Use of Performance Metrics: Current Work Position Filter				
	Position	**Yes**	**No**	**Unsure**
Marketing claims	Staff	33%	45%	22%
	Management	50%	50%	0%
	Executive Management	25%	75%	0%
Project status reporting	Staff	100%	0%	0%
	Management	83%	17%	0%
	Executive Management	75%	25%	0%
Proposal development	Staff	67%	11%	22%
	Management	83%	17%	0%
	Executive Management	100%	0%	0%
Site ranking	Staff	78%	0%	22%
	Management	67%	33%	0%
	Executive Management	100%	0%	0%
Site selection	Staff	100%	0%	0%
	Management	67%	33%	0%
	Executive Management	100%	0%	0%
Site qualification	Staff	67%	22%	11%
	Management	67%	33%	0%
	Executive Management	100%	0%	0%

Once filtered for current work position (staff, management and executive management), the six largest discrepancies in response-type when asked if performance metrics are useful when used in a specified instance were identified.

Table 9.

Question 20. Assigning Performance Metrics: Research Work Experience Filter				
Performance Metric	**Experience**	**Site**	**CRO/Sponsor**	**Site and CRO/Sponsor**
Average days outstanding for invoice submission	CRO	14%	43%	27%
	CRO+CRC	60%	20%	20%
	CRO+Sponsor	25%	25%	50%
Average days outstanding for query resolution	CRO	57%	14%	27%
	CRO+CRC	0%	0%	100%
	CRO+Sponsor	75%	0%	25%
Number of protocol amendments	CRO	0%	100%	0%
	CRO+CRC	0%	100%	0%
	CRO+Sponsor	0%	25%	75%
Number of protocol deviations	CRO	71%	0%	29%
	CRO+CRC	0%	0%	100%
	CRO+Sponsor	50%	0%	50%
Percent non-compliance for SAE/UADE reporting	CRO	14%	29%	57%
	CRO+CRC	0%	0%	100%
	CRO+Sponsor	25%	25%	50%

Once filtered for past work experience (CRO, CRO and CRC, CRO and Sponsor), the five largest discrepancies in response-type when asked to assign performance metrics as either at the site, CRO/sponsor or site and CRO/sponsor level, were identified.

Table 10.

Question 21. Use of Performance Metrics: Research Work Experience Filter				
	Experience	**Yes**	**No**	**Unsure**
Budgeting future work	CRO	83%	17%	0%
	CRO+CRC	100%	0%	0%
	CRO+Sponsor	100%	0%	0%
CRO comparison/vendor selection	CRO	50%	17%	33%
	CRO+CRC	100%	0%	0%
	CRO+Sponsor	100%	0%	0%
Feedback to CRAs, individually	CRO	100%	0%	0%
	CRO+CRC	80%	0%	20%
	CRO+Sponsor	100%	0%	0%
Feedback to sites, individually	CRO	83%	0%	17%
	CRO+CRC	80%	0%	20%
	CRO+Sponsor	100%	0%	0%
Marketing claims	CRO	67%	17%	17%
	CRO+CRC	20%	60%	20%
	CRO+Sponsor	25%	75%	0%
Proposal developments	CRO	50%	33%	17%
	CRO+CRC	100%	0%	0%
	CRO+Sponsor	75%	0%	25%
Site ranking	CRO	67%	33%	0%
	CRO+CRC	100%	0%	0%
	CRO+Sponsor	75%	25%	0%

Once filtered for past work experience (CRO, CRO and CRC, CRO and Sponsor), the seven largest discrepancies in response-type when asked if performance metrics are useful when used in a specified instance were identified.

Table 11.

Question 20. Assigning Performance Metrics: Unfiltered (100% Respondents)

Performance Metric	Site	CRO/Sponsor	Site and CRO/Sponsor
1. Number of protocol amendments	0%	85%	15%
2. Average days outstanding for invoice submission	30%	35%	30%
3. Average days outstanding for invoice payment	0%	55%	45%
4. Average days outstanding for query resolution	45%	5%	50%
5. Percent non-compliance for SAE/UADE reporting	15%	15%	70%
6. Average time to first subject enrolled post initiation	45%	0%	55%
7. Average cost of monitoring visits per site	2%	95%	5%
8. Primary CRC turnover	70%	10%	20%
9. Enrollment rate	35%	0%	65%
10. Percent initiated sites	0%	85%	15%
11. Number of planned visits completed	10%	70%	20%
12. Number of protocol deviations	50%	0%	50%
13. Number of queries	30%	10%	60%
14. Percent compliance for MVR submission	0%	90%	0%
15. Percent compliance for regulatory document submission	30%	20%	50%
16. Percent planned monitoring visits completed	5%	85%	10%
17. Screen failure rate	55%	0%	45%
18. Expedited safety report compliance rate	20%	25%	55%
19. Percent compliance for monitor visit confirmation/follow-up communications	10%	85%	5%

Results from 100% respondents when asked to assign a performance metric as a Site, CRO/Sponsor or Site and CRO/Sponsor metric.

Table 12.

Question 21. Use of Performance Metrics: Unfiltered (100% Respondents)	Yes	No	Unsure
1. Feedback to CRAs, individually	95%	0%	5%
2. Project status reporting	90%	10%	0%
3. Workload management/resource allocation	100%	0%	0%
4. Site selection (based on past performance track-record)	90%	10%	0%
5. Feedback to project team	100%	0%	0%
6. Site qualification	74%	21%	5%
7. Signaling a need for contract amendments/change of scope	95%	5%	0%
8. Proposal development	80%	10%	10%
9. Feedback to sites, individually	90%	0%	10%
10. Project timeline tracking	95%	5%	0%
11. Project planning	100%	0%	0%
12. Marketing claims	37%	53%	10%
13. Employee performance evaluations	90%	0%	10%
14. Site ranking	79%	21%	0%
15. CRO comparison/vendor selection	84%	5%	11%
16. Budgeting future work	95%	5%	0%
17. Feedback to sponsor	95%	0%	5%

Results from 100% respondents when asked to if the use of performance metrics is useful give a specific instance .

Discussion

This study surveyed 20 clinical research professionals in an effort to correlate various characteristics with understanding and perception of performance metrics. The respondent characteristics of interest included their lack of experience at the investigative site or sponsor level, or both, and their current work-position being at the staff, management or executive management level. Other general respondent characteristics that were identified include length of experience in the clinical research industry, general understanding of performance metrics, experience with performance metrics and opinions regarding the use of performance metrics. The respondents were found to be sufficiently experienced with 90% possessing greater than five years of experience in the clinical research industry.

Understanding

Questions seven through eleven were used to gauge respondent understanding of performance metrics. Question seven asked if the respondent had ever read about performance metrics. This particular question was used to estimate the proportion of respondents that have at least had some exposure to performance metrics; 85% of respondents claimed they have previously in their careers read about performance metrics, 5% said they have never read about performance metrics and 10% said they were unsure if they have ever read about performance metrics. As a result, it was safe to assume that most respondents have had at least some exposure to performance metrics. When asked to choose the correct performance metric for use at the investigative site level, 90% chose correctly. When asked to choose the correct performance metric for use at the CRO level, 100% chose correctly. However, when asked to choose the correct definition and description of a performance metric, just over 60% answered correctly. The fact that many, and in one instance, all respondents chose the correct performance metric for

a given scenario and almost 40% chose the wrong definition and description of what a performance metric, indicates a lack of uniform understanding of performance metrics among respondents.

Experience

When assessing respondent experience with performance metrics, a little over half of respondents said they have been involved in the reporting of performance metrics and know which performance metrics are key performance indicators for their current projects. These results show that a majority of respondents are active in the regular use of performance metrics within their organizations. When asked if they have reviewed performance metrics for a project that was ongoing, 60% answered "yes" while only 30% answered "yes" when asked if they have reviewed performance metrics once a project has been completed (not ongoing). This result implies that it is either not a common practice and/or clinical research professionals do not find it as useful to review performance metrics once a project has been concluded. This may be for a number of reasons, including the inability to take action in response to a retrospective performance metric once a project is no longer active.

Opinions

Part of the aim of this project was to gather and assess the professional opinions and perspectives of clinical research professionals regarding the use of performance metrics leading to the design of the survey being geared more toward accomplishing that task. In the beginning of the opinion-section of the survey, the respondent was asked if it would be useful to have performance metrics regarding project status and performance metrics relating to their work; 90% and 95% answered "yes", respectively. Of those respondents that answered "yes" to the

usefulness of performance metrics regarding project status, approximately half said they would like performance metrics regarding project status reported on a monthly basis and half would like performance metrics regarding project status reported on a quarterly basis. Of those respondents that answered "yes" to the usefulness of performance metrics relating to their work, only one-fifth would like performance metrics relating to their work reported on a monthly basis and almost 70% would like performance metrics relating to their work reported on a quarterly basis. These results on using performance metrics regarding project status and relating to individual work shows that almost all respondents see value in the use of performance metrics on project status and on their work. However, respondents said they would like metrics reported on project status three times more frequently than performance metrics relating to their work. This result may indicate a critical need for the frequent use and reporting of metrics on the status of a project.

Opinions- Assigning Performance Metrics (Survey Question 20)

In this section of the survey, the respondent was presented with 19 different performance metrics that measure commonly seen variables in clinical trial management (Question 20). Each respondent was asked to assign each metric as most appropriate for use at either an investigative site, a CRO/sponsor, or at an investigative site and a CRO/sponsor. The data displayed in Table 11 showed a significant lack of uniformity in opinions of respondents on the appropriate assignment of these performance metrics. This lack in similarity among respondent answers to this question prompted the inquiry into a possible variation in response type based on past and current clinical research experience. Proceeding with this inquiry, a filter was applied to all respondents which separated each respondent answer into one of three categories: the respondent possesses only CRO experience, the respondent possesses only CRO and CRC experience, or the

respondent possesses only CRO and Sponsor experience (Table 3). Once the filter was applied to question 20, the five performance metrics that had the most variability in responses across different types of research experience were isolated and are listed in Table 9. The discrepancies in responses to these performance metrics show a correlation with the type of clinical research experience of the respondent and where the respondent believes each performance metric should be assigned.. The great deviation in responses seems to be associated with whether the respondent lacks CRC experience or lacks sponsor experience. This lack of agreement between those who lack CRC experience and those who lack sponsor experience suggest a difference in expectations and perceptions of performance metric assignment based on where they have worked in their clinical research careers.

The clinical research work experience filter was removed and a current work position filter was added. Three broad categories of work-positions were adequately represented with 45% of respondents currently in a staff position, 35% currently in a management position and 20% in an executive management position (Table 2). Having these three levels or organizational experience, staff, management and executive management, provided a necessary diversity of perspectives regarding the measurement of performance within an organization. After the current work position filter was applied, the five performance metrics from question 20 that had the most variability in responses across current work positions were isolated and are listed in Table 7. This lack of alignment in responses may be attributable to the varying perspectives of individuals in different positions. Individuals at the staff, management and executive management level all have differing responsibilities and work within varying capacities in their organizations which may influence what they view as appropriate in the assignment of performance metrics in clinical research. Out of the 19 performance metrics listed in question 20

of the survey, two metrics, "Average days outstanding for query resolution" and "Number of protocol deviations", had significant variability in responses when responses were filtered for work experience and for work position which indicates a lack of agreement throughout the respondent pool.

Opinions- When to use Performance Metrics (Survey Question 21)

Question 21 of the survey listed 17 different instances where performance metrics might be used. The respondent was asked to answer "Yes" if they thought it would be appropriate to use performance metrics for a particular instance and "No" if the use would be inappropriate. Table 12 shows all responses for question 21. There was a majority consensus that the use of performance metrics would be appropriate in all instances but one, which was "Marketing claims". A work experience filter and work position filter was also applied to this question and is listed in Table 10 and Table 8, respectively. When answers were sorted based on the respondents work experience, minimal discrepancies existed in answer choices, except for marketing claims. This may indicate that respondents do not believe it is appropriate to use measurements of performance to market company services or that the respondents do not understand how performance metrics can be used for marketing purposes. When the work position filter was applied to question 21, there was a higher level of discrepancies among respondent answers and again, marketing claims showing the most disagreement among respondents. The fact that a difference in current work position provides for the greatest difference in answer choices, again supports the notion that individual roles within organizations heavily influence the perception of the appropriate use and designation of performance metrics.

Conclusion

Many performance metrics that were chosen for this project have been previously used for measuring outcomes and results during a clinical trial. However, the results of this project have made it apparent that there exists a disagreement on a few important aspects of performance metric in clinical trial management. The first major disagreement among respondents is where the performance metrics belong or should be assigned. This disagreement was respondent-wide but also existed between respondents, who possessed different clinical research experience. This discrepancy is significant because wherever a performance metric is assigned, the party to which it is assigned is responsible for the activities the respective performance metric is measuring. Those with different work positions were also unable to agree on where certain performance metrics should be assigned. As far as the use of performance metrics, there is no doubt that a majority agree that performance metrics are indeed useful.

In consideration of the misconceptions and the variance of lack of understanding, it is difficult to implement performance metrics during the management of a clinical trial when there are varying expectations, of all parties involved, regarding how and when to use the metrics. In order to successfully implement performance metrics within a CRO, agreement on what metrics to use, how and when to use them, where to assign them, how frequently they should be reported and who will be responsible for them, must be reached at the level of governance within the organization. Also, when using performance metrics with clients and third-party vendors, the metrics should be delineated and clearly defined, agreed upon and frequently revisited throughout the business relationship. Once a uniform understanding of performance metrics is captured and all expectations are outlined, performance metrics can be appropriately delegated throughout all levels of the organization and be used in current and future projects. In order for

all parties involved in the management of clinical trials to have a unified concept and understanding of performance metrics, whether at the investigative site, CRO or sponsor level, investments must be made into providing education on metrics and their use in clinical trial management. Meaningful metrics that measure critical factors so that tracking, reporting and handling can influence behaviors, will help avoid further disconnect in aligning concepts of performance metrics in clinical trial management. Ultimately, standardization and education will help align the implementation of performance metrics to enhance clinical trial management practices.

Appendix A

Survey Introduction

The purpose of this survey is to gather feedback on objective ways to measure performance in clinical trial management. This project is also a partial fulfillment for the student investigator's master's thesis at the University North Texas Health Science Center, Fort Worth, Texas.

Confidentiality: You will not be asked for your name or any other identifying information on the survey. This survey is completely anonymous.

Risk/Benefit: Since the survey is anonymous, there is no risk of loss of confidentiality from participating in this study. There is no direct benefit as a result of participating in this study.

Leaving the Study: Since the survey is not identifiable, there will be no way to withdraw from the study once you complete the survey online. Your participation (or non-participation) in the study will in no way affect your employment status.

Security: To learn about the security measures taken by Survey Monkey, please copy and paste this link into your browser: http://www.surveymonkey.com/Monkey_Security.aspx

Questions/Concerns: If you have any questions regarding this research project, please feel free to contact:

Principal Investigator: Rustin Reeves, Ph.D., Rustin.Reeves@unthsc.edu 817.735.2050

Co-Investigator: Patricia Gwirtz, Ph.D., Patricia.Gwirtz@unthsc.edu 817.735.2079

Student Investigator: Matthew Vandermause, mvandermause@medtrials.com 512.680.0461

If you have any questions about your rights as a research subject, please contact the UNT Health Science Center Institutional Review Board at 817.735.0409

At the end of the survey, you will have the option to enter into a drawing for a $20 gift card to Starbucks.

1. If you agree to participate in the survey, select "I agree". If you do not agree to participate in the survey, select "I do not agree". After your selection, click the "Next" button.

◯ I agree.

◯ I do not agree.

Background

2. How long have you worked in the clinical research industry?

- ◯ <2 years
- ◯ 2-5 years
- ◯ >5 years

3. Of the following, which best describes your current role?

- ◯ Staff
- ◯ Management
- ◯ Executive Management

4. Have you ever worked as a clinical research coordinator?

- ◯ Yes
- ◯ No

5. Have you ever worked at a CRO?

- ◯ Yes
- ◯ No

6. Have you ever been employed directly by a sponsor?

- ◯ Yes
- ◯ No

Understanding Performance Metrics

7. Have you ever read about performance metrics?

- ◯ Yes
- ◯ No
- ◯ Unsure

8. Performance metrics:

- ◯ are measures used to calculate milestone payments.
- ◯ represent ideal outcomes.
- ◯ are measures used to evaluate effectiveness or adequacy of work.
- ◯ reflect desired outputs.

9. Performance metrics can best be described as measures of

- ◯ time, cost
- ◯ time, cost, quality
- ◯ time, quality, frequency
- ◯ time, frequency, satisfaction

10. Of the following performance metrics, which is most applicable at the site level?

- ◯ The number of site-initiations completed per month.
- ◯ The number of protocol deviations per month.
- ◯ The number of monitoring visits completed out of the total number of monitoring visits required.
- ◯ The number of expedited events reported to the FDA outside the regulatory window.

11. Of the following performance metrics, which is most applicable at the level of the CRO?

- ◯ The number of protocol deviations per month.
- ◯ The number of monitoring visits completed out of the total number of monitoring visits required.
- ◯ The number of expedited events reported to the FDA outside the regulatory window.
- ◯ The monthly rate of subject enrollment.

Experience with Performance Metrics

12. Have you ever been involved in reporting study performance metrics?

- ◯ Yes
- ◯ No
- ◯ Unsure

13. Do you know which performance metrics are considered to be key performance indicators of any of your current projects?

- ◯ Yes
- ◯ No
- ◯ Unsure

14. Have you ever reviewed performance metrics for an ongoing clinical trial/project?

- ◯ Yes
- ◯ No
- ◯ Unsure

15. Have you ever reviewed performance metrics after a clinical trial/project had been completed?

- ◯ Yes
- ◯ No
- ◯ Unsure

Opinions Regarding Performance Metrics

16. Is it useful to receive quantitative feedback regarding a project status?

- ◯ Yes
- ◯ No
- ◯ Unsure

Opinions Regarding Performance Metrics

17. Is it useful to receive performance metrics relating to your work?

- ◯ Yes
- ◯ No
- ◯ Unsure

Opinions Regarding Performance Metrics

18. How often should you receive quantitative feedback regarding a project status?

- ◯ Monthly
- ◯ Quarterly
- ◯ Semiannually
- ◯ Annually

Opinions Regarding Performance Metrics

19. How often should you receive performance metrics relating to your work?

- ◯ Monthly
- ◯ Quarterly
- ◯ Semiannually
- ◯ Annually

Opinions Regarding Performance Metrics

20. Indicate if the following measures should be considered a site, CRO/sponsor or site and CRO/sponsor performance metric.

	Site	CRO/Sponsor	Site and CRO/Sponsor	Unsure
Percent initiated sites	◯	◯	◯	◯
Average days outstanding for query resolution	◯	◯	◯	◯
Primary CRC turnover rate	◯	◯	◯	◯
Average time to first subject enrolled post initiation	◯	◯	◯	◯
Percent compliance for monitor visit confirmation/follow-up communications	◯	◯	◯	◯
Expedited safety report compliance rate	◯	◯	◯	◯
Number of planned visits completed	◯	◯	◯	◯
Average cost of monitoring visits per site	◯	◯	◯	◯
Percent planned monitoring visits completed	◯	◯	◯	◯
Percent non-compliance for SAE/UADE reporting	◯	◯	◯	◯
Number of queries	◯	◯	◯	◯
Number of protocol deviations	◯	◯	◯	◯
Percent compliance for MVR submission	◯	◯	◯	◯
Number of protocol amendments	◯	◯	◯	◯
Average days outstanding for invoice	◯	◯	◯	◯

submission				
Average days outstanding for invoice payment	○	○	○	○
Percent compliance for regulatory document submission	○	○	○	○
Enrollment rate	○	○	○	○
Screen failure rate	○	○	○	○

Opinions Regarding Performance Metrics

21. How should performance metrics be used?

	Yes	No	Unsure
Project timeline tracking	○	○	○
Workload management/resource allocation	○	○	○
Feed back to CRAs, individually	○	○	○
Feed back to CRAs, individually	○	○	○
Marketing claims	○	○	○
Project planning	○	○	○
Employee performance evaluations	○	○	○
Budgeting future work	○	○	○
Site ranking	○	○	○
Proposal development	○	○	○
Project status reporting	○	○	○
CRO comparison/vendor selection	○	○	○
Site selection (based on past performance track-record)	○	○	○
Signaling a need for contract amendments/change of scope	○	○	○
Feedback to project team	○	○	○
Feedback to sponsor	○	○	○
Feedback to sites, individually	○	○	○
Site qualification	○	○	○

Survey Conclusion

Thank you for participating in the survey. If you would like to enter the drawing for a $20 gift card to Starbucks, please Click Here.

Appendix B

June 4

- MedTrials introduction with Manager B.A.
  -Signed MedTrials Confidentiality/Non-Disclosure Agreement (NDA)
- MedTrials services with Account Executive
- Human resources with Manager B.A.
- Office tour and introductions with Todd Almarez
- Office equipment training with Admin. Assistant
- Workplace safety with Manager B.A.
- Quality management system with QA Manager via telephone.
- Human resources videos
- Learning and development with Todd Almarez
- Information technology with Tech. Support.

June 5----------

- Group Wise and M-Files training with Tech. Support
- Basic Good Clinical Practice (GCP) Training with Todd Almarez

June 6----------

- MedTrials POL/SOP Review
  -POL-0000-001 Quality Policy
  -POL-0000-008 Protecting Confidentiality of Subject Personal Identifiable Information
  -SOP-0000-004 Protecting Client Confidential Information
  -SOP-3200-001 Research Personnel Training
- Therapeutic Training with Todd Almarez
  -Cardiovascular Disease: Reviewed treatments of plaque build-up in coronary artery disease (drug-eluting stent therapy, CABG) and viewed films of an angiography.
  -Age-Related Macular Degeneration (AMD): Reviewed the causes and physiology of Dry AMD along with potential treatments. Further discussion included diagnostic techniques and equipment used in characterizing this ophthalmic disease process.
- Reviewed protocols of two ongoing trials
  -Drug-Eluting Stent Therapy
  -Treatment for Dry AMD

June 7----------

- Discussed the Drug-Eluting Stent Therapy and Dry AMD protocols with Todd Almarez
- Reviewed the regulatory document process:
  -Regulatory document management
  -TrialWorks and the clinical regulatory document process
  -Challenges to regulatory document management
- Discussed regulatory document management and the role of the In-House CRA with CRA.
  -Reviewed the responsibilities of the In-House CRA at the study-level.

-Reviewed documents in Central File, regulatory and otherwise, pertaining to a single site participating in an ongoing study.

June 8----------

- Monitoring and the role of the Field CRA with Manager C.O.
  -Discussed the CRA position description, a day in the life of the regional CRA, monitoring visits, contact with sponsors, and the importance of SOP's and regulations.
- MedTrials POL/SOP Review
  -POL-0000-005 Record Retention
  -POL-0000-009 Inspection Policy
  -SOP-3100-020 Detecting and Handling Fraud and/or Research Misconduct
  -SOP-3100-021 Good Documentation Practices

June 11----------

- MedTrials SOP/WPG Review
  -SOP-3200-001 Research Personnel Training
  -SOP-3200-002 Employee Training File Management
  -WPG-3200-001 Development, Management, and Use of the QSM Matrix
  -WPG-3200-002 Development, Management, and Use of the PST Matrix
- Met with Admin. Assistant to outline a process in an effort to create a Work Instruction (WI) for that process:
  1. Creating and Updating Employee Review Records.
  2. Maintaining Employee Training Records.
     -other processes will be discussed including employee CV processing and management and employee training certificate and C.E. management.
- MedTrials SOP Review assigned by QA Manager
  -SOP-3100-002 Conducting Quality Audits
  -SOP-3100-005 Corrective and Preventative Action (CAPA)
  -SOP-3100-006 Internal Quality Systems Audit
  -SOP-3100-009 Regulatory Review
  -SOP-3100-025 Development, Approval and Maintenance of Audit Plans
  -SOP-3100-026 Development and Approval of an Audit Report

June 12----------

- Began creating a WI for Creating and Updating Employee Review Records.
- Sat-in a meeting with Lynn, Todd and QA Manager:
  -Conducted a C.O.R.E. risk assessment plan.
  -Identified the validation requirements for C.O.R.E.
- Met with QA Manager to begin an audit of four investigational sites participating in a study.

June 13

- Continued site audits with QA Manager.
- Continued WI for
    1. Creating and Updating Employee Review Records. *Title may change*
    2. Creating and Updating Employee Training Records
- Met with Admin. Assistant to outline a process in an effort to create a WI for that process:
    1. Creating and Updating Employee CV

June 14----------

- Completed site audits with QA Manager.
- Began creating a WI for:
    1. Creating and Updating Employee CV.
- Continued WI for
    1. Creating and Updating Employee Review Records.
    2. Creating and Updating Employee Training Records.

June 18----------

- Continued WI for:
    1. Creating and Updating Employee Review Records
    2. Creating and Updating Employee Training Records.
    3. Creating and Updating Employee CV
- TrialWorks introduction with In-House CRA.

June 19----------

- Met with Admin. Assistant to outline a process in an effort to create a Work Instruction (WI) for that process:
    1. Creating Continuing Education (CE) Certificates
- Continued WI for:
    1. Creating and Updating Employee Review Records
    2. Creating and Updating Employee Training Records
    3. Creating and Updating Employee CV
- Attended a GCP Update course led by Todd Almarez at Baylor Medical Center.
- Processed GCP Update sign-in sheet and course surveys.
- Created GCP Update CE certificates for participants.
- Organized documents in preparation for a sponsor meeting.

June 20----------

- Created two document templates:
    1. Employee Training Record Template
    2. Employee Review Record Template
- Sent the above documents to the QA Manager for approval.
- Completed WI for:

1. Creating and Updating Employee Review Records
2. Creating and Updating Employee Training Records

- Continued WI for:
  1. Creating and Updating Employee CV

June 21----------

- Completed WI for:
  1. Creating and Updating Employee CV
- Researched Methemoglobinemia
- Started WI for
  1. Creating Continuing Education (CE) Certificates
- Reviewed corrections made by Admin. Assitsant:
  1. Creating and Updating Employee Review Records
  2. Creating and Updating Employee Training Records

-will wait until Todd Almarez returns to the office on 6/25 before making any further changes to WIs

- Reviewed study-specific documents assigned by CRA in preparation for close-out visit (COV)
- Reviewed and navigated TrialWorks

June 22----------

- Completed WI for:
  1. Creating Continuing Education (CE) Certificates
- Reviewed study-specific documents assigned by CRA in preparation for close-out visit (COV)
  -Final Protocol
  -Investigator File
  -Drug Return Presentation
  -QSM SOP-1000-022 "Conducting Site Close-Out Visits"

June 25----------

- Discussed and finalized WIs for submission–with Todd Almarez
- Began creating an electronic training certificate template and certificate-process for in-house, remote and CORE training.
- Met with Todd Almarez to review and discuss weeks 6/11/2012 and 6/18/2012.

June 26----------

- Participated in a close-out visit with a MedTrials regional CRA
  -Reviewed and confirmed drug accountability log
  -Completed drug-return and destruction form.
  -Advised PI of post-trial obligations
  -Collected copies and/or originals of documents for the sponsor.
  -Shipped remaining investigational product back to sponsor.
- Continued designing electronic training certificate template with Todd Almarez.

June 27----------

- Completed electronic training certificate template with Todd Almarez
- Trained on how to make documents visible in CORE employee review checklist.
- Updated review and training records for four employees
- Completed WI for:
    1. Creating Training Certificates
- Updated CORE review-record requirements for each employee position per the signed QSM matrices.
- Completed training certificates for participants that completed a GCP Update course
  -initial implementation of e-certificate processing

June 28----------

- Attended in-house GCP Update course presented by Todd Almarez
- Updated GCP Update course attendees training records in M-Files
- Research and Brainstorm: Key Performance Indicators (KPI) in Clinical Trial Management.
  -What are KPIs?

June 29----------

- Amended the Certificate of Participation template as requested by Lynn and Todd.
- Created Certificates of Participation for MedTrials GCP Update course attendees.
- Researched and studied the KPI strategic hierarchy.
  -Strategic Objective→ Key Performance Question (KPQ)→ Key Performance Indicator (KPI)
- Brainstorm: KPIs in clinical trial management at the site level.

July 2----------

- Continued KPI research.
- Internship Meeting: Met with Lynn Van Dermark and Todd Almarez to discuss internship progress.
- Met with Todd Almarez for KPI idea session.

July 3----------

- Began the design of KPIs for clinical trial management during start-up.
- Organized clinical trial management (start-up) KPI concept and information into PowerPoint format.

July 5----------

- Continued the draft-design and organization of clinical trial management (start-up) KPIs into PowerPoint format.

July 6

- Continued the draft-design and organization of clinical trial management (start-up) KPIs into PowerPoint format.
- Assisted In-House CRA: Back-checked sponsor training logs for CRAs against in-house CRA training records. Organized sponsor training logs and made amendments to in-house training logs as needed.

July 9----------

- Completed the draft-design and organization of clinical trial management (start-up) KPIs into PowerPoint format.

July 10----------

- Met with Lynn and Todd to discuss KPI examples, design and format.
- Worked on MedTrials Metrics

July 11----------

- Met with Todd to create and modify MedTrials Metrics
- Began organizing metrics into a table format

July 12----------

- Finished organizing metrics into a table format.
- Screened sites for a future Dry-AMD study

July 16----------

- Screened sites for a future Dry-AMD study
- Researched current methods in subject recruitment and retention

July 17

- Screened sites for a future Dry-AMD study
- Researched current methods in subject recruitment and retention
- Amended MedTrials Metrics table
- Sent Thesis Proposal to Dr. Reeves and Dr. Gwirtz.

July 18----------

- Screened sites for a future Dry-AMD study

July 19

- Screened sites for a future Dry-AMD study

July 20----------

- Screened sites for a future Dry-AMD study
- Participated in monthly CRA meeting via teleconference

July 23----------

- Continued to research current methods in subject recruitment and retention
- Followed-up with sites for potential participation in Dry-AMD study

July 24----------

- Continued to research current methods in subject recruitment and retention
- Followed-up with sites for potential participation in Dry-AMD study

July 25----------

- As part of the site qualification process for an upcoming trial, I entered data from completed PSQ forms into an excel spreadsheet.
- Copied site files for MedTrials' archive for the closure of a study.

July 26----------

- As part of the site qualification process for an upcoming trial, I entered data from completed PSQ forms into an excel spreadsheet.
- Copied site files for MedTrials' archive for the closure of a study.

July 27

- As part of the site qualification process for an upcoming trial, I entered data from completed PSQ forms into an excel spreadsheet.
- Copied site files for MedTrials' archive for the closure of a study.

July 30----------

- As part of the site qualification process for an upcoming trial, I entered data from completed PSQ forms into an excel spreadsheet.
- Copied site files for MedTrials' archive for the closure of a study.

July 31----------

- As part of the site qualification process for an upcoming trial, I entered data from completed PSQ forms into an excel spreadsheet.
- Copied site files for MedTrials' archive for the closure of a study.

August 1----------

- As part of the site qualification process for an upcoming trial, I entered data from completed PSQ forms into an excel spreadsheet.
- Copied site files for MedTrials' archive for the closure of a study.

August 2----------

- As part of the site qualification process for an upcoming trial, I entered data from completed PSQ forms into an excel spreadsheet.
- Copied site files for MedTrials' archive for the closure of a study.

August 3----------

- As part of the site qualification process for an upcoming trial, I entered data from completed PSQ forms into an excel spreadsheet.
- Copied site files for MedTrials' archive for the closure of a study.

August 6----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.
- Shipped study files to sponsor.

August 7

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 8----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 9----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 10

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 13----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 14----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 15----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 16----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 17

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 20----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 21----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 22----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 23

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 23----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 24----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

August 27----------

- Contacted sites for incomplete PSQ follow up.
- Worked on performance metrics survey.

August 28

- Contacted sites for incomplete PSQ follow up.
- Worked on performance metrics survey.

August 29----------

- Attended a SQV with a MedTrials CRA

August 30----------

- Contacted sites for incomplete PSQ follow up.
- Worked on performance metrics survey.

August 31----------

- Out of Office: Dental Appointment.

September 3----------

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

September 4

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

September 5

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.
- Attended a Central Files Archiving meeting.

September 6

- Entered PSQ data for an upcoming study.
- Worked on performance metrics survey.

September 7

- Entered PSQ data for an upcoming study.
- Submitted thesis study materials, including the thesis survey, to UNT HSC OPHS for IRB exempt status.

September 10

- Addressed and corrected OPHS findings

September 11

- Addressed and corrected OPHS findings
- Sent corrected OPHS-IRB application for review.

September 12

- Studied materials related to a particular study currently in the start-up phase.
- Worked on outlining thesis report.
- Sat in on a study conference call with the VP of Clinical Operations.
- Worked on developing questions for personnel-profile interviews.

September 13

- Completed time-tracking spreadsheets for study-specific hours worked from July 16 through September 12.
- Emailed time-trackers to appropriate managers.
- Worked on developing questions for personnel-profile interviews.
- Interview for In-house CRA I position.

September 14

- Revised and re-sent OPHS-IRB study application
- Worked on personnel profile questions

September 17----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

September 18----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

September 19----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

September 20----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

September 21----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

September 24

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

September 25----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

September 26----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

September 27----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

September 28

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 1 ----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various

trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 2----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 3----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 4----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 5

- Out of Office

October 8----------

- Out of Office

October 9----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 10

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 11----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 12----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 15----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 16----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 17----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various

trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 18----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 19----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 22----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 23----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 24----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 25

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 26----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 29----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 30----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

October 31----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

November 1

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

November 2----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

November 5----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

November 6----------

- Assisted with several ongoing projects.
- Assisted with the management of regulatory documents, communication and information including but not limited to contacting potential sites to check for feasibility, maintaining various trackers, filing regulatory documents, conducting quality check on study sites, logging monitoring visit reports and maintaining updated training documentation for MedTrials employees.

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