
UNIVERSITY OF NORTH TEXAS
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1970

ABSTRACT

Kurschner, Jill E., Project Management in View of Increasing Sponsor Demands. Masters of Clinical Research Management (Biomedical Sciences), April, 2006, 190 pp., 24 tables, bibliography, 27 titles.

In an ever increasing environment of Sponsor demands, it is imperative that Contract Research Organizations (CROs) like Company A, provide a niche in which they deliver a clinical trial-related service which is faster, less expensive, and more ingenious than their competitors while still in compliance with federal regulations. Successful project management practices, specifically trial progress tracking tools, are the avenue by which this goal can be achieved.

As part of the internship practicum project, two company-wide questionnaires were disseminated to 34 applicable clinical operations employees at Company A. Questionnaire #1 was developed to assess employees' global views of clinical trial progress tracking. Questionnaire #2 was designed based on the results received from Questionnaire #1. This questionnaire surveyed employees' ideas and opinions regarding standardization of 5 specific trial progress tracking tools at Company A. Information gathered from the questionnaires will potentially assist Company A with the implementation of additional standardized trial progress tracking tools.

PROJECT MANAGEMENT IN VIEW OF INCREASING SPONSOR DEMANDS

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PROJECT MANAGEMENT IN VIEW OF INCREASING SPONSOR DEMANDS

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the
Graduate School of North Texas
Health Science Center at Fort Worth
in Partial Fulfillment of the Requirements
For the Degree of

MASTERS OF CLINICAL RESEARCH MANAGEMENT

By

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Fort Worth, TX
April 2006

ACKNOWLEDGEMENTS

I would like to thank first and foremost Dr. Annita Bens for her continued support, thoughtful words, guidance, and leadership in my life over the past three years. It truly has been a treasure having you as a mentor throughout my academic career here at UNTHSC. I would also like to thank Dr. LaChelle Arredondo for her professional guidance while working on this project, in addition to, her continued support and direction during pivotal personal and professional decision making milestones in my life. I would also like to thank Barbara Richardson, Bill Sams, and Timothy Smith for their time and energy dedicated to designing the trial progress tool questionnaires. Lastly, I would like to thank Kari, Karol, Wendy, Adam, Dianne, and Gary for always encouraging me that the end is near and that "this too shall pass." I couldn't ask for better friends and family to walk alongside me during this season of my life. For this I am truly grateful.

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CHAPTER I

INTRODUCTION

In order to understand the smaller picture of project management and trial progress tracking at the Clinical Research Organization (CRO) level, it is imperative to understand the industry "trend" permeating the CRO environment. The governing body enforcing ethical and scientific quality standards for designing, conducting, recording and reporting research studies that involve the participation of human subjects is the United States Food and Drug Administration (FDA). These standards are referred to as Good Clinical Practices (GCP), and originated in the 1940s when abuses were documented in clinical research (Trapani, 2005). In the last 20 years, the FDA has taken an "increasingly skeptical and adversarial stance regarding clinical trials" (Hindin, 2004). In this atmosphere, CROs and sponsors alike "are being tasked with strict vigilance of all stages of the clinical trial process to ensure that the laws, regulations, and industry standards designed for the protection of human subjects and data integrity are maintained"(Beach, 2001). As a result, CROs implementing trials on behalf of pharmaceutical or device companies (sponsors) can expect comprehensive audits by these sponsor companies, FDA, and/or other regulatory agencies.

A study entitled, "A study of warning letters issued to clinical investigators by the United States Food and Drug Administration," reviewed FDA warning letters issued to

drug and device researchers between the period of February 2002 through February 2004. The findings of this paper concluded the following: a total of thirty-six FDA warning letters, addressing 58 protocol violations, were issued to researchers during the 25-month long study. "The most common regulatory violations were deviations from the research plan, a flawed or nonexistent consent process, and failure to report or late reporting of adverse events." In addition, the credibility of the FDA, as a regulatory agency, has recently come under fire with Merck's withdrawal of Vioxx in 2004. Circumstances such as these have led to the claim that the FDA "has tilted too far in favor of industry in response to an expanded legislative mission" (*FDA credibility crisis: 1990 generic drug scandal may be blueprint for 2005,* 2004). Unfortunately, the prevailing public view of the FDA, as a result of this publicity, may be deteriorating. This "regulatory" environment has become a challenge to sponsors participating in clinical research. Over the last decade, Sponsors have been turning to CROs as a cost-effective alternative for the implementation of clinical trials in order to concentrate their resources on research and development and marketing. However, more often CROs are sought out for their specialized proficiency in specific therapeutic areas along with their expertise in regulatory affairs (Wikipedia, July 29, 2005).

In light of regulatory challenges presenting themselves to CROs, successful project management will provide the framework for how CROs accomplish the task of creating an environment synergistic with regulatory compliance while assuring client satisfaction.

CHAPTER II

CLINICAL TRIALS

PROJECT MANAGEMENT IN VIEW OF INCREASING SPONSOR DEMANDS

A. Background

1. Clinical Research

The underlying principles and practices of successful clinical trial implementation is the utmost protection and welfare of subjects participating in clinical research. The development of federal guidelines and regulations for the protection of human subjects has been the result of pivotal historical events which have changed the course of how research is conducted, and therefore managed.

In 1901, a serious diphtheria epidemic swept through St. Louis, Missouri. The medicinal product used to combat the disease was the diphtheria antitoxin. Medical workers and the public expressed their concern regarding "the poor supervision of antitoxin production and the lack of inspection and testing of the final product. Even though many believed that federal oversight was necessary, no action was taken until a tragedy occurred" (U.S Food and Drug Administration, 2002, July; University of Kentucky, Louisville, Hyperessay, n.d.). In late October of 1901, a young girl died by

tetanus-contaminated antitoxin prepared by the city's Health Department. All distribution of the antitoxin was halted immediately. More than 13 children died as a result of receiving this antitoxin. As a result of this tragedy, The Biologics Control Act of 1902 was passed. This act required biologics to be manufactured in a manner that assured their safety, purity, and potency.

By the 1900s, most American states poorly enforced the enacted food laws they had put in place. Dr. Harvey W. Wiley was a pioneer who led the efforts to enact federal laws governing the purity of food and drugs. Initially his efforts were met with hostility and frustration; however, the tide turned in favor of Dr. Wiley's position after a series of "sensational" articles by mudslinging journalists. These articles exposed the concern for the quality of food supplied to our US troops in the Spanish-American War of 1898, the greed and corruption of the Beef Trust, and the pernicious compounds of alcohol and drugs used for patent medicines (University of Kentucky, Louisville, Hyperessay, n.d.). Amid this environment of accusation, the Pure Food and Drug Act of 1906 was enacted. This Act defined "adulterated or misbranded" drugs, prohibited interstate commerce of adulterated drugs, and required labeling for the amount of alcohol, narcotics or additives in food and drugs.

In the 1930's, sulfonamides were praised for being one of the first class of drugs marketed for successful treatment of bacterial infections. This discovery eventually led to Daniel Bovet winning Nobel Prizes in 1932 and 1936. As the growing popularity of and need for this drug arose, finding forms for children and those patients who didn't want to take tablets or the injectable forms became a priority. In 1937, Harold Watkins

discovered that sulfanilamide could be dissolved in an agent known as diethylene glycol (DEG) and, in turn, liquid forms of sulfanilamide would be available. Unfortunately, Dr. Watkins didn't know before he shipped more than 1300 bottles of the Elixir Sulfanilamide to pharmacies and physicians, that DEG is a chemical cousin of antifreeze. John Swann, a historian and author of *Elixir of Death,* was quoted as saying, "Elixir Sulfanilamide was essentially slapped together without a thought to testing, without a thought to assessing its toxicity, or certainly without a thought to even looking into the literature to see what you were putting into the product" (Young, n.d.). Within only a couple of days, reports of deaths resulting from patients taking the Elixir Sulfanilamide surfaced, and eventually this tragedy would claim more than 100 lives. On October 19, 1937, after the manufacturer of the Sulfanilamide Elixir had issued two recall notices, the FDA undertook its largest operation at the time, and recalled every bottle of lethal elixir still circulating (Young, n.d.). As a result of this catastrophe, Congress passed the Food, Drug, and Cosmetic Act of 1938. This act required the FDA to certify the safety of new drugs before being marketed to the general public, and authorized the FDA to inspect manufacturers.

In 1946 immediately following the end of the Second World War, 23 leading German physicians and their administrators, who were responsible for planning and instituting the "Euthanasia" program, were indicted for their willing participation in war crimes and crimes against humanity. The Euthanasia program allowed German physicians to kill those people who had been deemed "unworthy of life" (United States Holocaust Memorial Museum, n.d.). The innocent victims included in this terror were

the mentally challenged, physically disabled, and the institutionalized. Furthermore, pseudoscientific medical experiments were conducted on thousands of prisoners of war during World War II without even a thought of obtaining their consent. As a result of these tragedies, thousands of victims were left dead or permanently crippled. On August 20, 1947 after 85 testimonials, submission of more than 1500 documents, and proceedings lasting almost 140 days, sixteen doctors were found guilty (including seven of whom were sentenced to death) (United States Holocaust Memorial Museum, n.d.).

The aftermath of this misfortune resulted in the development of the Nuremberg code of 1948. The Nuremberg code outlined 10 standards for physicians to abide by when carrying out experiments on human participants. A paraphrased version of these standards is as follows:

- Volunteers freely consent to participation
- Researchers fully inform volunteers concerning the study
- Risks associated with the study are reduced where possible
- Researchers are responsible for protecting participants against remote harms
- Participants can withdraw from the study at any time
- Qualified researchers conduct the study
- Cessation of the study if adverse effects emerge
- Society should benefit from study findings
- Research on humans should be based on previous animal or other research work

- A research study should never begin if there is a reason to believe that death or injury may result (University of Waterloo, Ontario, Office of Research Ethics, 2005, July).

In addition to the Nuremberg Code, the Declaration of Helsinki of 1964 was instituted as another ethical guideline. The World Medical Association developed this guidance document to emphasize the importance of individual patient interests above the interests of the society (University of Waterloo, Ontario, Office of Research Ethics, 2005, July). Even today, the Declaration of Helsinki is the gold standard for providing physicians and researchers with recommendations, guiding them in biomedical research involving human subjects.

In the 1960s, a popular drug called thalidomide was prescribed to pregnant women for treatment of their morning sickness in both Canada and Europe. Fortunately, the drug had not been approved by the FDA in the United States as a result of insufficient proof of the drug's safety in humans. An association between thalidomide and severe birth defects was observed during an FDA medical review following the application to market the drug in the United States. In a November 1998 newsletter published by the March of Dimes, the devastating effects of the use of thalidomide by pregnant women in the 1960s were discussed:

> "More than 10,000 children around the world were born with major malformations, many missing arms and legs, because their mothers had taken the drug during early pregnancy. Mothers who had taken the drug when arms and legs were beginning to form had babies with a widely

> varying but recognizable pattern of limb deformities. The affected babies almost always had both sides affected and often had both the arms and the legs malformed. In addition to the limbs, the drug caused malformations of the eyes and ears, heart, genitals, kidneys, digestive tract (including the lips and mouth), and nervous system. Thalidomide was recognized as a powerful human teratogen" (Center for the Evaluation of Risks to Human Reproduction, n.d).

The thalidomide crisis in 1962 led Congress to enact the Kefauver-Harris Drug Amendments. These amendments required manufacturers to prove both product effectiveness and safety in well-controlled studies, applied requirements such as informed consent to clinical studies, and increased the FDA's review of drugs to 180 days (Kinsel & Straus, 2003).

Possibly the most publicized incident of gross misconduct in medical research our nation has seen was the Tuskegee Syphilis Study. The Tuskegee Syphilis Study was started in 1932 by the United States Public Health Service (USPHS) and lasted until 1972. The goal of this study was to determine the natural course of untreated latent syphilis in African Americans. The study enrolled 600 African American males from Tuskegee, Alabama, 399 of whom had syphilis and 201 of whom did not have the disease. The subjects were wrongly recruited into the study based on misleading promises of free medical exams, free meals, and burial insurance (Center for Disease Control and Prevention, n.d). In addition, subjects were enrolled in the study without their informed consent. In 1932, during their "therapy," subjects underwent heavy metal

therapy. Even when reports clearly documented penicillin as the standard safe and effective treatment for syphilis in 1947, and also became the preferred drug of choice for treating syphilis in the 1950s, therapy continued to be withheld from the Tuskegee experiment participants (Heintzelman, Fall 2003).

In 1972, the Department of Health, Education, and Welfare (HEW) halted the experiment after a front-page New York Times story about the Tuskegee Study caused public outcry. By the time the study was halted, only 74 of the test subjects were still alive (at least 28 and possibly more than 100 had already died from advanced syphilis). In August of 1972, the HEW panel found the study to be "ethically unjustified" and argued that the men participating in the experiment had a right to receive the standard of care allowed to them-penicillin. The National Association for the Advancement of Colored People (NAACP) filed a class-action lawsuit resulting in a settlement of more than $9 million dollars awarded to the Tuskegee Study participants (Center for Disease Control and Prevention, n.d). Sixty-five years after the inception of the Tuskegee Syphilis Study, survivors and family members of those subjects who participated in the experiment received a public apology on behalf of the nation from President Clinton on May 16, 1997.

The highly publicized nature of the Tuskegee Experiment led Congress to pass the National Research Act of 1974. The National Research Act was the institution of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission was responsible for identifying "the basic ethical principles that should underlie the conduct of biomedical and behavioral research

involving human subjects, and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles"(University of Nevada Las Vegas, Office For the Protection of Research Subjects, n.d.). A milestone in the history of clinical research was the development of the Belmont Report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.

The Belmont Report established three basic ethical principles which continue to serve today as the basis for regulations involving human subjects: respect for persons, beneficence, and justice.

Two pervading ethical standards are evident in truly "respecting persons": (1) each individual has the right to be treated as an autonomous agent; and (2) in the case that a person's autonomy is diminished they are still entitled to be protected. When acting on behalf of autonomy, "we show lack of respect for persons when we repudiate a person's considered judgment, deny them the freedom to act on their judgments, or withhold information necessary to make a considered judgment" (Gallin, 2002). In respecting persons, it must also be understood that not all persons are capable of self-determination. Typically self-determination is a process of maturing; however, some people may be limited or have lost this capacity as a whole due to age, mental disability, illness, etc. Regardless of what the reason may be that a person lacks autonomy, protection provided to these persons must be meticulously balanced with their specific risk/benefit ratios (National Institutes of Health, n.d).

"Beneficence" is a fundamental ethical principle that requires one to go beyond their general societal obligation to do no harm. Beneficence calls one to a higher standard of maximizing potential benefits while also minimizing potential harms. This principle is illustrated by the observation that "even if there were a patient in the hospital who had three good viable organs that could be transplanted to save the lives of three other patients, we would not kill the one patient to save the other three" (Gallin, 2002). A delicate balance between carefully assessing an individual's (or even a society's) benefit in light of their inherent risks with regard to their participation in a particular research project, with the potential risks of not conducting the research at all, should provide the framework to conducting clinical research in the most beneficent and ethical manner.

The third ethical principle outlined by the Belmont report is "justice". Justice requires us to ask the question, "Who receives the benefits and who bears the burdens of research?" Justice does not allow the "burden" of serving as a research subject to fall upon the poor or compromised patients exclusively, only for the beneficial medical outcomes of their participation to be felt among the privileged and affluent (National Institutes of Health, n.d). Justice requires that persons participating in research receive: benefits for which they "deserve" to have, equal treatment, and "fairness" in the distribution of the risk/benefits ratios.

As history has lain out, historical events have paved the road to the enactment of laws which, in turn, have tightly regulated how clinical research is currently performed. In the midst of such events, the commonality running throughout all of history is the preservation of the principle of protection; protection of the rights and welfare of persons

who participate in research. Protection of persons not only finds its roots deeply imbedded in historical events, but presently flourishes as part of the trend in clinical research towards tighter and stricter oversight provided by the FDA.

In conclusion, protecting the rights and welfare of the persons involved in research is not the "why" of research but the "how" of conducting research. This underlying principle is woven into all phases of research and development, whether from the perspective of the FDA, the Sponsor Company, the CRO, or even the project manager.

2. Project Management

Project Management, as defined by Wikipedia, is the discipline of defining and achieving targets while optimizing the use of resources (time, money, people, materials, energy, space, etc) over the course of a project (a set of activities of finite duration). Project management has been around for centuries- Egyptians were building pyramids a couple millennia before Christ (Harpham, n.d). However, only in the last one-hundred years have flourishing businesses proven that project management is a tool that can be broken down into a science.

Anyone who has been in business has felt the pressure of deadlines. Businesses in the 21st century can count on tighter budgets, shortened time lines, and fewer resources to achieve a goal/product than ever before (Baker & Baker, 2000). These changes are a result of new technologies, multiple projects competing for resources, the speed of change continually increasing and continued competitive growth within industries. This atmosphere contributes to making project management, at the very least, a necessity. The

Center for Business Practice published a survey stating that the deliverables from improved project management included: improved project execution by 50%, improved financial performance by 54%, improved customer satisfaction by 36%, and improved employee satisfaction by 30% (Sieple, 2005).

Sponsors and Clinical Research Organizations (CROs) who conduct clinical research are not exempt to this atmosphere. Building a faster, cheaper, and better drug and/or device allows for fewer mistakes and requires maximized successful business practices. The race against the clock is very evident in the field of clinical research. With patents extending 20 years in duration, and the length of time between pre-clinical research/development to market approval for drugs continuing to increase; it is important to therefore understand that streamlining and maximizing successful practices such as project management on the front-end of product research and development leads to lucrative gains on the back-end.

B. Project Management

1. The "Why" of Project Management

Understanding the "why" of project management is as important, if not more so, than the actual implementation of project management practices. "Project management is a proven way to accelerate the pace of the project and reduce the chance of project failure." As previously mentioned, the velocity at which change is occurring within the environment of clinical research has continued to increase over the past decade. This atmosphere is further augmented by the development timelines for new drugs extending from pre-clinical testing to market approval reaching 13.9 years, in addition, the pre-approval cost of a new compound estimated at $802 million (DiMasi, Hansen, & Grabowski, 2003). Global competition, cost of failure, and multiple projects competing for resources are also reasons, previously stated, that clinical research organizations (CRO) such as Company A are sense an increased need for successful project management practices (Sieple, 2005).

2. Why Projects Fail

Thomas Edison was quoted as saying, "The successful person makes a habit of doing what the failing person doesn't like to do." This quote applies the principle of learning from the mistakes of others so as to not repeat those same mistakes again in the future. Managing a project is no different, and therefore learning why projects fail provides tools for successful project management practices. The following reasons were

identified by Sunny and Kim Baker in the book *Project Management*, in addition to, *Project Management Training Module I* as to why projects fail (Sieple, 2005):

- Not enough resources are made available to complete the project (under financed)
- Not enough time is approved to complete the project
- Unclear project expectations which lead to inappropriate or incomplete results
- Necessary changes in the scope of the project are not understood or agreed upon by the stakeholders, leading to varying views of the quality, budget, or time frame expected for the project. This means that stakeholder expectations have been poorly managed, which is a failure of the project manager as well as the project
- Not supported by senior management and/or project manager
- Poor team selection-skills on team do not match skills required
- No disaster recovery plan/risk analysis

3. Project Lifecycle/Product Lifecycle

The development of a project goes through a series of phases which are cumulatively known as a *project lifecycle*, different from the *product lifecycle* which will be explained in further detail later. As Figure 1 depicts, the project lifecycle consists of four different phases: the project initiation phase, project planning phase, project execution phase, and project closure phase. Each phase serves as an integral component of successfully managing a project, and must be meticulously planned and executed. The different phases allow us to understand what happens at each level of development; and more specifically what technical work should be performed and what personnel should be involved at each phase (Project Management Institute, 2000). As a project moves from

one phase to the next, there is a "pivotal" locality at the end of each phase of the project lifecycle where "there is an implied decision point; often the decision point occurs when the stakeholders decide either to proceed with the project or to terminate the work and cut their losses" (Baker & Baker, 2000).

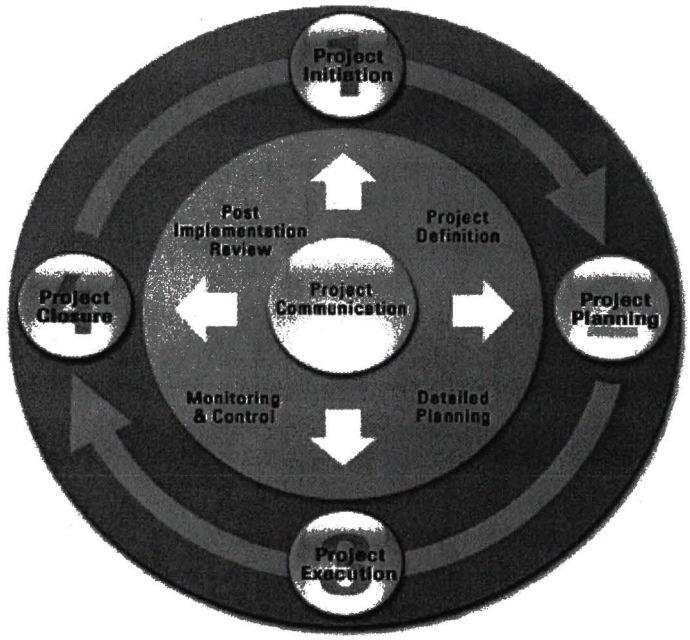


Figure 1 Project Lifecycle: **www.method123.com/ lifecycle.php**

As part of my internship practicum, I worked on the COSEAR (pseudo name) project during the execution phase of the project lifecycle. Project execution practices for the COSEAR project included: site initiation visits, monitoring visits, communication with the Sponsor Company and the Data Management Company, trial progress tracking, team performance evaluations (hiring and firing), team meetings, achieving sponsor-initiated deadlines, etc. Even while working during the execution phase of the project lifecycle, detailed planning continued to be an important factor within this phase. It will

be seen later that having a detailed project plan; which includes defining project goals and objectives, specifying tasks or how goals will be achieved, establishing what resources will be needed, and negotiating budgets and timelines for completion, will form the foundation from which all phases of the lifecycle will draw from.

The *project lifecycle* is different from that of a *product lifecycle.* If the project lifecycle is considered the view of clinical research from 50 feet above, the product lifecycle would be considered the view of clinical research from 10,000 feet above. A cogent argument could be made that without thoroughly grasping the larger picture of a particular event (product lifecycle); one therefore cannot truly understand the smaller aspects of that event (project lifecycle).

Figure 2 depicts a pharmaceutical product lifecycle from discovery to approval (Project Management Institute, 2000). For medical devices, the discovery to approval lifecycle differs somewhat. Medical device research is not conducted in phases, but is considered to be more "staged." Investigational device research includes feasibility, application development, and pivotal studies. In addition, medical devices are categorized into three classes based on their level of risk, "the risk the device poses to the patient and/or the user is a major factor in the class it is assigned to. Class I devices include those devices with the lowest risk and Class III includes those with the greatest risk" (U.S Food and Drug Administration, n.d.). When a device goes through the approval process, an Investigational Device Exemption (IDE), not an Investigational New Drug Application (IND) is submitted to the FDA. In addition, prior to marketing a device (specified classes) Pre-Market Approval (PMA) must be received from the FDA

before marketing of the device can occur (for drugs a New Drug Application (NDA) must be filed). Lastly, medical device companies may be required by the FDA to conduct post-market surveillance studies. These types of studies are not required by pharmaceutical companies.

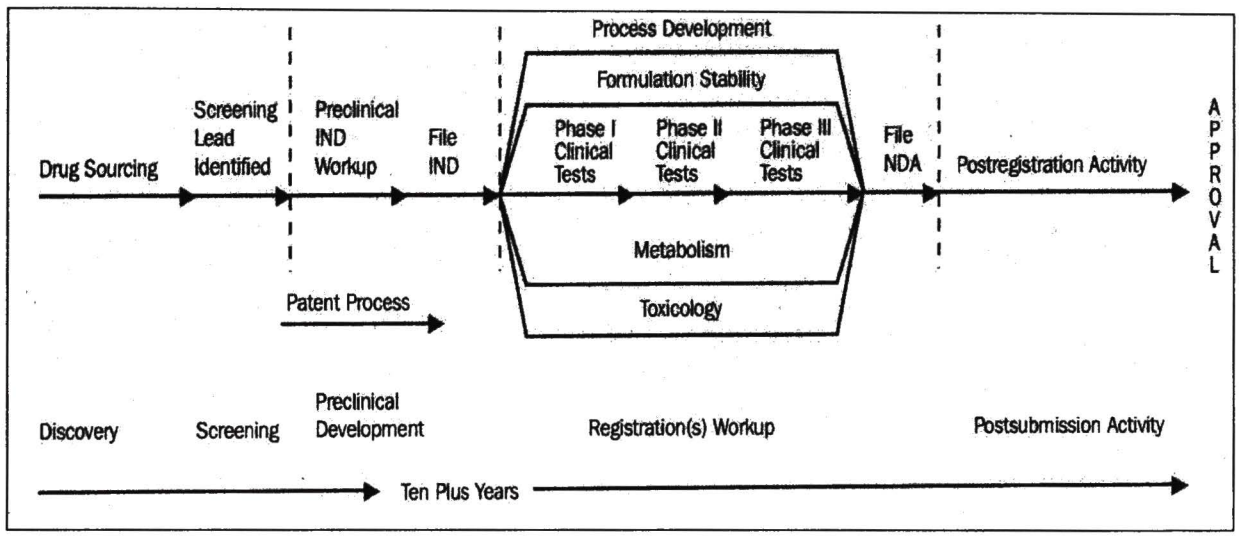


Figure 2: Representative Product Life Cycle for a Drug Project (Project Management Institute, 2000)

4. Project Plan

Project planning is not only a specific phase within the project lifecycle, but also is intrinsic to the initiation phase, the execution phase, and the closure phase. Every successful project begins with the project management process called a *project plan.* The project plan details the "who, what, when, where, and how" a study is conducted. A very brief paragraph describing each component of the project plan template at Company A has been included, along with application of that component to the COSEAR project. The following are the specific components of the project plan template at Company A:

- Project Summary
- Critical Constraints (Scope, Time Cost, Quality)
- Task Definition and Project Schedule
- Roles and Responsibilities
- Quality Plan
- Communication Plan (Tools and Trackers)
- Risk Assessment/ Mitigation
- Project Close-Out

Project Summary: As the name implies, the project summary is a brief description of the broad picture of the project, and offers a "snapshot" view of the project being proposed and/or conducted.

COSEAR Project Application: The project summary included a one to two sentence summary with additional information about the total number of investigative sites, number of Company A monitored sites, anticipated total enrollment, length of patient involvement, and anticipated project duration.

Critical Constraints: The critical constraints within a project are categorized as scope, time, cost, and quality. The scope refers to what will be accomplished at the end of the project and/or the deliverable(s) the project (if successful) will provide upon completion.

When the deliverables of a project are thoroughly understood, then factoring in the time frame in which these deliverables will be supplied is also important. Within the critical constraint of time, there may also be important milestones within the project timeline which should also be referenced.

The critical constraint of cost is designated as the overall budget for the project. The cost constraints may be in reference to all or some of the following: the sites, the CRO, the Data Management Company, and/or the Sponsor Company. Cost considerations are worked out through contracts between the Sponsor Company and the other respective entities.

The last critical constraint is quality. Within the project plan itself, this section is generally very broad and basic. Verbiage from the code of federal regulations (CFR), good clinical practices (GCP), and human subject protection requirements are also referenced here.

COSEAR Project Application: Investigating the safety and effectiveness of a novel coronary drug eluting stent was stated as the *scope* of the project. The critical constraint of *time* for the COSEAR project included a timeline of events starting with initial enrollment of May 2005, last enrollment of May 2006, 1-year follow-up May 2007, 2-year follow-up May 2008, 3-year follow-up May 2009, 4-year follow-up May 2010, and 5-year follow-up May 2011. In addition, discussions with the Sponsor Company led to the development of a particular percentage of the approved sites being allowed to enroll beginning May 2005, and then after a specified period of time (based on subject enrollment) all sites would be open for enrollment into the COSEAR study.

The COSEAR project was contracted by the Sponsor Company to provide all services under a "fixed" budget agreement- *cost* constraint. The "fixed" budget included the contingency to amend the fixed project estimations when necessary; however,

amending the budget was shown to be a challenge between the Business Operations department at Company A and the Sponsor Company.

The *quality* constraint within the COSEAR project plan stated, "This project will be conducted under applicable USFDA regulations. The project will be monitored per GCP, Company A and the Sponsor SOPs, and all applicable local and IRB regulations."

Task Definition and Project Schedule: Within this section, the following will be referenced: excel spreadsheets, calendar of events, Gantt charts, and/or Microsoft Project. Also mentioned will be the project deliverables and project milestones. In addition, a very detailed project schedule will be provided, which will include specific dates of completion for each aforementioned milestone/task defined by the project.

COSEAR Project Application: Within the COSEAR project plan, a specific reference of a task definition or a project schedule was not found. However, within the COSEAR protocol provided by the Sponsor Company; a time course of events with corresponding dates, and primary and secondary endpoints were provided.

Roles and Responsibilities: Within this section of the project plan, all applicable personnel working on the study and their corresponding responsibilities are listed.

COSEAR Project Application: There were 5 roles defined in the project plan: Project Manager (PM), Project Lead (PL), Clinical Research Associate (CRA), In-house CRA, and a Quality Assurance (QA) Representative. Position specific responsibilities were also briefly mentioned. The PM was delegated the role of the person who was primarily responsible for the project. The PL was responsible for completing those tasks which were assigned to him/her by the PM. The CRA was responsible for site management,

field monitoring, and timely reporting of findings and/or issues to the PM. The In-house CRA was responsible for assisting with site management, maintaining TrialWorks and central files, and reporting issue escalation to the PM. The QA representative was responsible for performing internal and external QA audits; in addition to providing support to the project team as requested.

Quality Plan: This area of the project plan is provided by the Quality Assurance Department. The quality plan outlines specific recommendations in reference to oversight of the project, audit procedures, processes and procedures occurring at the research sites, and evaluation of project management practices.

COSEAR Project Application: The quality plan is provided by the Quality Assurance Department at Company A. The quality plan for the COSEAR project included United States Food Drug and Administration (USFD) Regulations (21 CFR Part 50, 54, 56, 312, 812, 814), Company A's Standard Operating Procedures (SOPs), and Work Instructions (WI) provided by the Sponsor Company. The quality plan also outlined the "audit schedule" that would be performed during the course of the study, which included: the different types of audits performed (site audits, project file audits, audit reports, document control), the number of files that would potentially be audited, the number of investigational sites audited, the location of the audits, and the timeframe in which these audits would be performed.

Communication Plan: As the name implies, the Communication Plan describes the types of communications that will occur between Company A employees, the Sponsor Company, and the Data Management Company. Other significant contributors to the

Communication Plan include: the frequency of the communications, who the responsible parties are for distributing the communications, and trial progress tracking tools. Trial progress tracking tools will be mentioned in further detail in the next section.

COSEAR Project Application: The Communication Plan drafted for the COSEAR project was an Excel spreadsheet outlining the reports to be distributed (Site Initiation Visit Schedule, TrialWorks Visit Schedule, Screening Logs, Pre-post Checklists, Laboratory Trackers, CRF Missing Pages, Query Tracker, Patient Calendar, Enrollment, etc.), the entity responsible for providing the reports, the frequency of distribution of the reports, and the party responsible for disseminating the reports.

In addition the COSEAR Communication Plan outlined the frequency of teleconferences. The COSEAR project had bi-weekly teleconferences with the Sponsor Company and the Data Management Company, in addition to, weekly teleconference with the Data Management Company. Specific dates and times for all parties involved in the teleconferences were detailed in the Communication Plan.

The Communication Plan also outlined the specifics of the personnel responsible for handling contact with the sites. A brief summary of responsibilities were mentioned for the In-house CRA, the field monitors, and the project manger in reference to site communication (scheduling site initiation visits, weekly updates, amendment updates, memos to sites, visit confirmations, case report form (CRF) questions, etc.).

Risk Assessment/Mitigation: This section of the project plan is used to identify any potential risks that may significantly impact the success of the project. Additionally,

documentation of mitigation strategies for the identified risks are also to be mentioned here.

COSEAR Project Application: One of the risks assessed for the COSEAR project included achieving specific enrollment deadlines. Some concern was expressed that if centers did not enroll fast enough, the initial agreed upon study timeline would be expanded.

It was also noted in this section, that the level of device monitoring experience of the personnel staffed to the COSEAR project was highly diverse. The mitigation strategy for this risk referenced the project manager evaluating the training needs of the team members on a regular basis as the project progressed.

The nature of the "fixed" budget was documented as a potential risk to the success of the project. The mitigation plan stated that a very "disciplined approach to monitoring and documenting budgetary variance" would need to be instituted. As a result, having these practices in place would provide the leverage for potential contract renegotiations (amendments).

Project Close-Out: This section of the project plan is dedicated to describing how the "lessons learned" during the course of the study will be identified, in addition to, how these lessons will be communicated to Company A as a whole.

COSEAR Project Application: A very general statement was included within this section of the project plan stating: the status of the project would be reviewed on a monthly basis, all efforts would be made to document the "lessons learned," and that any

applicable knowledge acquired during these reviews would be communicated to Company A.

5. Tracking Tools

One of the most integral aspects of successful clinical trial project management are the trial progress tracking tools in place to support the minutia of information (protocol deviations, informed consents, outstanding issues, serious adverse events, visit report compliance, etc.), which so easily can be forgotten when the abundance of correspondences from the Sponsor, the sites, and the Data Management Company. In addition, trial progress tracking tools provide the foundation for achieving Sponsor initiated deadlines, and most importantly regulatory compliance.

Trial progress tracking tools, for the purpose of this internship practicum report, will be delineated into three main categories: global Company A trackers, project specific trackers, and site specific trackers. A couple of examples of global Company A trackers would be TrialWorks™, and a non-commertial tracker routinely used at Company A called the Monitoring Visit Report Compliance Tracker.

As part of my internship practicum, I spent a good portion of my day working with the TrialWorks software program, and as a result, a more in-depth description and discussion of TrialWorks will be provided. TrialWorks is a software system utilized by Company A in order to aid in their project management needs. TrialWorks is capable of tracking trial activity and regulatory document tracking by study and by site. Special features provided by TrialWorks include: security levels, correspondence with automatic email functions, real-time remote data input or access, tracking of investigators and

payments, tracking of monitoring costs for each site, tabulating monitoring visits completed per site, offering over 100 standard reports, and also provided customized reports which can be created by the user through a special filter feature or by exporting into word or excel (Richardson, 2001) (TrialWorks, 2006).

The monitoring visit report (MVR) tracker was also a document I routinely used at Company A during my internship practicum. This tracker is responsible for "real-time" monitoring of ongoing compliance with Sponsor requirements for MVR submission. The COSEAR project I worked on at Company A required that all monitoring visit reports be submitted to the Data Management Company no more than 15 days after the last visit day. As the in-house CRA, I was responsible for populating the fields within the tracker such as: investigator name, site number, visit date, monitor name, days at site, date MVR due at Sponsor, date sent to sponsor, and date received at sponsor per FedEx. This tracker is used, across studies, as a very important tool for ensuring that MVR compliance is achieved.

Trackers such as TrialWorks and the MVR compliance tracker provide a very broad or "global" view of the study at just a glance. Tools such as these are primarily used by project managers, clinical directors, and key stakeholders at Company A.

Project specific trackers allow for a more narrow view of the project of interest. If global trackers provide a 10,000 foot view of the study, than project specific trackers provide a 500 foot view of the study. These trackers are usually populated by the in-house CRA, project manager, and project lead. The project specific trackers I used for the COSEAR study were the Master Spreadsheet Tracker and the COSEAR Site Visit

Calendar. Both of these trackers were specifically developed for the COSEAR project. However both trackers could be used across all studies at Company A if modified appropriately.

The Master Spreadsheet Tracker is a tracking tool that was routinely referenced and updated for the COSEAR project. Information contained within this document included: a complete listing of all patients pertinent to a particular patient enrollment deadline set by the Sponsor, a patient visit window calendar (range of dates for patients to return back to the clinic for a specified follow-up visit), information regarding laboratory results received from the sites to the Data Management Company, and a listing of all case report forms that had been monitored and/or retrieved by the field monitors at their respective sites, etc.

The Site Visit Calendar was also a trial progress tracking tool referenced and routinely updated for the COSEAR project. This calendar incorporated site initiation visits and monitoring visits conducted by field monitors from Company A, in addition to visits conducted by sponsor representatives to the sites. Each visit also incorporated the initials of the monitor and /or the sponsor representative responsible for conducting the visit, along with the visit number to the site. This tracker was sent to the Data Management Company and the Sponsor Company on a semiweekly basis. Information contained within this tracker provided the Data Management Company and the Sponsor Company an overview of the schedule of events in order to prepare the necessary documents to the monitors before they arrived at the sites (pre-post visit checklists and device dispositions).

Project specific trackers allow very specialized pieces of information, which are only applicable to a particular study, to be tracked in the most efficient and user-friendly manner possible. Both the Master Spreadsheet Tracker and the Site Visit Calendar were key trial progress tracking tools used on a very regular basis for the COSEAR project to ensure successful compliance with Sponsor-initiated deadlines and demands.

The third and final level of trial progress tracking tools is the site level trackers. Keeping with the analogy, site level trackers provide a 50-100 foot view of the study. Typically, in-house CRAs and field monitors are the primary parties responsible for populating these trackers. Site level trackers, as the name implies, provide information that is only pertinent to the particular site of interest. These trackers may include: Protocol Deviation Trackers, Serious Adverse Event Trackers, Informed Consent Log Trackers, and the Outstanding Issues Tracker.

During my internship practicum I was not directly involved in populating any of the site level trackers listed above. However, I worked closely with the in-house CRA who was responsible for populating the COSEAR Outstanding Issues Tracker for each site. This tracker is a specialized tool created to capture those items which have not been resolved by the end of the monitor's visit at a particular site. As a result, these issues are referenced as currently "outstanding." Fields captured within this tracker include: date item was first known, monitor who can provide information, issue description, planned action or instructions, on-going status and follow-up information (if applicable), and date and description of the actual resolution. This is a great tool to ensure that any items

brought up during a monitoring visit are tracked and followed at some point in time during the study.

Trial progress tracking tools are an integral component of successfully managing a project whether it is at a global level, project level, or a site level tracker. Ensuring that the most efficient, user-friendly, and all-encompassing trial progress tracking tools are used by companies such as Company A, establishes a special area of demand or a "niche" within an environment of increasing Sponsor demands.

C. Specific Aims

The specific aims of my internship project are as follows:

1.) Provide a thorough understanding of CRO Project Management. A specific focus will be directed towards trial progress tracking tools.

2.) Evaluate employee opinions and satisfaction of current trial progress tracking tools, on a global level, that Company A utilizes via a company-wide questionnaire.

3.) Evaluate employee opinions and satisfaction of five specific trial progress tracking tools at Company A via a company-wide tailored focus questionnaire.

D. Significance

The significance of my internship project is multifaceted. My internship project will provide Company A with results obtained from a company-wide questionnaire (Questionnaire #1) addressing their employees' trial progress tracking tool usage, satisfaction, and opinions on standardization. This questionnaire will also provide Company A with the current trial progress tracking needs of study personnel. In addition, results from a second questionnaire will be provided to Company A outlining employees' involvement, frequency of use, benefit, and opinions of standardization regarding five specific trial progress tracking tools.

The outcomes of my internship project will provide information in which to assist in standardizing and/or creating new trial progress tracking tools conducive to more concise, efficient, and user-friendly methods of tracking clinical trials. Streamlining a particular practice such as trial progress tracking, not only allows immediate fruitful benefits for the CRO personnel involved with completing these tasks, but also for the company as a whole. Shortened product to market timelines, leading to increased customer satisfaction, resulting in greater revenue potential; provides businesses with increased efficiency and therefore productivity (Noferi & Worden, 2000).

E. Issues and Limitations

Potential limitations included the following concerns: the quantity and quality of responses received back from the "Tracking Tools Questionnaires;" employees seeing this only as a survey or questionnaire may not take the time to fill out the questionnaire, or will provide non-thorough answers; and employees, who anticipate not having the time to dedicate to filling out a questionnaire, will in turn only provide the most necessary information without fully developing their thoughts/concerns.

Following the dissemination of the "Tracking Tools Questionnaires," the following issues/limitations were noted. Questionnaire #1 yielded a 35% response rate (12 respondents out of 34). Collaborations between two of Company A's clinical directors, in addition to, two in-house CRAs were responsible for the design of the questionnaires. The consensus between group members was that this response rate was lower than expected; however, given the global nature of information collected from this questionnaire a 35% response rate was deemed adequate.

Discussions were conducted on how to ensure a higher response rate for Questionnaire #2. It was decided that reminders would be sent to all recipients on a periodic basis after receiving the questionnaire. Recipients would also be required to print out their final page and submit it to one of the clinical directors as verification of completion. These directives proved to be very beneficial. Questionnaire #2 yielded an 85% response rate (29 respondents of 34).

The quality of the respondents' answers being non-thorough or very discrete was of some concern prior to the questionnaires being sent out. This concern was shown to be unwarranted. In fact, the "quality" of answers supplied by the respondents was notably thorough and, as a result, condensing the information into a summarized format was very challenging.

F. Materials and Methods

The materials and methods used to assess the employees views of clinical trial progress tracking tools were two custom-designed questionnaires (Appendix A and B). Tracking Tools Part I and Tracking Tools Part II will be referred to throughout this document as Questionnaire #1 and Questionnaire #2. Both questionnaires were disseminated to all applicable personnel at Company A including: clinical directors, project managers, in-house clinical research associates, and clinical field monitors (office-based and regional). In order to preserve the integrity of unbiased results, the responses to these questionnaires were anonymous.

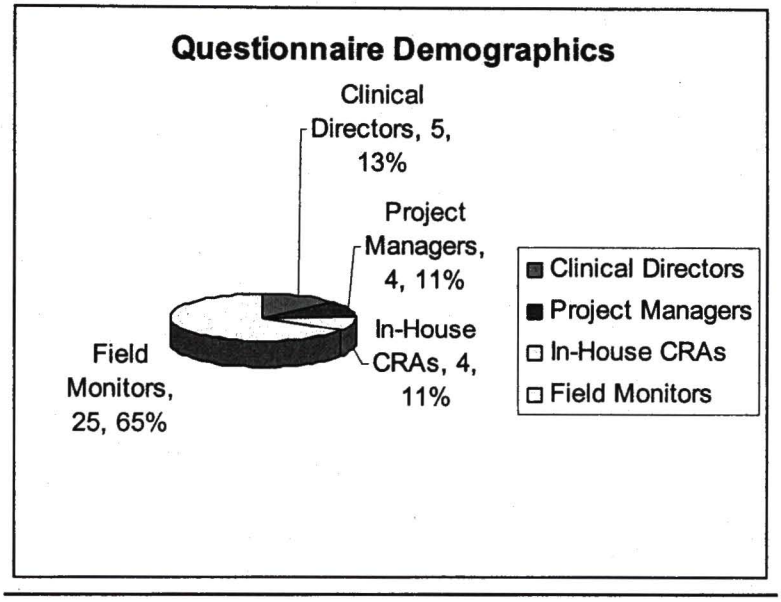
Questionnaire #1 (Appendix A) was designed to assess the employee's global views of clinical trial progress tracking tools. Open-ended questions were implemented into the design of this questionnaire as to thoroughly assess the employee's progress tracking tool usage, views, and opinions on instituting standardized trial progress trackers at Company A. The questionnaire was distributed by email to all applicable employees, who were given 10 business days to respond.

Questionnaire #2 (Appendix B) was designed after the responses were received from Questionnaire #1. The intention of Questionnaire #2 was to use the global responses received from Questionnaire #1 in order to provide a second questionnaire tailor-focused as to inquire about the views and opinions of 3-6 specific clinical trial progress trackers. Several statements within Questionnaire #2 were rated on a five-point

Likert scale. The Likert scale allows researchers to collect information based on the strength of the participant's agreement (Strongly Disagree=5, Somewhat Disagree=4, Neutral=3, Somewhat Agree=2, or Strongly Agree=1). Additional open-ended questions were included within the questionnaire to allow the participant to express concerns, suggestions, etc. in reference to the specific trial progress trackers featured. This questionnaire was disseminated by email to all applicable employees who were then allowed 15 business days to complete the questionnaire. A statistical analysis program was not necessary for the analysis of results received from the questionnaires, however, where applicable means and standard deviations were reported.

G. Results

Both Questionnaire #1 and Questionnaire #2 were disseminated to a total of 34 applicable staff employed by Company A. Please refer to the pie chart depicted below for questionnaire demographical information.



Questionnaire #1 yielded 12 responses out of 34, a 35% response rate. Questionnaire #1 was designed to obtain a global understanding and perspective of the clinical trial progress tracking tools used by applicable employees of Company A. In addition, Questionnaire #2 was designed based on results from Questionnaire #1 to obtain employee opinions, usage, and knowledge regarding five different clinical trail progress tracking tools. Questionnaire #2 yielded 29 responses out of 34, an 85% response rate.

Refer to Appendix H and I for a list of responses that were provided from Questionnaire #1 and Questionnaire #2 respectively.

Summarized Answers from Questionnaire #1

1.) What are the trackers you currently use for documenting the progress of your study(ies)?

- Informed Consent Document Tracker
- Adverse Event Trackers
- Query Trackers
- Patient Visit Window Trackers
- Case Report Form (CRF) Trackers (monitoring progress)
- TrialWorks Summary
- Living Document Tracker
- Enrollment Trackers
- Monitoring Visit Schedules
- Monitoring Visit Report Sponsor Submission Compliance Tracker
- Outstanding Items Tracker
- Protocol Deviation Tracker
- Data Safety Monitoring Board Availability for Conference Call Trackers
- Institutional Review Board (IRB) Approval/Renewal Tracking
- Site Reminders Tracking
- Case Report Form Receipt Tracking

- Regulatory Document Trackers

2.) What pieces of information do you find are essential for tracking in your study?

- Complete Medical Charts
- Updated TrialWorks Reports
- Weekly Submissions to Sponsors
- Regulatory Documents Collected
- Case Report Forms (CRFs) Collected
- Everything Tracked in TrialWorks
- Number of Patients Enrolled at Each Site
- Upcoming Deadlines
- Monitoring Visit Dates
- Subject Follow-up Status
- Serious Adverse Events
- Outstanding Queries
- Randomized Group Assignment
- Previous MVR

3.) Are you satisfied with the trackers you now have available for your use? If not, what types of information are you not able to capture on the current trial progress trackers you are using?

This question yielded 8 out of 12 (66.7%) respondents answering "yes," and the remaining 4 (33.3%) respondents answering "no." The following verbiage was

assembled in response to additional information respondents are not able to capture on current trial progress trackers.

- One respondent stated that CRF tracking could be better and more standardized across studies at Company A.
- A second respondent identified a need for a tool for prospective planning of the monitoring visit schedule that incorporates the study specific monitoring plan and data management reports.
- A third respondent was "unsatisfied" with trackers that are provided to Company A from other vendors.
- A fourth respondent commented on the color scheming of particular trackers (please keep colors to a minimum).

4.) Have you designed any trackers for documenting the progress of your study(s) that you think might be useful for other projects? These may be trackers you currently use of have used before.

- Site specific versions of any trackers provided by the data management company for efficiency.
- Living document (A comprehensive tool this monitor has used to document the natural progression of events in response to amendments and/or revisions of the protocol, consent form, and case report forms (CRFs). This document also captures study specific nuances potentially important for filling out specific answers on the CRFs. This would include any additional information that would be pertinent to documenting the "story" of the trial at hand.)

- CRF Submission Data Deadline Trackers
- Outstanding Items Trackers
- MVR Submission Trackers
- Missing CRF Pages Tracker
- Monitoring Visit Tracker (with multiple CRAs on-site)
- Device Trackers
- MACE Trackers
- Excel Device Accountability Tracking
- Regulatory Document Tracker
- CRF Status Tracking

5.) What is your opinion on having standardized trial progress trackers for all studies conducted at Company A?

- It would be simpler to find specific trackers in GroupWise (decide on a trial-by-trial basis)
- I strongly believe this is the best way to go, for each and every trial. This will allow us to become gradually an expert at tracking and much more effective in making those important deadlines. If trackers change with each study, I can easily see how CRAs will become frustrated.
- I highly recommend it. Standardization and process streamlining is something that is definitely needed here at Company A. I don't want to be limited by a standard tracker but simple/generic tracker that can be customized might help.

- Very good idea if it makes sense. Sometimes a tracker for one study will not work for another study without modification. Standardization should be done whenever possible.
- If it can be tailored by the individual CRA then I like it.
- Good Idea
- I can see value as well as problems. The value is that a standardized tracking system could provide a structure eliminating the start up issue and adjustments needed for new project tracking, in addition to, support for procedural compliance. The problem with standardization is having to "work around" the standardized system because a particular project does not utilize all aspects of the standardized document. Consequently, the "work arounds" eliminate much of the value of the system.
- I don't think standardization is a feasible idea, because every study (even studies run by the same sponsor) will have different requirements. I think flexible templates would be useful to build trackers that are specific to the needs of each study and that can be changed part-way through the study in order to accommodate new requests for different pieces of information.
- Standardization is great, but must also allow for some variation depending on the needs of the individual study.
- All studies are a little different, however having a standardized tracker helps in finding information that should always exist.

Summarized Answers from Questionnaire #2

OUTSTANDING ISSUES TRACKER (Appendix C)

1. The attached Outstanding Issues Tracker is a Project Management tracking tool that is also an excellent CRA resource. Do you feel that this tracker will accurately assist in the management of the site?

Response	Frequency	Percent
Strongly Agree = 1	19	66
Somewhat Agree = 2	9	31
No Opinion = 3	0	0
Somewhat Disagree = 4	1	3
Strongly Disagree = 5	0	0
Total	29	100

Table 1: Outstanding Issues Tracker – Assist in Management of the Site

(n=29, mean=1.41, sd=0.68)

2. How frequently would you reference this Outstanding Issues Tracker?

Response	Frequency	Percent
Every Day = 1	1	4
Once a Week= 2	14	48
Every 2 Weeks = 3	3	10
Every 4-6 Weeks= 4	10	35
Never = 5	1	4
Total	29	100

Table 2: Outstanding Issues Tracker – Frequency

3. Do you find the attached Outstanding Issues Tracker user-friendly?

Response	Frequency	Percent
Strongly Agree = 1	15	52
Somewhat Agree = 2	9	31
No Opinion = 3	1	3
Somewhat Disagree = 4	4	14
Strongly Disagree = 5	0	0
Total	29	100

Table 3: Outstanding Issues Tracker – User-Friendly

(n=29, mean=1.79, sd=1.05)

4. If you don't find the Outstanding Issues Tracker user-friendly, please provide a brief answer as to why. The following summarized information was provided:

- One respondent stated that "Column O" needed to be further clarified.
- One respondent stated that at first glance this tracker looked potentially too busy and confusing; however, the respondent also stated that training to this document would probably be beneficial.

5. Would you say that this Outstanding Issues Tracker would provide an added benefit to successful monitoring?

Response	Frequency	Percent
Strongly Agree = 1	15	54
Somewhat Agree = 2	11	39
No Opinion = 3	1	3.5
Somewhat Disagree = 4	1	3.5
Strongly Disagree = 5	0	0
Total	28*	100

Table 4: Outstanding Issues Tracker – Successful Monitoring

(n=28, mean=1.46, sd=0.58)

*One Blank Answer

PROTOCOL DEVIATION TRACKER (Appendix D)

6. What has your involvement been in tracking Protocol Deviations?

Response	Frequency	Percent
I am actively involved in tracking protocol deviations in the studies I work on. = 1	16	57
The studies I work on do track protocol deviations, however I am not responsible for specifically keeping track of them. = 2	8	29
I am not aware of how protocol deviations are tracked in the studies I work on. = 3	1	3
I am not aware of how protocol deviations are tracked in the studies I work on, however, I do keep a personal record of the protocol deviations at my sites. = 4	3	11
Total	28*	100

Table 5: Protocol Deviation Tracker – Involvement

*One Blank Answer

7. Do you feel the following Protocol Deviation Tracker addresses all aspects necessary for protocol deviation tracking?

Response	Frequency	Percent
Strongly Agree = 1	9	32
Somewhat Agree = 2	16	57
No Opinion = 3	0	0
Somewhat Disagree = 4	3	11
Strongly Disagree = 5	0	0
Total	28*	100

Table 6: Protocol Deviation Tracker – Addresses Necessary Information

(n=28, mean=1.89, sd=0.88)

*One Blank Answer

8. If you don't find that the Protocol Deviation Tracker addresses all aspects necessary for protocol deviation tracking, please briefly list any category headings you would like to see in the box provided. The following summarized information was provided:

- One respondent suggested a potential column for "inclusion/exclusion deviations."
- Three respondents suggested variations of the following additional category headings: "protocol deviations (PD) listed on data management report," "PI signed off on PD," "PD reported via monitor generated form," "IRB response."

- One respondent suggested headings for "immediate reporting required" and "intentional/inadvertent error."

9. Do you find this Protocol Deviation Tracker user-friendly?

Response	Frequency	Percent
Strongly Agree = 1	12	43
Somewhat Agree = 2	13	46
No Opinion = 3	2	7
Somewhat Disagree = 4	1	4
Strongly Disagree = 5	0	0
Total	28*	100

Table 7: Protocol Deviation Tracker – User-Friendly

(n=28, mean=1.71, sd=0.76)

*One Blank Answer

10. If you don't find the Protocol Deviation Tracker user-friendly, please provide a brief answer as to why. The following summarized information was provided:

- One respondent stated that it would be beneficial to know where the deviations were generated from, because in their particular study deviations are generated by both the data management company and the monitor themselves.
- One respondent requested that the "description" section would be more user-friendly if it was longer.
- One respondent said that this particular version of a protocol deviation tracker was labor intensive, and suggested to eliminate a few categories.

- One respondent mentioned that for lengthy studies this spreadsheet might potentially get overwhelming, and in turn suggested an individual worksheet for each year of the study within a PD workbook.

11. Would you support standardization of the attached Protocol Deviation Tracker at Company A?

Response	Frequency	Percent
Strongly Agree = 1	9	31
Somewhat Agree = 2	19	66
No Opinion = 3	0	0
Somewhat Disagree = 4	1	3
Strongly Disagree = 5	0	0
Total	29	100

Table 8: Protocol Deviation Tracker – Standardization

(n=29, mean=1.76, sd=0.64)

12. If you do not support standardization of the attached Protocol Deviation Tracker, briefly discuss as to why. The following summarized information was provided:

- One respondent stated that a standardized protocol deviation tracker wouldn't be necessary if a client provided a protocol deviation tracker of their own (unnecessary to have two trackers tracking the same information).
- Two respondents stated that if standardization did occur that these trackers would need to be tailored to each specific study.
- One respondent stated that, "standardization in this area can be challenging, since sponsor, data management and protocol requirements and conventions vary

broadly between projects." However, this same respondent said that a uniform monitoring tool can sometimes be a good resource.

SAE TRACKER (Appendix E)

13. What has your involvement been in tracking SAEs?

Response	Frequency	Percent
I am actively involved in tracking SAEs in the studies I work on. = 1	18	62
The studies I work on do track SAEs, however I am not responsible for specifically keeping track of them. = 2	7	24
I am not aware of how SAEs are tracked in the studies I work on.= 3	2	7
I am not aware of how SAEs are tracked in the studies I work on, however, I do keep a personal record of the SAEs at my sites. = 4	2	7
Total	29	100

Table 9: SAE Tracker – Involvement

14. Do you feel the attached SAE Tracker addresses all aspects necessary for SAE tracking?

Response	Frequency	Percent
Strongly Agree = 1	4	14
Somewhat Agree = 2	15	52
No Opinion = 3	1	3
Somewhat Disagree = 4	7	24
Strongly Disagree = 5	2	7
Total	29	100

Table 10: SAE Tracker – Address Necessary Information

(n=29, mean=2.59, sd=1.21)

15. If you don't find that the SAE Tracker addresses all aspects necessary for SAE tracking, please briefly list any category headings you would like to see. The following summarized information was provided:

- Ten respondents suggested the following headings, "date reported to IRB" and "date reported to other investigators"
- Three respondents suggested that a column be added to note what CRFs and source documents were sent into the data management company
- One respondent suggested that a column be added for "medical monitor/nurse review/CEC status." This same respondent suggested a comment box to be built into the tracker.
- One respondent suggested that a column be added for "MedWatch number."
- One respondent suggested an additional column for "time required to complete and justify billing accordingly."
- One respondent stated that the column heading "date noted by site," might need to be revised to state, "date site became aware of the event." This same respondent suggested that after the column "date of initial contact to sponsor" there should be a column for "date of initial contact to the IRB." In addition, this respondent suggested an additional column to reference a major adverse cardiovascular events (MACE) or endpoint.

16. Do you find the attached SAE Tracker user-friendly?

Response	Frequency	Percent
Strongly Agree = 1	13	45
Somewhat Agree = 2	16	55
No Opinion = 3	0	0
Somewhat Disagree = 4	0	0
Strongly Disagree = 5	0	0
Total	29	100

Table 11: SAE Tracker – User-Friendly

(n=29, mean=1.55, sd=0.51)

17. If you don't find the SAE Tracker user-friendly, please provide a brief answer as to why. The following summarized information was provided:

- One respondent stated, "The user-friendliness and the usefulness of the tracker could be improved by considering the different roles of the people who may be using the tracker by simply increasing its sorting/comparing potential."
- One respondent was concerned with the potential risk of having someone accidentally erase, move, or change information that they did not intend to have removed because of their novice abilities with working in Excel, etc. This respondent was also concerned with the fact that this tracker could potentially be "huge" if an entire monitoring team had sharing rights to it.

18. Would you support standardization of the attached SAE tracker at Company A?

Response	Frequency	Percent
Strongly Agree = 1	13	45
Somewhat Agree = 2	14	48
No Opinion = 3	2	7
Somewhat Disagree = 4	0	0
Strongly Disagree = 5	0	0
Total	29	100

Table 12: SAE Tracker – Standardization

19. If you do not support standardization of the attached SAE Tracker, briefly discuss as to why. The following summarized information was provided.

- One respondent stated that a standardized SAE Tracker wouldn't be necessary if a client provided a SAE tracker of their own (unnecessary to have two trackers tracking the same information).
- One respondent stated that he/she did not support standardization of this tracker unless the tracker allows the flexibility to address the various needs of the study team.
- One respondent stated that this tracker would be better suited to be completed by the data management company.

INFORMED CONSENT DOCUMENT TRACKER (Appendix F)

20. What has your involvement been in tracking Informed Consents?

Response	Frequency	Percent
I am actively involved in tracking informed consents in the studies I work on. = 1	24	83
The studies I work on do track informed consents, however I am not responsible for specifically keeping track of them. =2	4	14
I am not aware of how informed consents are tracked in the studies I work on. = 3	0	0
I am not aware of how informed consents are tracked in the studies I work on, however, I do keep a personal record of my informed consents at my sites. = 4	1	3
Total	29	100

Table 13: Informed Consent Document Tracker – Involvement

21. Do you feel the attached Informed Consent Document Tracker addresses all aspects necessary for informed consent tracking?

Response	Frequency	Percent
Strongly Agree = 1	11	39
Somewhat Agree = 2	11	39
No Opinion = 3	0	0
Somewhat Disagree = 4	4	15
Strongly Disagree = 5	2	7
Total	28*	100

Table 14: Informed Consent Document Tracker – Addresses Necessary Information

(n=28, mean=2.11, sd=1.29) * One Blank Answer

22. If you don't find that the Informed Consent Document Tracker addresses all aspects necessary for Informed Consent tracking, please briefly list any category headings you would like to see. The following summarized information was provided.

- One respondent suggested that the date of the subject's last visit be added as a heading (helpful in the case that a subject has been terminated from the study, so as to not be looking for signed versions unnecessarily).
- One respondent suggested that "IRB approval date" and/or "IRB assigned numbers for the ICF" be added as a heading.
- One respondent suggested that "versions" of this form could be used in order to accommodate multiple ICF amendments.
- Three respondents stated that a yes or no column for "consent executed properly" be added to the tracker.

23. Do you find the attached Informed Consent Tracker user-friendly?

Response	Frequency	Percent
Strongly Agree = 1	15	52
Somewhat Agree = 2	9	31
No Opinion = 3	2	7
Somewhat Disagree = 4	1	3
Strongly Disagree = 5	2	7
Total	29	100

Table 15: Informed Consent Document Tracker – User-Friendly

(n=29, mean=1.83, sd=1.17)

24. If you don't find the Informed Consent Document Tracker user-friendly, please provide a brief answer as to why. The following summarized information was provided.

- One respondent stated that a column denoting the date the patient signed the ICF would make this tracker more user-friendly.
- One respondent suggested tracking a single version (instead of all versions) of the consent form (date of signature, y/n column for any issues noted, and comment section for how issues were addressed and corrected).
- One respondent suggested that a spreadsheet format might make this tracker more user-friendly.

25. Would you support standardization of the following Informed Consent Document Tracker at Company A?

Response	Frequency	Percent
Strongly Agree = 1	19	65
Somewhat Agree = 2	6	21
No Opinion = 3	2	7
Somewhat Disagree = 4	2	7
Strongly Disagree = 5	0	0
Total	29	100

Table 16: Informed Consent Document Tracker – Standardization

(n=29, mean=1.55, sd=0.91)

26. If you do not support standardization of the attached Informed Consent Document Tracker, briefly discuss as to why. The following summarized information was provided.

- One respondent stated that a standardized Informed Consent Tracker wouldn't be necessary if a client provided an ICF tracker of their own (unnecessary to have two trackers tracking the same information).

IRB APPROVAL HISOTRY LOG (Appendix G)

27. At the sites you monitor, do you find that keeping track of the site-specific current protocol version and corresponding amendments is challenging?

Response	Frequency	Percent
Strongly Agree = 1	10	37
Somewhat Agree = 2	13	48
No Opinion = 3	2	7
Somewhat Disagree = 4	1	4
Strongly Disagree = 5	1	4
Total	27*	100

Table 17: IRB Approval History Log – Tracking

(n=27, mean=1.89, sd=0.97) *Two Blank Answers

28. Do you feel the attached IRB Approval History Log addresses all aspects necessary for documenting the IRB approval history?

Response	Frequency	Percent
Strongly Agree = 1	13	45
Somewhat Agree = 2	11	38
No Opinion = 3	0	0
Somewhat Disagree = 4	3	10
Strongly Disagree = 5	2	7
Total	29	100

Table 18: IRB Approval History Log – Addresses Necessary Information

(n=29, mean 1.97, sd=1.24)

29. If you don't find that the IRB Approval History Log addresses all aspects necessary for documenting IRB approval history, please briefly list any category headings you would like to see. The following summarized information was provided.

- One respondent stated that an additional heading for "policy/requirements for reconsenting" be added.
- One respondent suggested a category heading such as "comments" for miscellaneous information (patient information card, etc).
- One respondent stated that this tracker is "invaluable," however he/she expressed concerned over the possibility of this tracker overwhelming monitors, and therefore suggested a more simplified version.
- One respondent stated that a column heading for "version number" be added, because some IRBs track ICF versions by version numbers only (not by the approval date).
- Four respondents suggested a heading for the "expiration date."
- Two respondents suggested limiting the tracking to protocols, ICFs, and HIPPA documents only. As an alternative to the previous suggestion, the respondent also suggested modifying the tracker to include all types of IRB approvals.

30. Do you find the attached IRB Approval History Log user-friendly?

Response	Frequency	Percent
Strongly Agree = 1	16	55
Somewhat Agree = 2	11	38
No Opinion = 3	0	0
Somewhat Disagree = 4	0	0
Strongly Disagree = 5	2	7
Total	29	100

Table 19: IRB Approval History Log – User-Friendly

(n=29, mean=1.66, sd=1.04)

31. If you don't find the IRB Approval History Log user-friendly, please provide a brief answer as to why. The following summarized information was provided.

- One respondent suggested that only the most necessary information should be captured on the IRB approval history log, and therefore the tracker would incorporate less columns. The same respondent also suggested a column for amendments/modifications, in addition to a larger "comments" column.

32. Would you support standardization of the following IRB Approval History Log at Company A?

Response	Frequency	Percent
Strongly Agree = 1	14	52
Somewhat Agree = 2	8	30
No Opinion = 3	1	4
Somewhat Disagree = 4	0	0
Strongly Disagree = 5	4	14
Total	27*	100

Table 20: IRB Approval History Log – Standardization

(n=27, mean=1.96, sd=1.40)

*Two Blank Answers

33. If you do not support standardization of the attached IRB Approval History Log, briefly discuss as to why. The following summarized information was provided.

- One respondent stated that the information captured on the ICF log and the IRB history log could be combined into one document.
- One respondent stated that this information is already being tracked in TrialWorks and therefore monitors shouldn't spend their time creating "duplicate work."

34. Of the following five tracking tools, which one would you say ranks at the top of your list as a tool you feel would make your monitoring experience more successful?

Response	Frequency	Percent
Informed Consent Document Tracker = 1	8	28
Protocol Deviation Tracker = 2	3	10
IRB Approval Log = 3	5	17
Outstanding Issues Tracker = 4	10	35
SAE Tracker = 5	3	10
Total	29	100

Table 21: Ranking of Five Tracking Tools (top)

35. Of the following five tracking tools, which one would you say ranks at the bottom of your list as a tool you feel would make your monitoring experience more successful?

Response	Frequency	Percent
Informed Consent Document Tracker = 1	5	17
Protocol Deviation Tracker = 2	9	31
IRB Approval Log = 3	11	38
Outstanding Issues Tracker = 4	3	10
SAE Tracker = 5	1	4
Total	29	100

Table 22: Ranking of Five Tracking Tools (bottom

36. Do you feel adequately equipped to successfully track all aspects of your study with the above-mentioned standardized site tools and TrialWorks?

Response	Frequency	Percent
Strongly Agree =1	11	41
Somewhat Agree = 2	12	45
No Opinion = 3	0	0
Somewhat Disagree = 4	2	7
Strongly Disagree	2	7
Total	27*	100

Table 23: Adequately Equipped

(n=27, mean=1.96, sd=1.19)

*Two Blank Answers

37. If you do not feel adequately equipped to successfully track all aspects of your study with the above-mentioned standardized site tools and TrialWorks, please indicate as to why. The following summarized information was provided.

- One respondent stated that "special" trackers could be made to supplement the above mentioned tools for tracking if the occasion arose, because successful tracking is largely dependent upon the study, the sponsor, and the CRO; in addition to, what work has been contracted to Company A to perform.
- One respondent stated that documentation of IRB reporting of adverse events and protocol deviations are not covered by a specific tracker nor in TrialWorks. It may be tracked in the outstanding items tracker but the items tracker content is mostly dependent on the detail and effectiveness of the site monitor and the monitoring visit report (MVR). Thorough follow-up and investigation of on-going reporting of events and deviations to the IRB is currently a weakness seen at Company A. Additionally this respondent stated, "tracking of training of site personnel is not covered here, and when questions arise it is often difficult to identify previous training, follow-up on compliance issues, and dates of study activity."
- One respondent expressed concern over CRF tracking being omitted from this list, however otherwise the tools mentioned were satisfactory.

38. Please provide any additional comments you may have pertaining to the attached tracking documents and/or the standardization of these documents.

The following summarized information was provided.

- Two respondents stated that Company A should have standardized trackers and templates for all essential study tracking. In addition, both parties mentioned that

if modifications needed to be made based upon a specific study, they should be allowed to do so.

- Two respondents stated that standardization was "paramount" to a successful study, however, neither respondent felt that trackers should be "mandated.
- One respondent stated, "using Company A's standardized tracking tools would increase efficiency of CRA re-assignment of sites."
- One respondent stated that all the above-mentioned trackers would be useful as long as the "client did not have a requirement for the same information to be documented on their own tracker."
- One respondent expressed the following concerns, "that the excel trackers (outstanding issues, PDs, SAEs) will get to be huge spreadsheets for study-wide tracking, and if you have an entire monitoring team who has access to these trackers, you may be taking a risk that someone accidentally erases/moves/changes information on this large tracker." This respondent also expressed concern over the amount of remote monitoring time that would be spent completing these trackers, if the following trackers were introduced to the monitoring teams across all studies.

39. Which of the following statements best describes your current mental condition after filling out this questionnaire?

Response	Frequency	Percent
Pleasant...in fact, you are surprised at how a questionnaire of this nature is actually "refreshing." = 1	17	58
Anger...a small volcano is beginning to erupt, however, you feel "in-control" of these feelings!!!! = 2	0	0
Laughter...it is gut-wrenching laughter that closely resembles hysteria. = 3	4	14
Comatose...even here you still manage to have the will to survive.= 4	6	21
No comment...it hurts too much to talk about! = 5	2	7
Total	29	100

Table 24: Current Mental Condition

H. Discussion

Questionnaire #1 was sent to 34 clinical operations employees at Company A. A team of 2 clinical directors, in addition to, two in-house clinical research associates designed this questionnaire. As previously discussed in the materials and methods section, this questionnaire was designed to assess employees' global views of clinical trial progress tracking. Questionnaire #1 yielded a 35% response rate, which was noted by the design team as lower than expected. However, as the limitation section stated, a 35% response rate was deemed adequate given the global nature of information collected. Refer to Appendix H for an exhaustive list of responses to Questionnaire #1.

When employees were polled about the types of trackers they were currently using, more than 30 examples of different trial progress trackers ranging from informed consent document trackers to living document trackers were mentioned. The intent of this question was to get a very general idea of the types of trackers employees at Company A were accustomed to using.

The design group implemented the question, "What pieces of information do you find are essential for tracking in your study," in order to obtain a greater understanding of the types of information that would require the most successful tracking methods. Streamlining and perfecting the tracking tools for capturing the most relevant information should be a primary endpoint in successfully tracking the progress of any trial.

When employees were asked about their satisfaction with the current trial progress tracking tools, 66.7% of the respondents answered "yes," and the remaining respondents (33.3%) answered "no." Of the respondents who answered "no," we asked them to provide us with information that would further assist us in understanding what integral pieces of information were not currently being captured underneath the umbrella of trial progress tools provided to them. Four respondents expressed their findings, which have been summarized in the results section.

Many of the field monitors have trial progress tracking tools that they have used from previous studies, previous employers, in addition to ones that they have designed themselves. Employees were asked to provide names of the tracking tools they felt might be useful for other projects within Company A. This question was implemented to allow for trackers that had been designed and/or used outside the Company, or used primarily within one study, to be considered for possible usage and standardization within Company A or shared between studies.

In the initial discussions by the design team, moving Company A towards more standardized trial progress tracking tools, across all studies, was the direction of interest. As a result, employees were polled of their general opinion of having standardized trial progress trackers for all studies conducted at Company A. Open-ended questions were implemented into the design of the questionnaires (primarily Questionnaire #1). This format of "surveying" the employees did not yield results which were numerical in nature, but instead results identified "trends" in the answers of the responses interpreted. The following trends were noted: many of the respondents who were supportive of

standardization suggested that documents being standardized also offer an element of flexibility. No two studies are the same, and therefore offering one document across all studies, without the option of "customizing," was definitely noted among a majority of the respondents as a downfall to standardization. In addition, those who wholly supported standardization felt a general need for Company A to move in this direction in order to streamline cumbersome processes and more efficiently track essential pieces of information. Based on these findings, Company A should move forward in their goal of creating tailored, yet flexible, standardized trial progress tracking tools for all applicable studies.

Based on the results received back from Questionnaire #1, Questionnaire #2 was designed. The underlying principle governing the choice of tracking tools included within the questionnaire, and therefore the questions implemented into the questionnaire, was the goal to survey the employees regarding standardization of a selection of trial progress tracking documents at Company A. The following trackers were chosen by the design team as the top five trial progress tracking tools that would potentially be good candidates for standardization: Outstanding Issues Tracker, Protocol Deviation Tracker, Serious Adverse Events (SAE) Tracker, Informed Consent Document Tracker, and the IRB Approval History Log. The questionnaire was designed to capture the unique aspects of each tracker, in addition to gathering a general understanding of the tracker.

When employees were asked if the Outstanding Issues Tracker would accurately assist in the management of their sites, approximately 66% agreed, 31% somewhat

agreed and 3% somewhat disagreed. This suggests that the majority of the monitors view this tracker as an essential tool for successfully tracking the progress of their sites.

To better understand the usefulness of this tracker, the design team evaluated how frequent this document was being accessed; approximately 4% said they used the tracker everyday, 48% said that they used the tracker once a week, 10% said they used the tracker every 3 weeks, 35% said they used the tracker every 4-6 weeks, and 4 % said they don't use the tracker at all. These findings reinforced the team's previous understandings of how frequent this document was being accessed.

Standardizing a document that not only captures the essential pieces of information in a study, but also provides a format in which the user is comfortable and able to easily navigate through, are essential pieces of information to capture before implementing standardization. When employees were asked about the user-friendliness of the Outstanding Issues Tracker, approximately 52% strongly agreed, 31% somewhat agreed, 3% had no opinion, and 14% somewhat agreed. These findings suggest that at least 83% of the respondents felt that this particular "version" of the Outstanding Issues Tracker was user-friendly. A few comments were suggested how the tracker could be more user-friendly however; in light of such acceptance of the tracker I would be hesitant to incorporate too many changes into this version.

Employees were asked if this tracker would provide an added benefit to successful monitoring; approximately 54% strongly agree, 39% agree, 4% have no opinion, and 4% somewhat disagree. Results continue to suggest (93%) that this tracker

is a tool that is essential for successful trial progress documentation and tracking, and would be an advantageous resource as a standardized tool at Company A.

The second tracker evaluated was the Protocol Deviation Tracker. In order for the team to gain a better understanding of the employees' attitudes and opinions of the tracker, the questionnaire addressed the following areas of interest: involvement in protocol deviation tracking, whether the tracker was all-encompassing, the necessity of adding additional headings, the tracker's user-friendliness, and standardization of the tracker at Company A. Approximately 57% of the employees at Company A are actively involved in tracking protocol deviations in the study, 29% of the employees are not directly involved in protocol deviations but know that protocol deviations are tracked, 4% are not aware of how protocol deviations are tracked; and 11% are not aware of how protocol deviations are tracked within their study, but keep a personal log of their own. These findings suggest that a majority of the employees polled (57%) have a direct involvement with protocol deviation tracking, and therefore would potentially benefit from having this tracker made available to them in a more standardized format.

Employees were also asked if the respective protocol deviation tracker was all encompassing and addressed their protocol deviation tracking needs. Approximately 32% strongly agreed, 57% of the somewhat agreed, and 11% somewhat disagreed. It is apparent that a majority of employees expressed approval of the protocol deviation tracker (89%) for addressing their protocol deviation needs. These findings continue to suggest that the respective protocol deviation tracker is a useful tool for tracking protocol deviations, and therefore could p be a good candidate for standardization.

Modifications to the protocol deviation tracker were revealed by the employees as to enhance the value of the protocol deviation tracker. The following additional column headings were requested by employees at Company A: inclusion/exclusion deviations, protocol deviations listed on data management report, PI signed off on protocol deviation, and IRB Response. Respondents voiced their opinions on adding additional column headings, and therefore it is suggested that Company A seriously take into consideration the idea of reconstructing a new protocol deviation tracker which would include a revised listing of column headings.

The user-friendliness of the protocol deviation tracker was also polled. Approximately 43% of the employees strongly agreed that the tracker was user-friendly, 46% of the employees somewhat agree, 7% had no opinion, and 4% somewhat disagreed. The protocol deviation tracker was found user-friendly by more than 85% of the employees at Company A. The following modifications were requested by the respondents: adding a description section, in addition to, a section that would provide information stating where deviations were generated from (monitor or Data Management Company). These finding suggest that the user-friendliness of this document is not in question; however, a few revisions to the overall structure of the document will need to be considered before it would be a good candidate for standardization.

Employees were also asked whether they supported standardization of the Protocol Deviation Tracker at Company A. Approximately 31% strongly agreed, 66% somewhat agreed, and 4% somewhat disagreed. Employees are in favor of standardization (97%) of this document at Company A. However, employees also

expressed their concerns with standardization. Employees expressed that a document being standardized must allow for some "flexibility" to be built into the tracker to allow for study specific differences, otherwise standardization was not a beneficial option for them.

The third tracker evaluated was the Serious Adverse Event (SAE) Tracker. In order to get a better understanding of the employees' attitudes and opinions of the tracker, the questionnaire addressed the following: involvement in SAE tracking, whether the tracker was all-encompassing, the tracker's user-friendliness, standardization of the tracker at Company A, and additional comments/concerns by the employees.

Approximately 62% of the employees polled at Company A are actively involved in tracking SAEs in the studies they work on, 24% are not responsible for SAE tracking but understand that SAEs are tracked in their studies, 7% are not aware of how SAEs are tracked; and 7% are not aware of how SAEs are tracked in the studies they work on, but they keep a personal record for their own piece of mind. These findings suggest that the SAE tracking tool may potentially be a good candidate for Company A to standardize, especially if 62% of the employees are "actively" involved in tracking SAEs.

Employees were also asked if they felt that the SAE Tracker addressed all aspects necessary for SAE tracking. Approximately 14% strongly agreed, 52% somewhat agreed, 4% had no opinion, 24% somewhat disagreed, and 7% strongly disagreed. Many "suggestions" were expressed by employees (see the results section), who responded back to the questionnaire in reference to the general design of the tracker. Even with a total of 66% of the employees expressing agreement that the SAE Tracker addressed all

aspects necessary for SAE tracking, it is suggested that Company A proceed with caution when they discuss standardization of this document. Having 24% of the respondents express that they somewhat disagree with this tracker addressing all aspects necessary for SAE tracking, in addition to, the lengthy list of changes requested by the employees; it would be to Company A's best interest to restructure this document and seek further clarification by the employees as to their SAE tracking needs before standardization of this document occurs.

Employees were also poled as to their opinion of the user-friendliness of the SAE Tracker. Approximately 45% strongly agreed that this version of the SAE tracker was user-friendly and 55% somewhat agreed. A few additional comments were submitted by respondents, but these comments didn't necessarily address the user-friendliness of the document. These findings suggest that all employees polled found this document to be user-friendly, and a similar format should be instituted into future versions of a revised SAE Tracker.

Employees were also asked whether or not they supported standardization of the attached SAE Tracker. Approximately 45% strongly agreed, 48% somewhat agreed, and 7% had no opinion. These results indicate that standardization of a SAE tracker within Company A would be received very successfully, however considerable revision of the respective SAE tracker would first need to be implemented.

The fourth tracker evaluated was the Informed Consent Document Tracker. In order to gain a better understanding of the employees' attitudes and opinions of the tracker, as with the previous trackers, the questionnaire addressed the following:

involvement in Informed Consent Document tracking, whether the tracker was all-encompassing, if additional headings were needed, the tracker's user-friendliness, and standardization of the tracker at Company A.

Involvement of the Informed Consent Document Tracker by employees at Company A revealed the following: approximately 83% of the employees are actively involved in tracking informed consent documents in the studies they work on; 14% understand that informed consent documents are tracked, but they are not specifically responsible for tracking them; and 3% are unaware of how informed consent documents are tracked in their studies, but themselves keep a personal record of all the informed consents at their sites. These findings suggest that a majority of the employees that work at Company A track informed consents on a regular basis (97%). Because such a high number of employees track informed consent documents, capturing this type of information in a clear, concise, and efficient manner must be seen as vital to successful site management at Company A. In addition, standardizing a document which captures information that 97% of the employees at Company A are tracking, would allow for a more unified approach to tracking informed consent documents at Company A, and therefore streamline practices between studies.

When employees were asked if the Informed Consent Document Tracker addressed all aspects necessary for informed consent document tracking, approximately 39% strongly agreed, 39% somewhat agreed, 14% somewhat disagreed, and 7% strongly disagreed. Some employees also suggested that the following column headings be implemented into the design of the Informed Consent Document Tracker: subject's last

visit date, IRB approval date, consent executed properly; and one respondent requested that "versions' of this form could be used in order to accommodate multiple ICF amendments. Based on these findings, the majority of the employees polled, agreed (78%) that the Informed Consent Document Tracker addressed the necessary information for tracking informed consents. However, given that 21% of the employees disagreed with this statement, I would advise Company A to use the suggestions provided by the employees to modify the Informed Consent Tracker before standardization of the document takes place.

Employees were also asked whether or not they felt that the Informed Consent Document Tracker was user-friendly, approximately 66% of the employees strongly agreed, 21% of the employees somewhat agreed, 7% had no opinion, and 7% somewhat disagreed. The results unequivocally suggest (87%) that the Informed Consent Document Tracker was presented in a very user-friendly format. Company A should use a similar format if they anticipate revising the current version of the Informed Consent Document Tracker with the above-mentioned additions.

When employees were asked if they supported standardization of the Informed Consent Document Tracker provided to them in the questionnaire, the following results were obtained: approximately 66% of the respondents strongly agreed with standardizing this document, 21 % somewhat agreed, 7% had no opinion, and 7% somewhat disagreed. These findings strongly indicate that employees at Company A would definitely be in favor of standardizing the Informed Consent Document Tracker across studies (87%), and doing so would aid in successful management of their sites.

The fifth tracker evaluated was the Institutional Review Board (IRB) Approval History Log. As with the previous four trackers, understanding the employees' attitudes and opinions of the IRB Approval History Log was obtained from querying employees about whether or not the log addressed all aspects necessary for documenting the IRB approval history, if keeping track of protocol versions/amendments is a challenge at their sites, the tracker's user-friendliness, and standardization of the tracker at Company A.

When employees were asked if keeping track of site-specific current protocol versions and corresponding amendments was challenging at their sites, the following results were obtained: approximately 35% of the employees said that they strongly agreed that this task was challenging, 45% somewhat agreed, 7% had no opinion, 4% somewhat disagreed, and 4% strongly disagreed. These results suggest that 75% of the employees at Company A found tracking site-specific current protocol versions and amendments challenging at their sites, and therefore establishes a definite need for Company A to provide resources in which to assist with remedying this problem. In order to do so, it may be to Company A's benefit to provide a standardized trial progress tracking tool such as the IRB Approval History Log.

The employees were also asked if the IRB Approval History Log provided to them addressed all aspects necessary for documenting the IRB approval history. Approximately, 45% strongly agreed with the above-mentioned statement, 38% somewhat agreed, 10% somewhat disagreed, and 7% strongly disagreed. The following comments were mentioned by 10 employees as suggested category headings to be added to the tracker: policy/requirements for reconsenting, comments, version number, and the

expiration date of the consent form. Even with 83% of the employees agreeing that the IRB Approval Log provided the necessary information for documenting the IRB approval history, I would also suggest that Company A take into account the suggested column headings. This question also received many comments from those respondents who felt that this was a great tracker. It would be to Company A's advantage to revise the current version of the IRB Approval Log with the additional column headings, thereafter pole employees again regarding their satisfaction.

When asked if employees found the IRB Approval History Log user friendly, approximately 55% strongly agreed, 38% somewhat agreed, and 7% strongly disagreed. These findings suggest that a majority of the employees (93%) were very satisfied with the user-friendly format of this Log. As previously mentioned, if Company A chooses to revise the current IRB Approval History Log, keeping a similar format will ensure that employees will be able to easily navigate through the document and capture the most necessary information in an efficient manner.

Employees at Company A were also asked if they supported standardization of the following IRB Approval History Log at Company A. Approximately, 48% of the employees strongly agreed, 28% somewhat agreed, 4% had no opinion, and 14% strongly disagreed. Comments were mentioned in reference to standardizing this document; however, the results for the majority of the participants (76%) indicated that employees at Company A look favorable upon the idea of standardizing this document. Results also suggest that if the revisions (previously discussed) were implemented into the design of a

new IRB History Log, it is unlikely that 14% of the respondents would disagree with or disapprove of standardizing this document.

Employees were asked to rank their top trial progress tracking tool from the five trackers that were provided to them in the questionnaire. The majority of the employees felt that the top trial progress tracking tool which would assist in making their monitoring experience more successful was the Outstanding Issues Tracker (35%), followed by the Informed Consent Document Tracker (28%), followed by the IRB Approval Log (17%), and a tie for the final position was the Protocol Deviation Tracker and the SAE Tracker (10%). These findings suggest that if Company A has a limited amount of time, energy, and/or resources dedicated to standardizing documents across studies, that specific attention be placed on the Outstanding Issues tracker as a priority not only for employee satisfaction but for streamlining successful practices as a whole.

Employees were also asked to rank their bottom trial progress tracking tool from the five trackers that were provided to them in the questionnaire. Approximately, 38% of the employees at Company A said that the IRB Approval Log would rank at the bottom of their list of trackers for a tool they felt would make their monitoring experience more successful. Next was the Protocol Deviation Tracker with 31%, followed by the Informed Consent Document Tracker with 17%, followed by the Outstanding Issues Tracker with 10%, and lastly the SAE tracker with 4% of the votes. These findings were not congruent with the findings that were reported in the previous question. Due to anonymous responses received back from the Questionnaires, these discrepancies could not be further analyzed. In response, these results therefore cannot be explained without

a new type of investigation in order to clarify the nature of the discrepancy by the respondents who participated in Questionnaire #2.

Employees were also asked if the tracking tools provided to them in the questionnaire, in addition to TrialWorks, was sufficiently adequate to equip them to successfully track all aspects of their studies. Approximately 38% agreed that these tools did indeed allow for successful tracking of all aspects of their studies, 41% somewhat agreed, 7% somewhat disagreed, and 7% strongly disagreed. Of those participants who disagreed the following comments were provided: one respondent stated that documentation of IRB reporting of events and protocol deviations are not covered by a specific tracker nor in TrialWorks, in addition to, another respondent expressed concern over CRF tracking being omitted from the aforementioned list of trial progress document tools. These results strongly indicate that employees at Company A will feel adequately equipped (79%) for successful monitoring when provided with the trial progress document trackers and TrialWorks. Therefore working to standardize the trial progress tracking tools, with applicable revisions, will greatly enhance a monitor's performance and therefore Company A's performance.

Employees were also asked to make additional comments they may have had in reference to the attached tracking documents and/or the standardization of these documents. All comments mentioned in this section were repetitious in nature to the comments provided for each specific trial progress tracking tool.

The underlying theme built into both Questionnaire #1 and Questionnaire #2 was the idea of finding ideal (from the perspective of the employees and management at

Company A) trial progress tracking tools, which would serve as potential candidates for standardization across studies at Company A. In summary, the results indicated that all 5 trackers could potentially serve as beneficial resources for standardization. Based on the criteria established by the design team in the questionnaire, all five trial progress tracking tools were received by the employees as being: user-friendly, addressed their needs, and are potential documents to be standardized at Company A. Findings suggested that all five trial progress tracking tools were highly received; however, even with this response there were suggested "revisions" provided to Company A in which to make each document a more successful project management tool and/or monitoring tool.

The last question of the questionnaire was designed to gain a greater appreciation and understanding of the mental capacities of the employees at Company A after they had completed the labor and time intensive questionnaire. Approximately, 62% of the employees described their mental capacities after filling out the questionnaire to be pleasant, 21% reported feeling comatose, 14% experience laughter, and 7% had no comment. These findings suggest that the employees at Company A are more than generous to state that they felt pleasant after completing a questionnaire of this magnitude, and therefore deserve a very grateful thank you for their part

I. Summary

Surrounding every project within Company A is the ever increasing environment of Sponsor demands. Delivering a faster, less expensive, and more novel product can only happen when project management is at its very best. Within the COSEAR project this included having clearly defined goals, accurately "scoping" the project, and evaluating risk management at every phase of the project lifecycle.

My internship experience at Company A allowed me to see first-hand the vital importance of successful project management skills via utilizing clinical trial progress tracking tools. Clinical trial progress tracking tools were a part of my everyday experience as an in-house CRA at Company A, and were without a doubt one of the main contributors to the continued success of the COSEAR project.

Two company-wide questionnaires were disseminated to 34 clinical operations employees at Company A. Questionnaire #1 was developed to assess employees' global views of clinical trial progress tracking. Based on the results received from Questionnaire #1, Questionnaire #2 was designed. Questionnaire #2 surveyed employees' ideas and opinions regarding standardization of 5 specific trial progress tracking tools at Company A. The results received from Questionnaire #1 and #2 will assist with standardizing additional trial progress tracking tools at Company A. In addition, the results from both Questionnaire #1 and Questionnaire #2 indicated a large acceptance rate for the five proposed standardized trial progress tracking tools, however

some minor adjustments and an allowance for customization were noted by the employees polled at Company A.

CHAPTER III

INTERNSHIP EXPERIENCE

A. Internship Site

Company A
Dallas, Texas

Company A is a privately owned Contract Research Organization based out of Dallas, Texas. Since its inception (1993), Company A has developed into a full service, phase II-IV global CRO. Company A is dedicated to offering a complete range of clinical development and consulting services to the pharmaceutical, biotechnology, and medical device industries. The following extensive range of clinical services is provided by Company A: monitoring, auditing, consulting, training, data management, and statistical analysis.

In addition, Company A offers therapeutic expertise in the following specialties:

- Cardiology
- Dermatology
- Endocrinology
- Immunology
- Infectious Disease
- Medical Imaging Technologies
- Nephrology
- Neurosurgery

- Oncology
- Ophthalmology
- Orthopedics
- Pediatrics
- Pulmonology
- Rheumatology
- Transplantation
- Urology
- Vascular
- Virology
- Women's Health

Company A employs approximately seventy industry professionals nationwide. The infrastructure within Company A incorporates a Business Operations and Finance Department, Quality Assurance and Training Department, in addition to, a Clinical Operations Department. The personnel within the Clinical Operations Department serve as the primary liaison between the services that Company A provides and the clientele receiving these services. My specific role within Company A was within the Clinical Operations Department as a Clinical Research Associate I. As a Clinical Research Associate I, I was intricately involved in the day-to-day activities of clinical trial management.

B. Journal Summary

During my internship practicum I worked at Company A as a Clinical Research Associate I. Within Company A, a Clinical Research Associate may be more specifically classified as a field monitor or an in-house CRA. My respective role was as an in-house CRA. I was promptly assigned to a project which I will call COSEAR.

COSEAR is a five-year, pivotal device (class 3) study evaluating the safety and efficacy of a novel drug-eluting stent as compared to a comparable industry-standard drug-eluting stent. As an in-house CRA I, I was responsible for updating and maintaining clinical trial progress trackers on a daily basis. These trackers included: a monitoring visit report tracker, patient enrollment trackers, a patient visit window tracker, status of core-laboratory trackers, CRF-status tracker, etc.

In addition to working with the clinical trial progress trackers, I was also responsible for the COSEAR study calendar. Incorporated within this calendar was a comprehensive view of all COSEAR related study visits. COSEAR monitors and delegated sponsor representatives periodically sent me their site initiation visit and interim monitoring visit schedules. In turn, I was responsible for tracking this information on the COSEAR calendar, TrialWorks, and MVR Sponsor Submission Compliance Tracker.

I was fortunate enough to have entered into the COSEAR study while site initiation visits were still being conducted. As a result, I was responsible for

contacting site coordinators in reference to scheduling a site initiation visit at their site. I conversed with the coordinator regarding potential dates and times, applicable personnel who needed to be available at the visit, facility accommodations, etc.

On a daily basis, I worked closely with the COSEAR project manager. We were responsible for attending teleconferences with both the data management company and the Sponsor Company on a semiweekly basis. After each teleconference, I was responsible for preparing meeting minutes.

During sponsor initiated deadlines, the project manager and I spent a plethora of time coordinating monitoring visit schedules, contacting sites, and in turn, following up with sites to ensure appropriate CRF submission guidelines were successfully followed. During these periods it was paramount that the project manager and I maintain open communications via teleconferences, emails, and phone calls between the Sponsor Company and the data management company.

I quickly found out that the in-house CRA position required one to wear many hats. A large majority of my daily activities consisted of following-up with the superabundance of emails that were sent to me by the data management company, the Sponsor Company, field monitors, and site coordinators. It wasn't unusual for me to follow-up with a site regarding an email request for a particular COSEAR form they had misplaced, send a copy of a specific regulatory document to the data management company, contact the sponsor related to a question prompted by a monitor on-site, and the list of miscellaneous requests could go on and on.

On a weekly basis, I received a bolus of documents (regulatory document checklists, data queries and device dispositions) which I was responsible to disseminate to the monitors before their actual visit dates. The data management company was responsible for sending me a comprehensive listing of all the sites that had submitted their screening logs for the week prior. I was delegated the task to contact all the sites whom had been delinquent with turning in their screening logs, in order to "gently" remind them to do so next time.

I was also responsible for ensuring that each document (site initiation reports, monitoring reports, regulatory documents, note-to-files, etc.) were sent to the data management company within 15 business days following the monitor's visit. In addition, I was also responsible for ensuring that copies of these documents were stamped and labeled correctly, inputted into TrialWorks where applicable, and systematically filed into the COSEAR designated file folders located within central files.

My experience at Company A, as an in-house Clinical Research Associate, provided an ideal atmosphere for fostering a greater understanding and appreciation for the field of clinical research. My internship practicum allowed me to take what I had learned in the classroom setting, and apply it in a "real" life manner to the day-to-day world of clinical research. In conclusion, my internship practicum at Company A was an invaluable experience that I will deeply treasure and gleam from as I work towards a future in clinical research management.

APPENDIX A

Tracking Tools Part I

(Please see attached)

Tracking Tools, Part I

1. What are the trackers you currently use for documenting the progress of your study(ies)?

2. What pieces of information do you find are essential for tracking in your study?

3. Are you satisfied with the trackers you now have available for your use? If not, what types of information are you not able to capture on the current trial progress trackers you are using?

4. Have you designed any trackers for documenting the progress of your study (s) that you think might be useful for other projects? These may be trackers you currently use or have used before.

5. What is your opinion on having standardized trial progress trackers for all studies conducted at Company A?

Remember: If you do not desire to remain anonymous, please send examples of your tracker(s) to jkurschn@hsc.unt.edu. If you would like to remain anonymous please print out a copy of your tracker(s) and put it in my Company A mailbox. Thank you!

APPENDIX B

Tracking Tools Part II

(Please see attached)

Tracking Tools, Part II

Outstanding Issues Tracker

1. The attached Outstanding Issues Tracker is a Project Management tracking tool that is also an excellent CRA resource. Do you feel that this tracker will accurately assist in the management of the site?

- ○ Strongly Agree
- ○ Somewhat Agree
- ○ No Opinion
- ○ Somewhat Disagree
- ○ Strongly Disagree

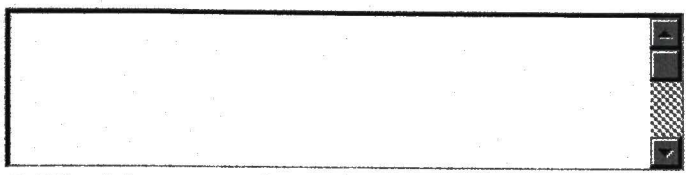
2. How frequently would you reference this Outstanding Issues Tracker?

- ○ Every Day
- ○ Once a Week
- ○ Every 2 Weeks
- ○ Every 4-6 Weeks
- ○ Never

3. Do you find the attached Outstanding Issues Tracker user-friendly?

- ○ Strongly Agree
- ○ Somewhat Agree
- ○ No Opinion
- ○ Somewhat Disagree
- ○ Strongly Disagree

4. If you don't find the Outstanding Issues Tracker user-friendly, please provide a brief answer as to why in the box provided below:



5. Would you say that this Outstanding Issues Tracker would provide an added benefit to successful monitoring?

- Strongly Agree
- Somewhat Agree
- No Opinion
- Somewhat Disagree
- Strongly Disagree

Protocol Deviation Tracker

6. What has your involvement been in tracking Protocol Deviations?

- I am actively involved in tracking protocol deviations in the studies I work on.
- The studies I work on do track protocol deviations, however I am not responsible for specifically keeping track of them.
- I am not aware of how protocol deviations are tracked in the studies I work on.
- I am not aware of how protocol deviations are tracked in the studies I work on, however, I do keep a personal record of the protocol deviations at my sites.

7. Do you feel the following Protocol Deviation Tracker addresses all aspects necessary for protocol deviation tracking?

- Strongly Agree
- Somewhat Agree
- No Opinion
- Somewhat Disagree
- Strongly Disagree

8. If you don't find that the Protocol Deviation Tracker addresses all aspects necessary for protocol deviation tracking, please briefly list any category headings you would like to see in the box provided below:

9. Do you find this Protocol Deviation Tracker user-friendly?

- ○ Strongly Agree
- ○ Somewhat Agree
- ○ No Opinion
- ○ Somewhat Disagree
- ○ Strongly Disagree

10. If you don't find the Protocol Deviation Tracker user-friendly, please provide a brief answer as to why in the box provided below:

11. Would you support standardization of the attached Protocol Deviation Tracker at Company A?

- ○ Strongly Agree
- ○ Somewhat Agree
- ○ No Opinion
- ○ Somewhat Disagree
- ○ Strongly Disagree

12. If you do not support standardization of the attached Protocol Deviation Tracker, briefly discuss as to why in the box provided below:

SAE Tracker

13. What has your involvement been in tracking SAEs?

○ I am actively involved in tracking SAEs in the studies I work on.

○ The studies I work on do track SAEs, however I am not responsible for specifically keeping track of them.

○ I am not aware of how SAEs are tracked in the studies I work on.

○ I am not aware of how SAEs are tracked in the studies I work on, however, I do keep a personal record of the SAEs at my sites.

14. Do you feel the attached SAE Tracker addresses all aspects necessary for SAE tracking?

○ Strongly Agree

○ Somewhat Agree

○ No Opinion

○ Somewhat Disagree

○ Strongly Disagree

15. If you don't find that the SAE Tracker addresses all aspects necessary for SAE tracking, please briefly list any category headings you would like to see in the box provided below:

16. Do you find the attached SAE Tracker user-friendly?

○ Strongly Agree

○ Somewhat Agree

○ No Opinion

○ Somewhat Disagree

○ Strongly Disagree

17. If you don't find the SAE Tracker user-friendly, please provide a brief answer as to why in the box provided below:

18. Would you support standardization of the attached SAE tracker at Company A?

- Strongly Agree
- Somewhat Agree
- No Opinion
- Somewhat Disagree
- Strongly Disagree

19. If you do not support standardization of the attached SAE Tracker, briefly discuss as to why in the box provided below:

Informed Consent Document Tracker

20. What has your involvement been in tracking Informed Consents?

- I am actively involved in tracking informed consents in the studies I work on.
- The studies I work on do track informed consents, however I am not responsible for specifically keeping track of them.
- I am not aware of how informed consents are tracked in the studies I work on.
- I am not aware of how informed consents are tracked in the studies I work on, however, I do keep a personal record of the informed consents at my sites.

21. Do you feel the attached Informed Consent Document Tracker addresses all aspects necessary for informed consent tracking?

- Strongly Agree
- Somewhat Agree
- No Opinion
- Somewhat Disagree
- Strongly Disagree

22. If you don't find that the Informed Consent Document Tracker addresses all aspects necessary for Informed Consent tracking, please briefly list any category headings you would like to see in the box provided below:

23. Do you find the attached Informed Consent Tracker user-friendly?

- Strongly Agree
- Somewhat Agree
- No Opinion
- Somewhat Disagree
- Strongly Disagree

24. If you don't find the Informed Consent Document Tracker user-friendly, please provide a brief answer as to why in the box provided below:

25. Would you support standardization of the following Informed Consent Document Tracker at Company A?

- Strongly Agree
- Somewhat Agree
- No Opinion
- Somewhat Disagree
- Strongly Disagree

26. If you do not support standardization of the attached Informed Consent Document Tracker, briefly discuss as to why in the box provided below:

IRB Approval History Log

27. At the sites you monitor, do you find that keeping track of the site-specific current protocol version and corresponding amendments is challenging?

- ○ Strongly Agree
- ○ Somewhat Agree
- ○ No Opinion
- ○ Somewhat Disagree
- ○ Strongly Disagree

28. Do you feel the attached IRB Approval History Log addresses all aspects necessary for documenting the IRB approval history?

- ○ Strongly Agree
- ○ Somewhat Agree
- ○ No Opinion
- ○ Somewhat Disagree
- ○ Strongly Disagree

29. If you don't find that the IRB Approval History Log addresses all aspects necessary for documenting IRB approval history, please briefly list any category headings you would like to see in the box provided below:

30. Do you find the attached IRB Approved Log user-friendly?

- ○ Strongly Agree
- ○ Somewhat Agree
- ○ No Opinion
- ○ Somewhat Disagree
- ○ Strongly Disagree

31. If you don't find the Informed Consent Document Tracker user-friendly, please provide a brief answer as to why in the box provided below:

32. Would you support standardization of the following IRB Approval History Log at Company A?

- ○ Strongly Agree
- ○ Somewhat Agree
- ○ No Opinion
- ○ Somewhat Disagree
- ○ Strongly Disagree

33. If you do not support standardization of the attached IRB Approval History Log, briefly discuss as to why in the box provided below:

34. Of the following five tracking tools, which one would you say ranks at the <u>top</u> of your list as a tool you feel would make your monitoring experience more successful?

- ○ Informed Consent Document Tracker
- ○ Protocol Deviation Tracker
- ○ IRB Approval Log
- ○ Outstanding Issues Tracker
- ○ SAE Tracker

35. Of the following five tracking tools, which one would you say ranks at the <u>bottom</u> of your list as a tool you feel would make your monitoring experience more successful?

- ○ Informed Consent Document Tracker
- ○ Protocol Deviation Tracker
- ○ IRB Approval Log
- ○ Outstanding Issues Tracker
- ○ SAE Tracker

36. Do you feel adequately equipped to successfully track all aspects of your study with the above-mentioned standardized site tools and TrialWorks?

- ○ Strongly Agree
- ○ Somewhat Agree
- ○ No Opinion
- ○ Somewhat Disagree
- ○ Strongly Disagree

37. If you do not feel adequately equipped to successfully track all aspects of your study with the above-mentioned standardized site tools and TrialWorks, please indicate as to why in the box provided below:

38. Please provide any additional comments you may have pertaining to the attached tracking documents and/or the standardization of these documents in the box provided below:

39. Which of the following statements best describes your current mental condition after filling out this questionnaire?

- Pleasant...in fact, you are surprised at how a questionnaire of this nature is actually "refreshing."
- Anger...a small volcano is beginning to erupt, however, you feel "in-control" of these feelings!!!!
- Laughter...it is gut-wrenching laughter that closely resembles hysteria.
- Comatose...even here you still manage to have the will to survive.
- No comment...it hurts too much to talk about!

APPENDIX C

Outstanding Issues Tracker

(Please see attached)

Outstanding Issues Document Tracker

Study Number XXXXXXX

Enter Site #	Enter PI	Update open items with current CRA	Enter Category Descriptions : Regulatory	Enter Subject ID#, unknown, or n/a, as applicable	**Enter Issue Descriptions:** MVR DM DCF MT PM/PL	Enter first known date.	Company A person who opened the issue	Enter issue description. Open new lines for items with multiple steps/issues.	Enter planned action or instructions.	Enter ongoing status and follow up information if applicable.	Enter description of the actual resolution.	**Identify Documentation of Resolution:** MVR Email	**Enter status:** Open Closed	**Enter the date of the document in Column N**
site #	**PI**	**CRA**	**issue category**	**Subject ID (if applicable)**	**issue origin**	**date opened**	**name of originator**	**issue**	**proposed action**	**follow up info**	**actual resolution**	**resolution document**	**issue status**	**date closed**
200	Jones, Jimmy	Stanley, Paul	Subject	200-108	MVR	28-Apr-2005	Stanley, Paul	Site to notify IRB of adverse event for pt 108.	8/1/05 CRA received email notification from CRC that IRB has been notified of this event. CRA to collect IRB report during next IMV.			MVR	Closed	10-Oct-2005
200	Jones, Jimmy	Stanley, Paul	Subject	200-122	MVR	30-Sep-2004	Criss, Peter	Pt. Did not initial/date last page of ICF. NTF needs to be generated for this.	4/28/05: Pt 122 initialed and dated last pg of ICF and NTF was written by CRC explaining oversight. Copy of NTF was submitted to MT for study files.			MVR	Closed	28-Apr-2005
200	Jones, Jimmy	Stanley, Paul			MVR	30-Sep-2004	Criss, Peter	Site Sig Log was not signed by all study coordinators	Monitor to forward copy of signed log to site 7/7/05: Updated clinical site sig log was filed in reg binder and copy obtained for study files.			MVR	Closed	07-Jul-2005
200	Jones, Jimmy	Stanley, Paul			MVR	16-Nov-2005	Stanley, Paul	Reg binder was not reviewed during this visit.					Open	
70	Smith, Joe	Simmons, Gene			MVR	3-Nov-2005	Smith, Joe	Review of reporting AEs and protocol deviations to the IRB was begun.	To be continued at next monitoring visit.				Open	
292	Bates, Norman	Tucker, Tanya	Subject	292-102	MVR	10-Oct-2005	Tucker, Tanya	Study coordinator to report MAEs for this subject to IRB per IRB reporting requirements					Open	
421	Wonka, Willy	Salt, Veruca			MVR	27-Jul-2005	Glum, Augustus	Current CAP certificate not yet available					Open	
52	Smiley, Guy	Tyler, Steven	Subject	052-103	MVR	7-Jun-2005	Perry, Joe	Cine for 103 was requested from an outside facility.	Film not able to be retrieved from outside facility. Issue closed.			MVR	Closed	01-Sep-2005
218	Quest, Johnny	Frehley, Ace			MVR	6-Oct-2005	Frehley, Ace	IRB is to be notified as required in the next AE summary report due in December					Open	
591	Bailey, George	Sewart, Jimmy	Subject	591-106	MVR	13-Jun-2005	Reed, Donna	Pt 106 has not been able to be contacted for the 4-year follow up yet. CRC to continue to try and obtain pt information.	pt 106 was contacted out-of-window. PDF completed and submitted w/ 4-year CRFs.			MVR	Closed	27-Sep-2005

APPENDIX D

Protocol Deviation Tracker

(Please see attached)

APPENDIX D

Protocol Deviation Tracker

(Please see attached)

Protocol Deviation Tracker

Subject ID / Initials	Description of Deviation	Date of Occurrence	Date Noted by Site	Date of Initial Report to Sponsor	Date of Initial Report to IRB	Date of Authorization Waiver	Impact on Subject Evaluability	Corrective Action Taken by Site	Preventive Action Taken by Site	Comments

APPENDIX E

Serious Adverse Event (SAE) Tracker

(Please see attached)

Serious Adverse Event (SAE) Tracker

Subject ID / Initials	SAE Description	Onset Date	Date Noted by Site	Date of Initial Report to Sponsor	Outcome	Outcome Date	Follow-up Information Pending?	Date Follow-up Information Received	Comments

APPENDIX F

Informed Consent Document Tracker

(Please see attached)

Informed Consent Document Tracker

Sponsor:		**Protocol:**	
Principal Investigator:		**Site #:**	

Consent Version						**Comments**
IRB Approval Date						
Subject ID	**Enrollment Date**	**Date Consent Versions Obtained from Subject**				

APPENDIX G

IRB Approval History Log

(Please see attached)

IRB Approval History Log

Sponsor:		Protocol:	
Principal Investigator:		Site #:	

This tool is intended to provide a site level summary of all protocol versions sent to this site. The information entered into this log should be reflective of the records available at the site. This tool can assist in reconciliation against Company A central files or the TrialWorks reports, which summarize Company A central files contents.

Reason for approval: (Original, Ammend., Cont. Review, Staff Change)	Protocol Version		Date of PI signature on Protocol Sig. Page	Date of letter from IRB approving this item	Date of IRB approval for protocol version	Approval includes a new ICF approval?	Approved ICF Version		Is ICF Stamped?	Comments
	Ver. #	Date				Yes or No	Yes, No, N/A	Date	Yes, No, N/A	
Original IRB approval										

APPENDIX H

Questionnaire #1 Results

(Please see attached)

Questionnaire #1 Results

	What are the trackers you currently use for documenting the progress of your study(ies)?	What pieces of information do you find are essential for tracking in your study?	Are you satisfied with the trackers you now have available for your use? If not, what types of information are you not able to capture on the current trial progress trackers you are using?	Have you designed any trackers for documenting the progress of your study (s) that you think might be useful for other projects? These may be trackers you currently use or have used before.	What is your opinion on having standardized trial progress trackers for all studies conducted at MedTrials?
Response 1	ICF Logs, AE logs, Query trackers, Visit Window Trackers, CRF trackers (monitoring progress), TW summary / Expired documents trackers, etc...	Complete medical charts! Without a proper baseline it is very difficult to differentiate btwn Med Hx & AEs... Updated/current TW reports assist me in determining what is inhouse at MT/Sponsor or what requires retrieval.	Yes :)	For the most part I save a site specific versions of any trackers provided by the data mgmt (AE/ICF/Query) for efficiency.	It would be simplier to find specific trackers in GW. However, these trackers would probably be used as needed per trial procedures. Therefore we would not have the need to use exactly the same trackers for each project.
Response 2	I always use a study specific living document, as items and information related to the study change on a daily basis and it's difficult to recall all this information. I also utilize the tracker which my PM sends out, on a bi-monthly basis, indicating enrollment at my sites. It always helps to highlight which subjects are in which data deadline, making it simple for me to plan and schedule accordingly.	The living document, and the "tracking sheet" (Which I use through-out the trial and is subject specific)	As I'm fairly new at MedTrials, I have not seen all my tracking tools as of yet. I do recall receiving one tracker for my sites and I believe it was not color coded to indicate which subjects and especially modules I need to monitor/pull/submit prior to the December 2nd deadline. I can also say from a personal preference to keep the colors to a minimum. I find it hard/difficult if there are 4 or 5 different colors and I need to scroll down to determine what this particualr color indicates and then scroll back up and put the puzzle together. Red is a great color to indicate all the subjects and their modules I need to retrieve prior to a specific date.	I have just sent Jill an example of a living document from another trial and gave 4 different copies of tracking sheets for subject tracking when I was there last but I will certainly send these electronically, if it would help. I found these two tools along with the bi-monthly user friendly color coded tracker relative to deadlines were indefensible for my progress.	I strongly believe this is the best way to go, for each and every trial we do, we gradually become an expert at tracking and much more effective in making those important deadlines. If trackers change with each study, I can easily see how CRA's will become frustrated.
Response 3	Monitoring Visit Schedules, MVR Sponsor Submission Compliance, Outstanding Items Tracker	Daily/Real-time updates and tracker upkeep, Weekly submissions to sponsor where relevent, LIMITED user access/edit rights in order to ensure better quality data and accuracy and order.	CRF Tracking could be better and more standardized across all studies here at MT.	Yes. CRF submission data deadline trackers, outstanding items tracking, MVR submission trackers	I highly recommend it. Standardization and process streamlining is somethig that is definitely needed here at MT. It has to come from the top, and has to be embraced by all the PLs and PMs in order for it to be successful.
Response 4	Weekly,TW monitoring visit tracker and other TW trackers. Trackers that I customize for my own trials.	Reg docs collected, CRFs collected.	yes	yes	I don't want to be limited by a standard tracker but simple/generic tracker that can be customized might help.
Response 5	TrialWorks for fields that are applicable to my studies; subject visit tracker w/ visit windows; CRF Review tracker; AE/ConMeds/Labs tracker; Informed Consent document tracker; MVR compliance tracker; protocol deviation tracker; DSMB AE & SAE listings trackers; DSMB availability for conference calls tracker;	Everything tracked in TrialWorks plus the trackers listed in question #1.	Yes, in general. See question #1. If an existing tracker does not supply needed information, a new tracker can always be custom made.	AE/ConMeds/Labs tracke; DSMB AE & SAE trackers; missing CRF pages tracker; IND Safety/CIOMS Reports; Monitoring visits tracker with multiple CRAs on site; Jill, this list is extensive and will not make sense to you - I suggest we meet to discuss the many trackers I have used in the past. Let me know when you are available for about an hour after Thanksgiving week. Anita Zacherl	Very good idea if it makes sense. Sometimes a tracker for one study will not work for another study without modification. Standardization should be done whenever possible.
Response 6	I have a tracker that I have all sites that I am currently monitoring which includes the number of patients at each site, when the last visit was, and when the next visit is scheduled or anticipated.	# of patients at each site, upcoming deadlines	I'm happy with what I use, and I like the compliance tracker that everyone is using.	device trackers	If it can be tailored by the individual CRA then I like it. However, standardized implies that it would not be able to be changed, and I think this could be a problem because everyone likes different types of information on their
Response 7	pt window crf tracker PD AE	previous MVR TW report summaries	yes.	MACE tracker for SECURE	good idea.

Questionnaire #1 Results

	What are the trackers you currently use for documenting the progress of your study(ies)?	What pieces of information do you find are essential for tracking in your study?	Are you satisfied with the trackers you now have available for your use? If not, what types of information are you not able to capture on the current trial progress trackers you are using?	Have you designed any trackers for documenting the progress of your study (s) that you think might be useful for other projects? These may be trackers you currently use or have used before.	What is your opinion on having standardized trial progress trackers for all studies conducted at MedTrials?
Response 8	TrialWork documents tracking, TW monitoring visit tracking, TW download to excel report for client, Excel Outstanding Items MT Tracking, Excel IRB Approval/Renewal MT Tracking, Excel Snapshot MT Report, Excel Payment Tool Client Report, Excel Monitoring Metrics MT Report, Excel MVR Compliance MT Tracking, TW CRA Assignment MT Report with Excel Download, Excel Site Contact MT Report, Excel Site Reminders MT Tracking, and Assorted data management Report for deviations, CRF receipt, adverse events, follow ups	monitoring visit dates, visit reports, subject follow up status, CRF receipt status, events, outstanding issues & f/u, utilization of the existing data management reports is essential	The recent implementation of the Excel Outstanding Items tracker report to replace the cumbersome TW oustanding items has been very useful, and we are already seeing greater efficiency and effectiveness with this tool. I'd like to develop or obtain a more efficient tool for prospective planning of the monitoring visit schedule that incorporates the study specific monitoring plan and data management reports.	The Excel Outstanding Items Tracker, developed with Tim and Bill, is being implemented in several projects. In the past, an Excel Device Accountability Tracking, became a useful model for other projects as well.	I can see value, as well as problems. The value is that a standardized tracking system could provide a structure eliminating the start up issues and adjustments needed for new project tracking. Standardization also provides support for procedural compliance. The most significant problem is that a standardized system necessarily encompasses all potential elements of a clinical trial. Frequently, we do not utilize all the elements and then find ourselves adjusting, or working around, the system to "fit" our projects. Consequently, the "work arounds" eliminate much of the value of the system. I would hope that any new standardized system that might be adopted would be carefully evaluated against the proven processes already in place. I don't think that is a feasible idea, because every study (even studies run by the same sponsor) will have different requirements. I think flexible templates would be useful (such as excel programs) to build trackers that are specific to the needs of each study and that can be changed part-way through the study to accommodate new requests for different pieces of information. Also our trackers need to have the flexibility to be able to provide partial information to different team members (i.e. filtering a spreadsheet for site-specific info for one monitor as opposed to sending an entire study report to the monitor and asking them to read thru everything and find their own info).
Response 9	CRF and visit window trackers, outstanding query reports, MVR completion and submission reports, monitoring visit trackers, outstanding issues tracker, adverse events trackers, regulatory document trackers	where is every piece of paper in the pipeline (at the site, in a fedex, at the data mgmt company, or lost)?, when will monitors be on-site, what are the outstanding items at each site that require resolution	I am satisfied with the trackers that MT creates and controls/updates because I am confident with their accuracy and timeliness. I am not always satisfied with trackers that are provided to MT from other vendors because they are usually not as current as our monitoring teams and mgmt teams need them to be.	Patient visit window tracker that we use for several Cordis studies - we provide these for the monitors and the coordinators.	
Response 10	TrialWorks, my own reg doc trackers, my own CRF trackers, sponsor query trackers.	AEs that were reported by the site to data mgt and the outstanding AEs I need to retrieve, outstanding queries, reg docs.	Using the trackers I listed in #1, I have all the information I need.	Yes I use my own reg doc and CRF status trackers.	It would be helpful to have trial progress trackers, if they could be modified for a study, as needed. Some trials may require items that another trial doesn't require.
Response 11	Trial Works, multiple Excel spreadsheets	Patient enrollment dates, visit windows, randomized group assignments	Yes		All studies are a little different, however having a standardized tracker helps in finding information that should always exist (i.e. regulatory docs, site info, etc.)
Response 12	Tracker: MVR Sponsor Submission Compliance SISR Outstanding Reg Doc Tracker SISR Visit Tracker SISR AE tracker SISR cohort CRF tracker	visit dates, submission info, CRF info, SAE info, regulatory documents	Yes	I have not designed any.	Standardization is great, but must also allow for some variation depending on the needs of the individual study. It would be nice to have a "MedTrials" tracking system that we could apply to all studies.

APPENDIX I

Questionnaire #2 Results:

Outstanding Issues Tracker

SAE Tracker

Informed Consent Document Tracker

Protocol Deviation Tracker

IRB Approval History Log

(Please see attached)

Questionnaire #2 Results: Outstanding Issues Tracker

Outstanding Issues Tracker	The attached Outstanding Issues Tracker is a Project Management tracking tool that is also an excellent CRA resource. Do you feel that this tracker will accurately assist in the management of the site?	How frequently would you reference this Outstanding Issues Tracker?	Do you find the attached Outstanding Issues Tracker user-friendly?	If you don't find the Outstanding Issues Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you say that this Outstanding Issues Tracker would provide an added benefit to successful monitoring?
1	Strongly Agree	Every 4-6 Weeks	Strongly Agree		Strongly Agree
2	Strongly Agree	Once a Week	Somewhat Agree		Strongly Agree
3	Somewhat Agree	Every 4-6 Weeks	Somewhat Agree		Somewhat Agree
4	Strongly Agree	Once a Week	Strongly Agree		Strongly Agree
5	Strongly Agree	Once a Week	Strongly Agree		Strongly Agree
6	Somewhat Disagree	Never	Somewhat Agree		Somewhat Disagree
7	Strongly Agree	Every 2 Weeks	Strongly Agree		Somewhat Agree
8	Strongly Agree	Every Day	Strongly Agree		
9	Strongly Agree	Once a Week	Strongly Agree		Somewhat Agree
10	Strongly Agree	Every 4-6 Weeks	Somewhat Disagree	Column O is unclear to me. Other than that, the tracker is user-friendly and could be very valuable.	Strongly Agree
11	Somewhat Agree	Once a Week	Somewhat Disagree	It's a bit too much information. Maybe after some training but at first glance it seems a bit busy and confusing.	Somewhat Agree
12	Somewhat Agree	Once a Week	No Opinion		Somewhat Agree
13	Somewhat Agree	Once a Week	Strongly Agree		Somewhat Agree

Questionnaire #2 Results: Outstanding Issues Tracker

Outstanding Issues Tracker	The attached Outstanding Issues Tracker is a Project Management tracking tool that is also an excellent CRA resource. Do you feel that this tracker will accurately assist in the management of the site?	How frequently would you reference this Outstanding Issues Tracker?	Do you find the attached Outstanding Issues Tracker user-friendly?	If you don't find the Outstanding Issues Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you say that this Outstanding Issues Tracker would provide an added benefit to successful monitoring?
14	Strongly Agree	Once a Week	Strongly Agree	'We used to call these "Action Item Logs" and they were running tallies. site specific created from the CRA. (If there were items found missing, etc. referenced on the MVR, then the action item log should also capture each and every one of these. This tool is the most valuable, never leave home and go to a site without it. If the action item is still pending at the next site visit, leave it "open" and reference when the CRA had initially asked for this, a good tool to track site compliance, as the site would receive a copy of this action item log along with their follow-up letter -	Strongly Agree
15	Strongly Agree	Once a Week	Somewhat Agree		Strongly Agree
16	Somewhat Agree	Every 4-6 Weeks	Somewhat Agree		No Opinion
17	Strongly Agree	Once a Week	Strongly Agree	Fpr a PM/PL - this is much better than tracking outstanding issues in TrialWorks!	Somewhat Agree
18	Somewhat Agree	Every 4-6 Weeks	Somewhat Agree		Somewhat Agree
19	Strongly Agree	Every 4-6 Weeks	Somewhat Agree		Strongly Agree
20	Strongly Agree	Every 2 Weeks	Strongly Agree		Somewhat Agree
21	Strongly Agree	Once a Week	Strongly Agree		Strongly Agree
22	Strongly Agree	Every 4-6 Weeks	Somewhat Disagree	A completion guide with conventions would be highly desirable.	Strongly Agree
23	Somewhat Agree	Once a Week	Strongly Agree		Strongly Agree
24	Somewhat Agree	Every 4-6 Weeks	Somewhat Agree		Somewhat Agree
25	Strongly Agree	Every 4-6 Weeks	Somewhat Agree		Strongly Agree
26	Strongly Agree	Every 2 Weeks	Strongly Agree		Somewhat Agree
27	Strongly Agree	Once a Week	Strongly Agree		Strongly Agree
28	Strongly Agree	Every 4-6 Weeks	Somewhat Disagree	A completion guide with conventions would be highly desirable.	Strongly Agree
29	Somewhat Agree	Once a Week	Strongly Agree		Strongly Agree

Questionnaire #2 Results:
Serious Adverse Events (SAE) Tracker

SAE Tracker	What has your involvement been in tracking SAEs?	Do you feel the attached SAE Tracker addresses all aspects necessary for SAE tracking?	If you don't find that the SAE Tracker addresses all aspects necessary for SAE tracking, please briefly list any category headings you would like to see in the box provided below:	Do you find the attached SAE Tracker user-friendly?	If you don't find the SAE Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you support standardization of the attached SAE tracker at MedTrials?	If you do not support standardization of the attached SAE Tracker, briefly discuss as to why in the box provided below:
1	The studies I work on do track SAEs, however I am not responsible for specifically keeping track of them.	Somewhat Disagree	Date reported to IRB; date reported to other investigators	Strongly Agree		Somewhat Agree	With the additions in #15 above.
2	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Agree		Strongly Agree		Strongly Agree	
3	I am not aware of how SAEs are tracked in the studies I work on, however, I do keep a personal record of the SAEs at my sites.	No Opinion		Somewhat Agree		Somewhat Agree	
4	I am actively involved in tracking SAEs in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	
5	I am actively involved in tracking SAEs in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	
6	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Agree		Somewhat Agree		Somewhat Agree	As with the Deviation tracker, provided a client does not have their own that is requried to be completed - don't need two trackers tracking the same details.
7	The studies I work on do track SAEs, however I am not responsible for specifically keeping track of them.	Somewhat Agree	I would add a column to note what event CRFs and source docs were sent into data management. I would also add a column labeled "Date of notification to IRB"	Somewhat Agree		Somewhat Agree	
8	The studies I work on do track SAEs, however I am not responsible for specifically keeping track of them.	Somewhat Agree	'I would recommend that the potential entries for follow up information including source documents and follow up SAE CRFs be expanded. Additionally, I would have entry for Medical Monitor/Nurse Review/CEC status. I would include the comment box, but I would also consider whether there are entries routinely expected in the comment box that should have their own column to prevent the comment box from becoming the problem box.	Somewhat Agree	The "user-friendliness" and the usefulness of the tracker could be improved by considering the different roles of the people who may be using the tracker and simply increasing its sorting/comparing potential.	Somewhat Agree	I like the tracker. As I noted earlier, I think a standardized tracker needs to address the various needs of the study team.
9	The studies I work on do track SAEs, however I am not responsible for specifically keeping track of them.	Somewhat Disagree	Does not have a column for MedWatch number?	Somewhat Agree		Strongly Agree	

Questionnaire #2 Results:
Serious Adverse Events (SAE) Tracker

SAE Tracker	What has your involvement been in tracking SAEs?	Do you feel the attached SAE Tracker addresses all aspects necessary for SAE tracking?	If you don't find that the SAE Tracker addresses all aspects necessary for SAE tracking, please briefly list any category headings you would like to see in the box provided below:	Do you find the attached SAE Tracker user-friendly?	If you don't find the SAE Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you support standardization of the attached SAE tracker at MedTrials?	If you do not support standardization of the attached SAE Tracker, briefly discuss as to why in the box provided below:
10	I am not aware of how SAEs are tracked in the studies I work on, however, I do keep a personal record of the SAEs at my sites.	Somewhat Disagree	I'm not sure if it would help to identify the CRFs and SDs that were submitted to data management for each SAE. I keep track of that for my sites and it helps me tremendously.	Strongly Agree		Strongly Agree	
11	The studies I work on do track SAEs, however I am not responsible for specifically keeping track of them.	Somewhat Agree		Somewhat Agree		Somewhat Agree	
12	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Agree	Date reported to IRB if applicable s/b captured as well.	Strongly Agree		Strongly Agree	
13	on do track SAEs, however I am not responsible for specifically keeping track of them.	Somewhat Agree	As with tracking PDs we would need to acknowledge the time required to complete and justify billing accordingly.	Somewhat Agree		Somewhat Agree	
14	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Agree	'In the column "date noted by site," should this be "date site became aware of the event?" Many times the site is not aware of an event and once the event has been learned, then the timeframe of reporting begins. After the column of "date of intial contact to Sponsor," should there be a column for "date of initial contact to the IRB? One more thing: should there be a column to reference a MACE or endpoint? These types of events dramatically need tracking, as the reporting timelines are often 24 hours to sponsor and 5-10 days to IRB.	Strongly Agree		Strongly Agree	
15	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Disagree	I think that more detail is necessary - for example CRF's and source docs that have been collected on each SAE	Somewhat Agree		Somewhat Agree	
16	The studies I work on do track SAEs, however I am not responsible for specifically keeping track of them.	Somewhat Agree		Somewhat Agree		Somewhat Agree	I support the SAE Tracker but, it can be cumbersome for the monitor to complete all fields. The tracker is better suited for data management.

Questionnaire #2 Results:
Serious Adverse Events (SAE) Tracker

SAE Tracker	What has your involvement been in tracking SAEs?	Do you feel the attached SAE Tracker addresses all aspects necessary for SAE tracking?	If you don't find that the SAE Tracker addresses all aspects necessary for SAE tracking, please briefly list any category headings you would like to see in the box provided below:	Do you find the attached SAE Tracker user-friendly?	If you don't find the SAE Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you support standardization of the attached SAE tracker at MedTrials?	If you do not support standardization of the attached SAE Tracker, briefly discuss as to why in the box provided below:
17	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Disagree	Need headings for IRB notification of SAEs.	Somewhat Agree	From my personal experience with tracking SAEs for the SISR study, this kind of tracker will get to be HUGE - and if you have an entire monitoring team with sharing rights, you're taking a risk of having someone accidentally erase/move/change info that they did not intend to - esp if someone is not comfortable with Excel and is not comfortable with working with very large spreadsheets.	Somewhat Agree	
18	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Disagree	Reported to IRB? Acknowledgement by IRB (if applicable)?	Somewhat Agree		Strongly Agree	
19	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Agree		Strongly Agree		Strongly Agree	
20	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Agree		Strongly Agree		Strongly Agree	
21	I am actively involved in tracking SAEs in the studies I work on.	Strongly Disagree	Reportable to Sponsor? Reportable to IRB? Date IRB notified	Strongly Agree		Somewhat Agree	
22	I am not aware of how SAEs are tracked in the studies I work on.	Strongly Agree		Somewhat Agree		No Opinion	
23	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Agree	date SAE reported to IRB could be added	Somewhat Agree		Somewhat Agree	
24	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Disagree	Reported to IRB? Acknowledgement by IRB (if applicable)?	Somewhat Agree		Strongly Agree	
25	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Agree		Strongly Agree		Strongly Agree	
26	I am actively involved in tracking SAEs in the studies I work on.	Somewhat Agree		Strongly Agree		Strongly Agree	
27	I am actively involved in tracking SAEs in the studies I work on.	Strongly Disagree	Reportable to Sponsor? Reportable to IRB? Date IRB notified	Strongly Agree		Somewhat Agree	
28	I am not aware of how SAEs are tracked in the studies I work on.	Strongly Agree		Somewhat Agree		No Opinion	

Questionnaire #2 Results:
Informed Consent Document Tracker

Informed Consent Document Tracker	What has your involvement been in tracking Informed Consents?	Do you feel the attached Informed Consent Document Tracker addresses all aspects necessary for informed consent tracking?	If you don't find that the Informed Consent Document Tracker addresses all aspects necessary for Informed Consent tracking, please briefly list any category headings you would like to see in the box provided below:	Do you find the attached Informed Consent Tracker user-friendly?	If you don't find the Informed Consent Document Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you support standardization of the following Informed Consent Document Tracker at MedTrials?	If you do not support standardization of the attached Informed Consent Document Tracker, briefly discuss as to why in the box provided below:
1	The studies I work on do track informed consents, however I am not responsible for specifically keeping track of them.	Somewhat Disagree	Add Date of subject's last visit if terminated from the study so that one is not looking for signed versions unnecessarily.	Strongly Agree		Strongly Agree	
2	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Agree		Strongly Agree		Strongly Agree	
3	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Agree		Somewhat Agree		Somewhat Agree	
4	I am actively involved in tracking informed consents in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	
5	I am actively involved in tracking informed consents in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	
6	I am actively involved in tracking informed consents in the studies I work on.	Strongly Agree		Strongly Agree		Somewhat Agree	As with the Deviation and SAE Trackers, as long as a client does not also have their own tracker that is required to be completed, ie no duplication
7	I am actively involved in tracking informed consents in the studies I work on.			Somewhat Agree	A column denoting the date the patient signed the ICF (this date can sometimes differ from the enrollment date)	Strongly Agree	
8	I am actively involved in tracking informed consents in the studies I work on.	Strongly Agree	I like it. I would use it as is.	Strongly Agree		Somewhat Agree	I would support it standardized as a monitoring tool.
9	The studies I work on do track informed consents, however I am not responsible for specifically keeping track of them.	Somewhat Agree		Strongly Agree		Strongly Agree	
10	The studies I work on do track informed consents, however I am not responsible for specifically keeping track of them.	Strongly Agree		Strongly Agree		Strongly Agree	
11	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Disagree	There should be a place for IRB approval date and/or IRB assigned numbers for the ICF.	Somewhat Agree		Strongly Agree	
12	I am actively involved in tracking informed consents in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	

Questionnaire #2 Results:
Informed Consent Document Tracker

Informed Consent Document Tracker	What has your involvement been in tracking Informed Consents?	Do you feel the attached Informed Consent Document Tracker addresses all aspects necessary for informed consent tracking?	Informed Consent Document Tracker addresses all aspects necessary for Informed Consent tracking, please briefly list any category headings you would like to see	Do you find the attached Informed Consent Tracker user-friendly?	If you don't find the Informed Consent Document Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you support standardization of the following Informed Consent Document Tracker at MedTrials?	standardization of the attached Informed Consent Document Tracker, briefly discuss as to why in the box provided below:
13	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Agree	We could offer versions to accommodate multiple ICF amendments.	Somewhat Agree		Somewhat Agree	
14	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Agree	"Should there be a yes or no column for "consent executed properly"? Many times, a subject forgets to initial each page (if required) or forgets to date and/or print name or perhaps the PI signed the ICF 13 days after the subject signed. These are all worth tracking and a great tool to present to the sponsor if continued deviations at which point a training course at MedTrials could be recommended for the site.	Strongly Agree		Strongly Agree	
15	The studies I work on do track informed consents, however I am not responsible for specifically keeping track of them.	Strongly Agree		Strongly Agree		Strongly Agree	
16	I am not aware of how informed consents are tracked in the studies I work on, however, I do keep a personal record of the informed consents at my sites.	Somewhat Agree		Somewhat Disagree	Instead of tracking all versions, maybe use a tracker that has one version, date of signature, a y/n column for any issues noted, and a comment section that addresses how issues were corrected	Strongly Agree	
17	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Agree		Somewhat Agree		Strongly Agree	
18	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Agree		Strongly Agree		Strongly Agree	
19	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Disagree	doesn't account for HIPAA. Consented properly column? - prompts CRA to look at all aspects - prior to procedure, etc.	No Opinion		Strongly Agree	
20	I am actively involved in tracking informed consents in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	
21	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Agree		Somewhat Agree		Somewhat Agree	
22	I am actively involved in tracking informed consents in the studies I work on.	Strongly Disagree	Date of 1st procedure Date POC/Witness signed Date PI/SI signed All required signatures present? Consent Note in Chart?	Strongly Disagree	Consent versions info section is confusing. The completed form will usually have lots of empty boxes. Format would be better as a spreadsheet like the preceding trackers.	Strongly Disagree	Consent versions info section is confusing; completed form will have lots of empty boxes. Format would be better as a spreadsheet like the preceding trackers.
23	I am actively involved in tracking informed consents in the studies I work on.	Strongly Agree		Somewhat Agree		No Opinion	
24	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Agree		Strongly Agree		Strongly Agree	
25	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Disagree	doesn't account for HIPAA. Consented properly column? - prompts CRA to look at all aspects - prior to procedure, etc.	No Opinion		Strongly Agree	
26	I am actively involved in tracking informed consents in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	
27	I am actively involved in tracking informed consents in the studies I work on.	Somewhat Agree		Somewhat Agree		Somewhat Agree	

Questionnaire #2 Results:
Informed Consent Document Tracker

Informed Consent Document Tracker	What has your involvement been in tracking Informed Consents?	Do you feel the attached Informed Consent Document Tracker addresses all aspects necessary for Informed consent tracking?	If you don't find that the Informed Consent Document Tracker addresses all aspects necessary for Informed Consent tracking, please briefly list any category headings you would like to see in the box provided below:	Do you find the attached Informed Consent Tracker user-friendly?	If you don't find the Informed Consent Document Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you support standardization of the following Informed Consent Document Tracker at MedTrials?	If you do not support standardization of the attached Informed Consent Document Tracker, briefly discuss as to why in the box provided below:
28	I am actively involved in tracking informed consents in the studies I work on.	Strongly Disagree	Date of 1st procedure Date POC/Witness signed Date PI/SI signed All required signatures present? Consent Note in Chart?	Strongly Disagree	Consent versions info section is confusing. The completed form will usually have lots of empty boxes. Format would be better as a spreadsheet like the preceding trackers.	Strongly Disagree	Consent versions info section is confusing; completed form will have lots of empty boxes. Format would be better as a spreadsheet like the preceding trackers.
29	I am actively involved in tracking informed consents in the studies I work on.	Strongly Agree		Somewhat Agree		No Opinion	

Questionnaire #2 Results:
Protocol Deviation Tracker

Protocol Deviation Tracker	What has your involvement been in tracking Protocol Deviations?	Do you feel the following Protocol Deviation Tracker addresses all aspects necessary for protocol deviation tracking?	Protocol Deviation Tracker addresses all aspects necessary for protocol deviation tracking, please briefly list any category headings you would like to see in the box provided below:	Do you find this Protocol Deviation Tracker user-friendly?	If you don't find the Protocol Deviation Tracker user-friendly, please provide a brief answer as to why in the box provided below.	Would you support standardization of the attached Protocol Deviation Tracker at MedTrials?	If you do not support standardization of the attached Protocol Deviation Tracker, briefly discuss as to why in the box provided below:
1	The studies I work on do track protocol deviations, however I am not responsible for specifically keeping track of them.	Strongly Agree		Strongly Agree		Strongly Agree	
2	I am not aware of how protocol deviations are tracked in the studies I work on, however, I do keep a personal record of the protocol deviations at my sites.	Strongly Agree		Somewhat Agree	'Maybe for specific studies (Conor) since deviations are generated by the database and the monitor it would be helpful to know where the deviation was generated. Sometimes the deviations from the database are inaccurate and this could help identify problems in the data management database.	Somewhat Agree	
3	I am not aware of how protocol deviations are tracked in the studies I work on, however, I do keep a personal record of the protocol deviations at my sites.	Somewhat Agree		No Opinion		Somewhat Agree	
4	I am actively involved in tracking protocol deviations in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	
5	I am actively involved in tracking protocol deviations in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	
6	The studies I work on do track protocol deviations, however I am not responsible for specifically keeping track of them.	Somewhat Agree		Somewhat Agree	Comment added: I think the description section should be a little longer.	Somewhat Agree	Comment added: Provided a client does not have their own that is required to be completed. ie - Don't need two trackers tracking the same details.
7	I am not aware of how protocol deviations are tracked in the studies I work on, however, I do keep a personal record of the protocol deviations at my sites.	Somewhat Agree		Somewhat Agree	I would add a couple of lines at the top to denote the study, site & PI to distinguish between our different assigned sites. Otherwise it is user-friendly.	Somewhat Agree	
8						Somewhat Agree	I like the tracker, and would employ it as applicable for studies. I think any document that we "standardize" needs to address the needs of the different roles in a study.
9	I am not aware of how protocol deviations are tracked in the studies I work on.	Somewhat Agree		No Opinion		Strongly Agree	
10	The studies I work on do track protocol deviations, however I am not responsible for specifically keeping track of them.	Somewhat Disagree	For Costar II some PDs are identified by edit checks, which the monitor may identify as invalid (not PDs at all). For this study the tracker could be modified.	Strongly Agree		Somewhat Disagree	This tracker may need to be tailored a bit for the study being performed. Please see my comment to #8 above.

Questionnaire #2 Results:
Protocol Deviation Tracker

Protocol Deviation Tracker	What has your involvement been in tracking Protocol Deviations?	Do you feel the following Protocol Deviation Tracker addresses all aspects necessary for protocol deviation tracking?	If you don't find that the Protocol Deviation Tracker addresses all aspects necessary for protocol deviation tracking, please briefly list any category headings you would like to see in the box provided below:	Do you find this Protocol Deviation Tracker user-friendly?	If you don't find the Protocol Deviation Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you support standardization of the attached Protocol Deviation Tracker at MedTrials?	If you do not support standardization of the attached Protocol Deviation Tracker, briefly discuss as to why in the box provided below:
11	The studies I work on do track protocol deviations, however I am not responsible for specifically keeping track of them.	Somewhat Agree		Somewhat Agree		Somewhat Agree	
12	I am actively involved in tracking protocol deviations in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	
13	The studies I work on do track protocol deviations, however I am not responsible for specifically keeping track of them.	Strongly Agree	The tracker addresses aspects of PD tracking and I think would be useful. We need to keep in mind that trackers take time when completing and that we have to build in this time as remote or report writing and then justifying the billing to the client.	Somewhat Agree		Somewhat Agree	
14	I am actively involved in tracking protocol deviations in the studies I work on.	Somewhat Agree	"Many times, a CRA "finds" a deviation and the site was not previously aware of this deviation, not that we want to put ALL the glory on the CRA, put that is certainly worth mentioning. Also, should there be a column for I & E deviations, the most relevant? This would be a great tracking tool, as the sponsor and IRB need to be aware of these pertinent deviations	Strongly Agree		Strongly Agree	
15	The studies I work on do track protocol deviations, however I am not responsible for specifically keeping track of them.	Strongly Agree		Somewhat Agree		Strongly Agree	
16	The studies I work on do track protocol deviations, however I am not responsible for specifically keeping track of them.	Somewhat Agree		Somewhat Disagree	It can be quite labor intensive. Possibly eliminate a few categories.	Somewhat Agree	
17	The studies I work on do track protocol deviations, however I am not responsible for specifically keeping track of them.	Somewhat Agree		Somewhat Agree	This could get to be a huge spreadsheet for a 5-year study - esp across all sites. Maybe make an individual worksheet for each year of a study within a PD workbook?	Somewhat Agree	
18	I am actively involved in tracking protocol deviations in the studies I work on.	Somewhat Agree		Somewhat Agree		Somewhat Agree	
19	I am actively involved in tracking protocol deviations in the studies I work on.	Somewhat Agree	Every study is different in regards to how protocols are reported and how the PI signs off on them. This is a great tool to start with, but would have to be tailored for each study it is used for. IE: PD listed on data mgmt report? PI signed off on PD?	Somewhat Agree		Somewhat Agree	Again, I think it would have to be tailored per study, but that even so, a standard tracker would be beneficial.
20	I am actively involved in tracking protocol deviations in the studies I work on.	Somewhat Agree		Somewhat Agree		Somewhat Agree	Standardization in this area can be challenging, since sponsor, data management and protocol requirements and conventions vary broadly between projects. A uniform monitoring tool, however can be goo resource.

Questionnaire #2 Results:
Protocol Deviation Tracker

Protocol Deviation Tracker	What has your involvement been in tracking Protocol Deviations?	Do you feel the following Protocol Deviation Tracker addresses all aspects necessary for protocol deviation tracking?	If you don't find that the Protocol Deviation Tracker addresses all aspects necessary for protocol deviation tracking, please briefly list any category headings you would like to see in the box provided below:	Do you find this Protocol Deviation Tracker user-friendly?	If you don't find the Protocol Deviation Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you support standardization of the attached Protocol Deviation Tracker at MedTrials?	If you do not support standardization of the attached Protocol Deviation Tracker, briefly discuss as to why in the box provided below:
21	I am actively involved in tracking protocol deviations in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	
22	I am actively involved in tracking protocol deviations in the studies I work on.	Somewhat Disagree	Immediate reporting required? Intentional?/Inadvertent error?	Strongly Agree		Somewhat Agree	
23	I am actively involved in tracking protocol deviations in the studies I work on.	Somewhat Agree		Strongly Agree		Somewhat Agree	
24	I am actively involved in tracking protocol deviations in the studies I work on.	Somewhat Agree		Somewhat Agree		Somewhat Agree	
25	I am actively involved in tracking protocol deviations in the studies I work on.	Somewhat Agree	Every study is different in regards to how protocols are reported and how the PI signs off on them. This is a great tool to start with, but would have to be tailored for each study it is used for. IE: PD listed on data mgmt report? PI signed off on PD?	Somewhat Agree		Somewhat Agree	Again, I think it would have to be tailored per study, but that even so, a standard tracker would be beneficial.
26	I am actively involved in tracking protocol deviations in the studies I work on.	Somewhat Agree		Somewhat Agree		Somewhat Agree	Standardization in this area can be challenging, since sponsor, data management and protocol requirements and conventions vary broadly between projects. A uniform monitoring tool, however can be goo resource.
27	I am actively involved in tracking protocol deviations in the studies I work on.	Strongly Agree		Strongly Agree		Strongly Agree	
28	I am actively involved in tracking protocol deviations in the studies I work on.	Somewhat Disagree	Immediate reporting required? Intentional?/Inadvertent error?	Strongly Agree		Somewhat Agree	
29	I am actively involved in tracking protocol deviations in the studies I work on.	Somewhat Agree		Strongly Agree		Somewhat Agree	

Questionnaire #2 Results:
IRB Approval History Log

IRB Approval History Log	At the sites you monitor, do you find that keeping track of the site-specific current protocol version and corresponding amendments is challenging?	Do you feel the attached IRB Approval History Log addresses all aspects necessary for documenting the IRB approval history?	If you don't find that the IRB Approval History Log addresses all aspects necessary for documenting IRB approval history, please briefly list any category headings you would like to see in the box provided below:	Do you find the attached IRB Approved Log user-friendly?	If you don't find the Informed Consent Document Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you support standardization of the following IRB Approval History Log at MedTrials?	If you do not support standardization of the attached IRB Approval History Log, briefly discuss as to why in the box provided below:
1	Somewhat Agree	Strongly Agree		Strongly Agree		Strongly Agree	
2	Strongly Agree	Strongly Agree		Strongly Agree		Somewhat Agree	
3	Strongly Agree	Somewhat Agree		Somewhat Agree		Somewhat Agree	
4	Strongly Agree	Strongly Agree		Strongly Agree		Strongly Agree	
5	Strongly Agree	Strongly Agree		Strongly Agree		Strongly Agree	
6	No Opinion	Somewhat Agree		Strongly Agree		Strongly Agree	
7	Strongly Agree	Strongly Agree		Strongly Agree		Strongly Agree	
8	Strongly Agree	Somewhat Agree	I'd like to see IRB policy/requirements for reconsent addressed. It is a question that comes up far too often and it's frequently hard to clearly document the status.	Strongly Agree	I'm assuming this question was for the IRB approval log.	Somewhat Agree	Yes, as a monitoring tool.
9	Strongly Agree	Somewhat Agree		Somewhat Agree		Strongly Agree	
10	Strongly Disagree	Somewhat Disagree	Where would it be best to capture other items that are approved, such as a patient information card. Maybe in comments.	Strongly Agree		Strongly Agree	
11	Somewhat Agree	Somewhat Agree		Somewhat Agree		No Opinion	I think the information on the ICF log and the IRB history log can be combined into one document.
12	Somewhat Agree	Strongly Agree		Strongly Agree		Strongly Agree	
13	Somewhat Agree	Strongly Agree		Strongly Agree		Strongly Agree	
14	Somewhat Disagree	Somewhat Agree	'This form is somewhat busy, the more one uses, it should shape up. IRB approvals from intiation to simple modifications are the most relevant, A CRA shoud always address this first prior to monitoring, in the event of a ICF version change or an expired approval. This tracker is invaluable, I just don't want CRA's to get scared by it, could be simplify it more?	Somewhat Agree	'Less columns, the information which really needs to be captured is date of intial IRB approval and if that particular site is on a yearly IRB approval or a 6-month IRB approval. Then reference the date/version of the corresponding ICF. A column for amendments/modifications and a larger comments column. This tool would aid in completing the outstanding issues/action item log, as a CRA should keep track of each site's IRB approvals, make an action items 2 months prior to expiration to show the sponor the CRA is indeed on top of this important factor.	Strongly Agree	
15	Somewhat Agree	Strongly Agree		Strongly Agree		Strongly Agree	
16	No Opinion	Strongly Agree		Strongly Agree		Strongly Agree	
17	Strongly Agree	Somewhat Agree	Some IRB's tracking ICF versions by only a version # and not an approval date on the ICF. I think you'll need to include a column for the verion # of the new ICF along w/ version date.	Somewhat Agree		Somewhat Agree	

Questionnaire #2 Results:
IRB Approval History Log

#	IRB Approval History Log	At the sites you monitor, do you find that keeping track of the site-specific current protocol version and corresponding amendments is challenging?	Do you feel the attached IRB Approval History Log addresses all aspects necessary for documenting the IRB approval history?	If you don't find that the IRB Approval History Log addresses all aspects necessary for documenting IRB approval history, please briefly list any category headings you would like to see in the box provided below:	Do you find the attached IRB Approved Log user-friendly?	If you don't find the Informed Consent Document Tracker user-friendly, please provide a brief answer as to why in the box provided below:	Would you support standardization of the following IRB Approval History Log at MedTrials?	If you do not support standardization of the attached IRB Approval History Log, briefly discuss as to why in the box provided below:
18		Somewhat Agree	Somewhat Agree		Somewhat Agree		Somewhat Agree	
19			Somewhat Disagree	Expiration date	Somewhat Agree		Strongly Disagree	This is already being tracked in Trial Works, and the information requested is almost identical. Everyone should be using TW for their studies and this should be updated accordingly. Trackers are great, but there is no sense in creating duplicate work.
20		Somewhat Agree	Strongly Agree		Strongly Agree		Strongly Agree	
21		Strongly Agree	Strongly Agree		Strongly Agree		Somewhat Agree	
22		Somewhat Agree	Strongly Disagree	Approval expiry New ICF required? Approved HIPAA form?	Strongly Disagree	The IRB Approval History Log states it is for tracking PROTOCOL versions, but also tracks ICF approvals and other docs. Entries under the column headings will all be N/A for items like staff change.	Strongly Disagree	Recommend limiting tracker to protocol, ICF and HIPAA, or making it for all types of IRB approvals.
23		Somewhat Agree	Somewhat Agree		Somewhat Agree			
24		Somewhat Agree	Somewhat Agree		Somewhat Agree		Somewhat Agree	
25			Somewhat Disagree	Expiration date	Somewhat Agree		Strongly Disagree	This is already being tracked in Trial Works, and the information requested is almost identical. Everyone should be using TW for their studies and this should be updated accordingly. Trackers are great, but there is no sense in creating duplicate work.
26		Somewhat Agree	Strongly Agree		Strongly Agree		Strongly Agree	
27		Strongly Agree	Strongly Agree		Strongly Agree		Somewhat Agree	
28		Somewhat Agree	Strongly Disagree	Approval expiry New ICF required? Approved HIPAA form?	Strongly Disagree	The IRB Approval History Log states it is for tracking PROTOCOL versions, but also tracks ICF approvals and other docs. Entries under the column headings will all be N/A for items like staff change.	Strongly Disagree	Recommend limiting tracker to protocol, ICF and HIPAA, or making it for all types of IRB approvals.
29		Somewhat Agree	Somewhat Agree		Somewhat Agree			

APPENDIX J

Internship Journal

(Please see attached)

Internship Journal

Jill Kurschner

8/15/05- Today was my official first day on the job. First thing in the morning Lachelle showed me around the office again. I was reintroduced to many of the employees I had met at my pre-internship meeting. Originally it was planned that I would be working on a team who was going to be responsible for developing a specific type of training module. However, my first day I was informed that one of their CRA I would be leaving and that I would be taking over her position. To make a long story short it will be a very busy couple of weeks because Karen and I only have two and a half weeks together. Training started immediately that day. Karen is a busy, busy woman and her title is as an "in house" CRA I for a project I will call COSEAR. This project is in its early stages here at Company at an involves the investigation of a particular drug eluting stent as compared to a current market approved drug eluting stent. I have found that Karen is the "go to" woman of this project. It will be very tough filling her shoes. I was introduced to TrialWorks, their email archiving system, and GroupWise. I was given a copy of the protocol and the manual of operations (MOPS) binder. Needless to say, I will be reading for a while. At 3:00 we had a group meeting where the team discussed their challenges they had faced to date regarding the study. This meeting lasted until I headed home at 5:00.

Overall, this was an introductory day of information overload, but I am looking forward to seeing what this will all turn into.

8-16-05 I managed to get to work just fine today (yesterday was unbelievable). I actually was able to catch the bus today. Karen was here bright and early. We started the day off running. We had a conference call with the data management company and COSEAR today. It was an atypically short phone teleconference (an hour or so). I am still in "learning mode" so much of what was discussed was way over my head, but some of the things are beginning to come together. Karen introduced me to all the trackers they have in place for the study. These tools are very important for being able to closely monitor the trial at all time points during the study. Initially, all of this seems very difficult to keep everything organized in my head. Again, it was a day of information overload. I was also introduced to interim monitoring visit (IMV) reports and their deadlines and also to central files. In addition to that, I read portions of the study manual of operations. This was a very busy day.

8-17-06 Today was a really good day. I am beginning to feel that some of the things I have learned are starting to come together. I am still a little worried about Karen leaving. She really is a hard worker, knowledgeable, and a great resource to have at Company A. We started out with a telephone conference call with our data management company. It was very informative. In my spare time I have been reading the study protocol, so some of the verbiage they used in the teleconference actually resembled a new vernacular of English called clinical

research. There have been a few glitches in the case report forms (CRFs), so the call was primarily to get everyone on the same page. I am going to be totally honest; I have walked into a new world that surrounds itself with acronyms. It really will take some good time to not have to think about every acronym before I understand what everyone is saying. Today I also spent some good time reading the protocol. Karen is very busy, so having time to sit down and actually go through the chronology of events for what she does on a day-to-day basis has been difficult. We were able to do a little of that today. I think being able to do a little more of that will really help me transition into her position. She outlined what a typical Monday looked like for her. I also began using TrialWorks to track some of the monitors' newly scheduled visits. This information is tracked on about 4 trackers so trying to connect everything together has also been a challenge, but in time it should become second nature. The IT department came by to set me up with a computer so that has been great. However, I wasn't set up with my job specific programs so it will be a day or so before I start really doing things on my own. I think having my own computer and programs will help increase the slope of my learning curve here. Overall, today was a really good day. It was the first day that all this information is beginning to quasi come together. Keeping track of all the trackers, deadlines, monitors, FedEx sending, general protocol knowledge, teleconferences, reminders, screening logs, etc. will be a challenge, but a fun one. I am realizing that without the clinical research class I took in the spring, a whole lot of the information I am reading, the

acronyms people are using, and documents people are submitting wouldn't make very much sense.

8-18-05- I started off the day by going over some of the specifics on 5 or so of our study trackers. My computer isn't fully set up so I used Karen's computer. This is the first time I am able to do things on my own, so it was nice to work on the trackers "real time." I am solidified in my feeling that there are trackers for everything. Today was also my TrialWorks tutorial. I worked a while on my computer figuring out TrialWorks. Karen had already gone over a few things with me, so I was somewhat familiarized with the program prior to my tutorial. The tutorial lasted a little under 2 hours. It was long but informative meeting. Tim (TrialWorks In-house CRA I) was very knowledgeable and helpful regarding the topic. I had a lot of questions for him and he was both patient and understanding. I am still very much in the learning process, so having Tim around to help when Karen leaves will be a huge positive. I have figured out that much of Karen's job is overall general knowledge about the study itself, how to run the study, nitty-grittys about the CRFs, etc. She never has a full hour uninterrupted while she is working. CRAs, project managers, etc. are periodically dropping by to discuss various topics all throughout the day. As I have mentioned above, she truly is the "go-to" woman. I couldn't ask for a better trainer for the job. She has been great!

8-19-05- Today I came in for a short day. I was instructed that my internship is 30 hours a week on-site and 10 hours a week working on my proposal/literature search, so that allows my schedule to be Mon.-Thurs at Company A. Since I only have a

short time with Karen, combined with us having a conference call today with COSEAR and the data management company, I figured it was important for me to come in. We updated all of our trackers this morning. One of the monitors came in after his visit and updated us on a few questions that came up during one of his visits to the site. Karen jotted the questions down, so that during our call on Tuesday with the data management company, we can address them. The conference call was basically to catch everyone up on all the sites, which would be the next sites to begin enrollment, universal problems occurring amongst the sites, etc. It was interesting to hear what was going on with each site. The conference call lasted around 1.5 hours. It was very informative. These meetings will tell me when a site is ready to assign one of our monitors to conduct a site initiation visit (SIV). A few more sites are on board for SIVs.

8-22-05- Good 'ole Mondays... we started off the day by updating some of our trackers. One of our monitors had a report due to the sponsor the next day so I saw my first fed-ex shipment. A lot goes into making sure a report is prepared correctly, shipped off, and lastly making sure it gets to the Sponsor by the sponsor driven deadline. There was a lot of talk about reports today. I also did quite a bit of filing in central files (CF) today. Today, I finally feel like I am getting a good grasp of correctly labeling all the documents that get archived into central files.

8-23-05- Today we began by updating some of our trackers. A couple of SIVs were scheduled today. I have found that any new visit put into the calendar affects most of the trackers. I have also found that the specific material that I am

learning is not overly difficult; however, keeping track of what goes where is where the challenge presents itself. With so many trackers, I am worried about forgetting to do something or forgetting to put new information in the database somewhere. I will really need to be on top of things the first few weeks Karen is gone. Today we also had teleconference with COSEAR and the data management company. We went over a couple of protocol discrepancies, in addition to the site status review, and the conversation ended with a few questions by my project manager. These discussions are very informative and have really given me a better understanding of the general direction of this project. I ended the day by asking Karen a barrage of questions, which had came up periodically throughout the day. She continues to be a great resource and mentor.

8-24-05 Today was a busy day, I began the day by updating my journal. Karen and I went through a huge stack of papers that needed to be sorted and stamped. We haven't quit filed them into CF yet, but hopefully today. Lots and lots of paperwork I have found goes along with is profession. We had our weekly meeting with the data management company. As usual this was very interesting. I follow the conference calls better when there are fewer people on the phone. I am still trying to figure out who is saying what during these conference calls. Sometimes there can be 8 people on these calls, so distinguishing voices can be confusing. The call basically updated the status of all the sites. My project manager asked a few questions about multiple vessel stent placement versus single vessel stent placement. The new deadline for our next 100 patients will be

Sept. 15. This date is quickly approaching, so this should be interesting. I am still feeling a little out of my element with my role and responsibilities as an intern. I am a little worried about Karen leaving because I don't feel fully confident in my abilities to perform up to the standards that I think they may be expecting. I talked with my on-site mentor yesterday, and she seemed optimistic about figuring out my "definite" role in the very near future. Today should bring more clarification.

8-25-05 Today was another busy day. As usual I updated my trackers as necessary. I am still trying to figure out what exactly will be my internship project for my thesis. I was able to sit down with my on-site mentor today and go over my project. It was nice to finally hammer a few things out. I am feeling better about the practicum proposal, but it will be a challenge because I am not too familiar with the topic just yet. Today we also had a few monitoring visit reports (MVRs) that needed to be sent out. My first official assembly of an MVR was today; I think it went alright. I missed a few things, but not too bad for my first time. I also had a lot of central files work to do with all the incoming papers from the site initiation visit (SIV). I spent the last part of the day filing.

8-26-05 I start everyday by updating as many trackers as I can. We had a conference call at 12:00, so we spent most of the morning preparing for that. I was in charge of doing the minutes for this conference call. I still feel like I am not quite up to speed with my knowledge or understanding of all that is going on. It is really difficult to walk into something right in the middle of things and just start

running. I found myself struggling to understand a few of the topics mentioned during the conference call, and as a result it made it difficult for me to do the minutes. At this point I am trying to take each task at a time and try as hard as I can to fit the bits and pieces into a larger picture. After lunch, Karen and I did a ton of filing and data input into TrialWorks. My new mantra at work, "basically everything is tracked everywhere." TrialWorks is slowly becoming more familiar to me. I am still trying to identify what every piece of paper means, and then figure out how to input that paper into TrialWorks in order to show that it is being tracked. One of my clinical research management teachers was right when she said that the documents in any trial tell a very complex story. I am in the midst of trying to learn how to read this story. It is still up in the air what will be happening once Karen leaves. I have voiced my concerns to my on-site mentor, project manager, etc. about making sure that the right move for everyone happens. I just really want Karen's transition out and my transition into performing some of her responsibilities to occur as smoothly as possible.

8-29-06 I was able to sit down and chat with Bob today. He is responsible for all the training regarding project management. He gave me a few books and a couple of training modules to look over. I really have no background in this information so this will be interesting. Dr. Bens contacted me via email over the weekend. She requested that my on-site mentor and I try to call her today to discuss my project. Unfortunately, my on-site mentor was very busy today, so she requested me to email Dr. Bens the information she was requesting and we would follow-up after

that. I prepared another MVR today. I will be sending it out tomorrow. I spent quite a bit of time in central files today. I feel like I am learning so much so fast, I seem to have 100 questions for Karen everyday. I am trying to get everything out of her that I can. She is a bottomless pit of information and guidance. I am really trying to get down the emailing archiving business they have in place for this project. I am not in the habit of "CC" internal, sponsor, site, etc on every email that I send. It will take some getting use to.

8-30-05 I started off running when I arrived to work today. Our weekly shipment of screening logs was faxed to us today. It was my responsibility to stamp and send them off to their respective monitors. I also informed the sites that did not send in their logs to make sure that they send in their screening logs to the data management company of a weekly basis. Afterwards, I was left with a plethora of papers to file. I had a brief tutorial with Tim today regarding all the TrialWorks information. I had 3 MVRs that needed to be entered into TrialWorks and we were able to get through one very large packet. He is really good at his job, and extremely patient. I was able to learn a lot from him. Today we also had a conference call with COSEAR and the data management company. The call lasted about an hour. As the project continues to expand, we potentially may institute daily conference calls. Things have been really busy, because today is our deadline for our first 50 patients enrolled into the study. I think we were able got all pertinent data in. In the latter part of the afternoon, I stamped a very large stack of regulatory documents for central files, along with finalizing

the minutes from our last teleconference call. The last part of my day I typed the rough draft for the minutes from today's teleconference. Still no answer on what will be happening with Karen, hopefully we will find something out tomorrow.

8-31-05 We just found out that Karen will be staying on as a contract worker remote from Arizona for 2 months. I am so relieved. This will really help me make the transition. When I sat down with Tim yesterday he told me that I needed to pull all the CV's for the sub-investigators, the Delegation of Authorities (DOA), and the site visit logs so that I can plug them all into TrialWorks. I spent most of the morning and the afternoon finding these forms, plugging them into TrialWorks, and then re-filing them all. Today we also had a teleconference call with our data management company. It was only about 45 minutes, so that was nice. I updated my file folders in GroupWise to incorporate the coordinators. The last part of the afternoon was spent tying up loose ends with Karen before she headed out. Friday I will be sitting down with my on-site mentor to narrow the scope of my project down a little more. Well, here we go. Friday will be my first official day on my own... "let's play ball" as they say.

9-2-05 Well, today was my first official day on my own. How scary! It actually went really well. I have had a very busy day. I had about 20 emails waiting for me when I came into work this morning, so I spent a lot of time following up with the emails, in addition to, updating our schedule and trackers. Today I also worked on preparing 5 MVRs that sneakily found their ways into my office to be fedexed out. I almost had a minor coronary when I thought I lost one of them, but I

eventually found it stuck behind one of the other MVRs. I actually thought there was going to be reason to get the big boot my first day. Later on that day, I had a meeting with my on-site mentor regarding my thesis project. She had a couple of good ideas, which might potentially narrow down my project scope a bit. I will be having another meeting with my committee on Tuesday to discuss the specifics of my thesis project. Today my project manager and I sat down for a teleconference. Again, I was pleasantly surprised that it went pretty well for my first teleconference call. I spent most of the afternoon sending the MVRs off and stamping all the papers I received today from the monitors. I have a huge stack to go over with Tim, put into TrialWorks, and then file into central files. All in all, it was a good day. Oddly enough, I think that I learn things faster and more efficiently when I am just thrown into them. Overall, I am happy with how my first day went... no catastrophes.... yet! It is Labor Day weekend, so I get a long weekend to celebrate.

9-6-05 Boy, it was a great weekend. It was hard to come back and get into the move and groove of things. However, when I saw the overabundance of emails waiting for me, it wasn't too hard. I started the day by updating the IVUS (Intravascular Ultrasound) and ECG (Electrocardiograms) labs that came in. I also updated the calendar with the new monitoring visits. When visits are scheduled and finished I update my trackers; so I did a little of that today. I had a lot of stamping to do today before the stack could be sent off to central files to be archived. We had a teleconference call at 12:00. Quite a few directives came out of this call, so I was

busy with a following up with emails to the sites when the call was over. I was also able to finish up my minutes for last week. I sat with Tim for about an hour and a half and put information into TrialWorks. I also needed to get one of the MVRs that I had received out today; so I packed that up and sent it off. I feel like I do a million things at once here; so I am trying to keep track of everything. I ended the day with two MVRs that were dropped by my office and a long list of things to do tomorrow. I like being busy, and busy is this job. It is amazing how much I feel like I have learned in the past three weeks. My project manager continues to be a great help during this transitory process.

9-7-05 It is so hard to remember the specifics of what I do in a day, because by the end of the day I am in a big fog. I started off the day by reading all of the emails I was sent by my project manager, monitors, Sponsor Company, and data management company. I caught up with Karen by email and by phone. I still have a few questions about central files, in addition to, what documents that I need to specifically forward onto the monitors. I went through some of my MVRs and stamped them for central filing. I also started putting information into TrialWorks today without the "hand-holding" by Tim. I think I am growing up. I will still have Tim check a few things over, but I think I am starting to get a little faster at this. My project manager and I had a teleconference at 10:00. It lasted about 45 minutes. After the teleconference, I typed out the minutes for our last teleconference. Typing up minutes can be something that just snow piles unless you keep ahead of the game. When I chatted with my project manager yesterday,

we went over what sites needed to send in their IVUS and Angio. films. Today I sent emails to all the respective monitors telling them that their sites hadn't sent in their films yet. I also faxed out two MVR packages. I spent about an hour pulling emails out of their attachments from the COSEAR internal database. That job duty is probably not at the top of my list of favorite job duties to perform, however it needs to be done. I had my first IMV that I scheduled today. As usual, I had to document this on 2-3 different trackers along with TrialWorks. I hope I can continue to remember all of this. Our Sept. 16 deadline is coming up, so things will probably be getting a little more hectic around here in the next few weeks. Tomorrow is my meeting with Annita, Barb, and Dr. Kaman. It will be so nice to hammer out a specific topic for my thesis.

9-8-05 As usual, I started off the day by reading the deluge of emails I had waiting for me. It is crazy how fast I have jumped into this study. It actually feels pretty accomplishing. There is so much information continually transmitted between the sponsor, site, CRO, and data management companies that keeping up with all of this is a feat in itself. However, even in saying that, it was a little bit of a slower morning than I am used to. Tim and I finished up some of our TrialWorks information. Just when I think I have something down, something else comes up that throws a wrench into things. Annita came today to chat with Barbara and me about my thesis. It feels really good to finally nail something down. I am still a little bit confused to what exactly my project will look like, but I think after a little bit of research on the general topic I will feel better directed. After the

meeting, I updated a few trackers. I am slowly trying to take over Karen's duties. I find when I have a spare moment on my hands, I am trying to take on more of her tasks. I need to make sure I pace myself. A few more screening logs came in today; I stamped those and filed them in central files. I had a few other things to file in central files, so I did that at the end of the day. I finally completed my take-home quiz on proper central files archiving processes. Hopefully now I will be given a password in order to finally gain access into the "golden" room (in order to have the autonomy to enter the room at my leisure instead of relying on other co-workers to open the door for me), and even better... the back door (I arrive early so waiting for someone to open the door can sometimes be a hassle). Things are really starting to come together. I am enjoying my position here better each day. Everyone on the team has been so helpful, and I am extremely thankful for that.

9-9-05 Unfortunately, I didn't have time to write on this specific day, so I am writing after-the-fact after a long weekend in Houston. I updated all of the new patients we had into all of our trackers. Karen wasn't able to keep up with one of the trackers she is responsible for, so after she phoned me I spent quite a bit of time bringing that tracker up to date. We had a conference call today at 12:00. I spent a good portion of the morning making sure I had all of my papers ready. Our conference call started at 12:00 and ended at 1:45. Our deadline has almost arrived; so everyone is getting a little stressed with the logistics of everything. This call ended only to begin another conference call at 2:00. During this call we

really hammered out the nitty gritty of what was missing in respect to CRFs sent to the data management company. The data management company is very concerned with not having enough time to analyze the data for their Tuesday meeting with the Data Safety Monitoring Board (DSMB). There were some heated discussions and as a result the game plan changed a bit. Company A was instructed to contact all the sites and have them send in their unmonitored data ASAP. There is so much more that went into this conversation, but my role was to email each site and update them on this change. So I stayed here until 7:00 to catch the sites and monitors up to speed on the new agenda. I was happy to get on the road to Houston after a long day at the office.

9-12-05 Deadlines, deadlines, deadlines! We have 4 days until our first 100 patient CRFs are due to be in at the data management company. It was crazy today, I logged into my computer to see about 50 emails waiting for me. Luckily they all were not needing me to reply back to them directly, but nonetheless there were still 50 emails. I spent a large part of the morning following up with coordinators as a result of a new game plan for getting in all of our CRFs. It ends up I spent close to 2 hours emailing everyone on Friday only for that to be the wrong information. This was a little frustrating, but at the time we thought it was necessary. We had quite a few new patients I needed to add to our trackers; so I spent a good portion of morning working on that. I prepared one MVR to be sent off. Today my project manager and myself had a conference call with the data management company. It went really well. The project manager and myself

have been contacting the monitors and the sites to follow up with all of the CRFs; so our update to the data management company was pretty good. I spent a lot of time sending emails updating the monitors, asking them site specific questions, etc. It was a busy day. As the deadline approaches, I am sure things will get more hectic, but today's game plan went well.

9-13-05 It was pretty busy yesterday, with everything going on. We had a conference call with COSEAR and the data management company to discuss all of the site status updates. We are beginning to schedule new sites to be trained to this protocol. It won't be an official site initiation visit (SIV), but instead a training visit. The schedule is getting ready to be very busy. The call was actually pretty short. Today was another day working on emailing sites and contacting the data management company in order to ensure that all of our CRFs arrived on-time. We are constantly monitoring every site to make sure they are on top of sending their CRFs in. One site in particular, I have been spending a lot of time "consoling." It seems like one thing after another seems to come up. We also had our daily teleconference with the data management company at 3:00 today. This conversation also went well. I think that data management company is more laid back than on Friday. It was nice, because we had tracking numbers waiting for every CRF they asked about. It feels good to be on top of things. I received a ton of MVRs to process today. I have quite a large stack of papers to be stamped, and filed. Another busy day down and a whole lot more to go.

9-14-05 Today is our early morning call at 10:00 with the data management company. I updated all of the new patients who have been enrolled into the study. I think we are up to 180 patients as of today. I also updated the necessary trackers for the conference call. I am responsible for informing the data management company as to how many SIVs have been scheduled and completed, in addition to, monitoring visits that have been scheduled and performed. I had a ton of follow-up with the site coordinators to do today. As I mentioned above, one site in particular seems to be "high" maintenance. This site's coordinator has been reluctant to follow-through with the directions given to us by the Sponsor Company. As a result, multiple phone calls are placed to the site by Company A, the data management company, and the Sponsor Company. Our conference call with the data management company went quick. I think it was only about 30 minutes. There really wasn't much to talk about since we chat everyday at 3:00 pm. I received a few more MVRs today. I also had 4 MVRs to send off to the data management company, in addition to, 6 MVRs that I needed to get stamped and ready to be archived into central files. I have currently been working a lot on trying to get a few specific reports into the Sponsor on time. This is hard when some of the monitors are not in-house a good majority of the week. I was afraid we were going to have 2 late reports, but I finally was able to see the light at the end of the tunnel. No late reports....Yeah! The day ended with our conference call with the data management company, they seemed very pleased with our work during the past couple of deadlines. The last part of the day was

spent conversing with my project manager about the last of our "final" duties in order to successful reach our deadline. Our deadline is Friday, so this information was very important.

9-16-05 Well, our deadline was today. It ended up turning out very well. My project manager and myself had a teleconference with COSEAR and the data management company today. Everyone seemed very pleased with the progress of the trial timelines. All CRFs, except for a few outstanding CRFs from the outside the United States (OUS) sites were into the data management company for number crunching. It is funny how when deadlines approach people are not as stressed, because the legwork has been performed the days leading up to the deadline day. It almost feels like everyone was frantic the week before the deadline, but when everything fell into place by the day of the deadline no one was in "over-drive" mode anymore. I also spent a large portion of the day updating all of our trackers. I also updated our Intravascular Ultrasound (IVUS), electrocardiogram (EKG), and CRF spreadsheets, which took a good deal of time. To be honest, I usually spend quite a bit of the day answering random questions; questions about the schedule, about the protocol, about MVRs, about anything and everything. It is almost a full-time job keeping my email mailbox from exploding due to the number of emails I get in a days period of time. I have found that it is really good working for the specific project manager I am interning under. I don't find much time to socialize with a lot of the other workers, and as a result I find myself alone most of the day. I guess that comes

with being busy. In the afternoon, I was scheduled to stand guard the central files door. Since our the woman who was previously in charge of covering central files has "moved-on," the in-house CRAs are now responsible for this duty. Everything went smoothly, no one tried to run out with any of the files. The day ended anti-climatically. We didn't even have our daily 3:00 conference call. All was well. I finished the day writing minutes for both the teleconferences we had this week.

9-19-05 Good 'ole Mondays. After having our 100-patient deadline, things have quieted down a bit. We haven't quite hit 200 patients yet, so our next deadline is still tentative. We should probably hit 200 patients tomorrow. I think we are at 196. I spent a good portion of the morning updating all of our trackers. I also followed up with one of our monitors, because she has 2 reports pending to be sent to the sponsor this week. It is interesting how some monitors are on top of things and still others wait until the last minute to get their work done. Oh, the nature of man. I wanted to make sure my MVR submission tracker was correct; so I did some double-checking using my calendar. Everything looked good. I processed and fedexed two MVRs today. Tim and I worked together inputting a couple of MVR and associated documents into TrialWorks today. I think I am almost ready to go out on my own with inputting the TrialWorks information. Tim has been a huge help. I also spent some good time stamping papers and filing documents into central files. Overall, this was a pretty low-key day. I don't think it has been this quiet since I started. It feels good to catch up with all

the loose ends that I haven't had time to dedicate to. I spent the last part of my day updating the dry-erase board calendar in my project manager's office with all of the monitoring visits for the next couple of months.

9-20-05 Happy birthday to me! I spent most of the morning updating my trackers. We officially hit our 200-patient deadline; so the race has begun. This means that our 200-patient deadline is Oct. 20. Personally the timing isn't too good for me. I will be off to MN the weekend before the deadline, so hopefully I can do as much as I can before I leave. We also had our weekly Tues. conference call with COSEAR and the data management company. Today the teleconference call lasted longer than normal. So much to catch up on, we needed to follow-up on the 100-patient deadline, establish the 200-patient deadline, and outline all of our SIVs and MVRs. Needless to say, it was quite busy. I think my project manager is a little stressed with everything that happening at once. Oddly enough, I am not feeling overwhelmed at all, in fact, I feel I could take on additional responsibilities. I hope he feels comfortable passing me on additional tasks in order to help relieve his load a little bit. My on-site mentor stopped in to chat yesterday, so I passed on that tidbit of information. I also did some work in TrialWorks to end off my day. All in all, it was a pretty normal day. Oh, I forgot… I also did the minutes for the conference call we had today. On top of that, I sent out the minutes for the two previous teleconferences to all participants on the call.

9-21-05 As usual, I updated all of our trackers and followed up on copious emails in my inbox. My project manager and myself chatted with the data management company about the 200-patient deadline. I think they are feeling a little stretched also. A new version of the protocol recently came out, so it was nice to finally receive that document and review it. After lunch, I updated TrialWorks and stamped quite a few documents for central files. My central files stack is getting larger by the day. I am trying to hold off from filing until Friday when it is my time to "watch" central files. I have a lot of emails that I need to pull from their attachments in the COSEAR database. This will probably take me at least a couple of hours. I received comments back from Annita and Barbara regarding my proposal. It looks like things are finally starting to come together.

9-22-05 I spent today working on my internship proposal.

9-23-05 Today was a busy day updating trackers, scheduling, filing in central files, answering emails, etc. We spent a lot of time on the conference call today. In fact, my whole afternoon was on a conference call with COSEAR. We had numerous site updates to go over. We also had a conference call discussing CRFs and how certain circumstances needed to be addressed at the site level.

9-26-05 Mondays are always very busy. I usually have around 40-60 emails waiting for me when I get into the office. I spent quite a bit of time getting a couple of MVRs processed and ready to be sent out. A few people from our team have decided to move on from the company very recently; so some restructuring has

been going on as of late. It will be nice to get a couple additional new people on board. Mondays always seem to be a great catch up day. I updated all of the trackers and organized the gigantic piles of papers lying all around my desk.

9-29-05 Boy, so much was waiting for me while I was gone; I could hardly believe it. I think I came back to around 50 emails. I feel like I am always talking about the number of emails I receive, but it continues to fascinate me just how many I can have waiting for me in my inbox. Our second deadline is approaching so we are busy planning visits for the month. I was able to update all the trackers today. My project manager and I sat down and chatted for a while to catch me up to speed. I was assigned 10 additional sites to call and schedule for training visits. I sent an email to all of these sites. We had an "unscheduled" teleconference with COSEAR today. This is where I initially found out about the 10 additional sites we needed to contact. So needless to say, I hit the ground running the rest of the afternoon finding the contact information for these sites.

9-30-05 Thank goodness its Friday (TGIF). Now this is an acronym I am familiar with. Currently, I am feeling like there is so much to do with not enough hours in the day. My pile of "to-dos" for Tim is getting larger and larger. I haven't had much time to do central file paperwork lately, so I am beginning to feel like everything is piling up. Normally I am on top of knowing when particular MVRs are due to be sent out to the sponsor (this is my job), however, since I have been gone for a few days I was a little behind with remembering that a couple of our MVRs were due to be sent out on Monday and I hadn't reminded

my project manager of this. It is my job to be on top of this; so when Bill came to remind me about sending off a particular MVR I was disappointed in myself. I don't think he thought twice about it, but I was disappointed. After chatting with Bill I processed and sent out 3 MVRs. I was also able to send one of our new monitors on the study her comprehensive folder of study related materials to familiarize herself with before her official training. I just didn't have enough time in the day today. We had our conference call with COSEAR today. That went smoothly. I also called 10 sites to attempt to schedule training visits with them all. Surprisingly enough, two sites have already committed to dates. I think that covers the big picture of things I did today. Lastly, I was also able to update our IVUS, ECG, and CRF reports today. TGIF.

10-3-05 Mondays always seem to be a little rough. I have so much paperwork I hardly know what to do. I started off the day answering all of my emails. I think I had close to 50 to follow-up with. I called the remaining 8 sites that I am in charge of scheduling training visits for. It is amazing how you can call someone, email someone, and even in some cases fax someone and they don't seem to get the idea that you want to chat with them. Well, I was able to finalize two more visits today, so that was successful. I had a ton of emails to "pull" from the COSEAR database so that kept me busy for a good portion of the morning. Today I spent a great deal of time inputting regulatory documents into TrialWorks. It seems that the MVRs never stop piling up on my desk to be stamped, put into TrialWorks, and filed into central files. On that note, I also processed and sent off 6 MVRs

today. The last part of my day was spent communicating with monitors, sites, and the sponsor regarding scheduling the training visits and coordinating schedules.

10-4-05 I finally updated all of our patient trackers. It has been so busy I haven't been able to do that much. We had 20 new patients that needed to be added to all of our trackers. This took me a good portion of the morning to finish. I processed and sent off 1 MVR in the morning. My project manager and I had a teleconference call today with COSEAR and the data management company. After the conference call, I spent a good portion of the afternoon inputting information into TrialWorks. I also was able to finish one of my minutes from a previous teleconference. It feels like I never actually catch up in this job, but at least I am not bored. I ended the day contacting a few sites to solidify training visit times and agendas.

10-5-05 Today has been a crazy busy day. I have spent quite a bit of time coordinating all of the training visits. There are so many peoples' schedules you have to coordinate with in order to make a visit a successful visit. I probably made 20 phone calls today trying to coordinate everyone's schedules. I was really hoping to get to my very large stack of papers accruing on my desk for filing into central files, but that wasn't able to happen today. However, Loraine helped me get a bit more organized by alphabetizing my stack of papers and categorizing them. I sent off 1 rush MVR today. I also was able to update my project manager's dry erase board calendar today with all of our visits. We scheduled a couple

monitoring visits today as well. I spent a little bit of time in the afternoon inputting information into TrialWorks. I also spent some time looking over my trackers and making sure that dates, times, information was inputted correctly. Today I went out to lunch with my project manager for the first time. It was nice to meet the man behind the name. We have worked together since my first day on the job; however, with the business of the project he and I haven't made the time to sit down and talk. I enjoyed our time very much. The last part of the afternoon was spent communicating via email with sites and COSEAR representatives in order to solidify a few visit dates. It is amazing how so many little things are able to come up that seem to need addressing. It was very, very, busy today, but that is exactly the way I like it. However, I will feel like a huge load has been lifted off of me once I get the opportunity to file my stacks of regulatory documents into central files.

10-6-05 I really could use 2 more days in the 7-day week in order to hammer out all the paperwork piling up on my desk. There just doesn't seem to be enough time in the day to do all of what I would like to accomplish. I chatted with my project manager yesterday about getting some help. He said he would ask one of the monitors to help me. No conference calls today, but lots of calling around to sites and contacting sponsor representatives to try and get our new batch of SIVs scheduled. I did do some TrialWorks data entry, but not enough. My project manager spent most of his time today making one of our trackers "more efficient." He truly is a genius with Microsoft excel. By the end of the day we

had a totally different spreadsheet. I also spent a little bit of time sending out MVRs today. Some deadlines we meet by the skin of our teeth (the MVR had just been finalized). A couple of monitors on-site requested information for their principal investigators, so I ran around a lot today. It was a "hodge-podge" day, but a large portion was corresponding by email to the sponsor, my project manager, the data management company, and our monitors. Lastly, I finished my minutes for the week and sent them onto my project manager for revision.

10-7-05 My project manager was nice enough to update one of my spreadsheets today, however, it confused me because I usually update all 3 spreadsheets at once. I spent a good portion of the morning trying to get everything entered into the spreadsheets and making sure that all 3 spreadsheets had identical information captured on them. My TrialWorks program decided not to work today, so my stack of information to be entered in only became larger today. We had one of our bi-weekly phone conversations with COSEAR and the data management company. It was a very productive phone conversation. Quite a bit of new scheduling went on and I have a lot of updating on the calendars to do. We finished our teleconference just in time to go to the in-service meeting provided at lunch here at Company A. It was my first in-service meeting. The speaker talked about Diabetes and transplant of insulin producing cells into the liver for diabetic patients who cannot control their diabetes. It was a very informative lecture. I will really enjoy these Friday lunches. I had about an hour of "quick" random scheduling activities I needed to do before I headed home. I tried to

leave a little early today, but I got caught scheduling a couple sites for SIVs, so I wasn't too successful. However, I was able to get home in time to stop by the school and finish some business for writing my proposal.

10-10-05 Monday, Monday...It has been kind of a laid back day for me. My TrialWorks program is still not working, so I am not able to "attempt" the large stacks sitting on my desk. I sent an email to our IT department to try and remedy this problem, so they my computer should be up and running in no time. I spent a lot of time updating the calendars, responding back to emails, and setting up a few more SIVs. I have about 5 whom I am communicating with on a very regular basis. Between phone calls and emails it gets difficult keeping up with everyone, but I enjoy the challenge. A lot of the monitors are heading out this week, so I spent quite a bit of time making sure everything would be in place for them before they left. This includes ensuring that everyone had their checklists, CRF transmittal forms, and other extraneous forms. Since a deadline is approaching, I try to make processes as streamlined as possible. I think all of our monitors are out on the field this week. Donova (field monitor) called me and asked if I would follow-up with two of her sites to make sure they were still aware of their visits. I think I spent most of the day corresponding between Donova, the sites, and the sponsors just for these two sites. All in all, it was good Monday.

10-11-05 Well, I finally accomplished getting into central files and began my never ending filing endeavors. A good portion of the day was dedicated to central files work. I feel like such a load has been taken off of me. I was able to file one huge

pile of papers and now I have one huge file of papers to go. I will try to finish the second stack sometime later this week. We had one of our bi-weekly teleconferences this week. It was busy. We are all gearing up for the 200-patient deadline. Everyone is feeling the pressure of the slow-cooker, so this will be interesting as the deadline approaches. I find that I spend most of my day corresponding with sites and the Sponsor Company answering random questions or directing people to who they need to talk to. I think responding to my emails could be a full time job in itself.

10-12-05 Things keep getting busier and busier. I was able to make a small dent on my second large stack of papers left to be filed. I have so much stacking up on my desk that I am beginning to worry that people will think that my office is for document storage. I was able to input about 10 MVRs or so into TrialWorks today, so I felt very accomplished. I feel accomplished because everything was able to get stamped and put in the "Tim" folder. When I receive everything back from him I am then able to file these documents into central files. Tim is responsible for inputting all outstanding items listed within the MVR into TrialWorks and also an excel spreadsheet he has created. My project manager and I had quite a few conversations regarding study progress timelines today. Our deadline is approaching next week, so we are busy making sure that people are sending in their CRF transmittal forms, etc. Today I also went over a few SOPs with Tonya. I didn't actually read anything yet, but I was set up with the software to do so. I updated the calendar and double-checked all the visits in TrialWorks.

Let me back track for a moment, Wednesday is my day to send all the updated visit totals to the sponsor, so I spent a good portion of the morning performing this task.

10-13-05 It has been a busy day. So many site correspondences and visits to schedule. I continue to have my central files stack accumulate to great heights. I found out today that I have filed a few documents in central files incorrectly, so I will be going back into specific site folders to remedy this problem. I am not looking forward to doing this, but it really is a necessary item to perform. I updated all the patient trackers today. I haven't been able to update these for a while, so it was a much needed task. In addition, I was also able to do my minutes for the teleconference call we had last week. Screening logs were received this week, so I dispersed those out to their respective monitors, and also sent reminders out to the sites that were tardy with sending in their screening logs. The last part of the day I spent inputting information into TrialWorks.

10-18-05 Well, I have been gone for a few days because I went home to attend my 10-year high school reunion. I came back to 50 emails waiting for me to be opened and addressed. This probably sounds worse than it is. Sometimes I can whip through all of these in a couple of hours. Fortunately, it didn't take me the whole morning to get through all of them, and on top of that, I was also able to do quite a bit of work in TrialWorks. I wanted to be prepared for the teleconference we had at 11:00, so I printed off everything and put it all in a nice neat stack for the conference call. The conference call went fairly quickly. These are the last few

days before the deadline so things are busy. After the teleconference I was prompt today and wrote out the minutes. Since everything is fresh in my head, it helps doing the minutes ASAP. I received all the screening logs today. I sent out emails to all the coordinators who were tardy with sending their logs, in addition to, emails to the monitors informing them which of their sites they needed to remind to send in their screening logs. I had a lot of miscellaneous things to catch up on today. After the teleconference I had a few emails/phone calls I was instructed to make. The data management company requested some site contact information that they wanted me to follow-up with. I sent out one MVR today, and processed a few more. I think paperwork this week might be slow, but everything else will be busy. I have a ton to do tomorrow in regards to updating the patient trackers. It will feel great to have these updated.

10-19-05 Today was a good catch up day. I did a lot of my paperwork. I updated the calendar. I processed and sent out two MVRs. I called and emailed quite a few sites for our 200-patient deadline. Most of my activities today surrounded around the 200-patient deadline. We had a conference call at 3:00 today. Time is ticking down, so people are starting to get more frazzled. My project manager and I are working at trying to contact all the sites with outstanding CRFs. There truly are only so many times you can contact a site before they get mad and frustrated with your efforts. We had one incident with a site coordinator where she sent a really nasty email. I ended up talking to her on the phone in addition to emailing her to diffuse the issue. On a school-associated note, Anita requested that I turn in an

updated resume. I spent a good portion of the day gathering information on how to update my resume. It will be nice to have that finished.

10-20-05 Today has been a pretty good day. I finished up my resume today and sent it off to Anita. I had some help from Laura and Dena (fellow co-workers). I followed up with a few more sites today, making sure they will be getting in their 200-patient deadline CRFs into the data management company on time. I also was able to update the calendar with jumpstart personnel schedules. I sent out two MVRs. I plan on spending some good time updating Tim's MVR tracker. I received an email from Bill yesterday saying that a few of our visits were not on that tracker. I think what has happened is that the delegation of duties between Karen and I has allowed a few things to fall through the cracks. All in all, it has been a pretty laid back day. We have a conference call tomorrow that I need to get prepared for, but things seem to be steady instead of frantic the past few days. Hopefully this atmosphere will last.

10-24-05 Our official deadline was pushed to today. It has been chaos trying to figure out how packages, sent from sites, can be lost "in-transit" within our data management company. We had a conference call today where the data management company basically said that they weren't sure where our CRFs were within the company. They knew that they were there, but they just didn't know what room they were in. So we had to call the sites back and make sure they sent the CRFs to the correct building. Ten minutes into us calling the sites, a representative from the data management company called and said they had found

all the missing packages. What a relief. This means that we officially met our 200-patient deadline with 187 patients. With Sponsor deadlines, it is assumed that if you get 90% or more of the desired anticipated total, that you have "successfully" reached your deadline. This feels like a relief, but our 400-patient deadline will be here before we know it. No rest for the weary. I spent quite a bit of time chatting with sites to follow-up on odds and ends things. I updated new visits on our calendars and trackers. I also processed and sent out 6 MVRs today. It has been steady most of the day. Today my thesis proposal was due, so I sent that in also.

10-26-05 Today has been crazy. I have spent most of the day following up with monitors to make sure they turned in their MVRs. I processed more than 16 MVRs today. I spent a large amount of time putting all of these MVRs into TrialWorks. I think Tim is overwhelmed with the stack I gave him. I'm pretty sure I would be also. Today was supposed an in-house project management meeting I was eagerly anticipating going to, but it was cancelled because quite a few of the project managers were too busy to attend. I sat in on a conference call with COSEAR today. They were discussing revisions on the CRFs. I updated the IVUS tracker, and the calendar. I misplaced an MVR to be filed into central files; so I ended up contacting the Sponsor Company to see if they could make a copy and send it to me. I was worried about talking with my project manager about this, but he was really great. I have been putting my nose to the grindstone today with all the miscellaneous MVR things. It is difficult with some of the monitors to get them

to turn in their reports on time. All in all, it was a good day! My project manager and I had a good chat about the project today. I also sat with my on-site manager today and discussed potential employment at Company A in the future.

10-27-05 Today was a day to catch up on some paperwork. My stack is getting taller and taller so I wanted to take a jab at it. Overall, it was a typical day of being a liaison between the site, sponsor, monitors, and data management company. Busy day!

10-28-05 Luis was gone today so I was our main representative for the project today. I had a meeting with Bill at 9:15 to discuss monitoring visits and CRF questions. Our meeting lasted for a good while. I was forced to scramble to update a few of the trackers before our teleconference call at 11:00. Today the office celebrated Halloween, so it was a fun day. I had a shorter day than normal; so everything seemed very rushed. I was able to send out 6 MVRs today. After the teleconference call, I went through my TrialWorks stack and entered a ton of data into TrialWorks. My eyes were cross-eyed after that endeavor. I ended the day updating a few calendars, and called one of our sites for a monitor to schedule a few monitoring visits for Nov. and Dec.

10-31-05 Today has been really busy also. I had two interviews today, along with all the regular tasks that go along with being an in-house CRA. I had quite a few of emails waiting for me; so that took a good deal of time to sort through. We are approaching our 400-patient deadline, so scheduling of IMVs is very important right now. As a result, most of the monitors are emailing me their schedules. When I receive their visit dates, I log these dates onto our COSEAR calendar,

TrialWorks, and Tim's MVR tracker. Today I was also able to process and send out 3 MVRs today. I was supposed to have my final interview with Bill today, but he had to reschedule for tomorrow. We are working on hiring a new monitor so lots of interviews have been happening around the office. All in all, my stacks are getting higher, but I am hoping to tackle part of them tomorrow.

11-1-05 Today was an early day. I was able to have my last interview with Bill shortly after I was in the office at around 8:00. It was about 1 hour long on the phone. I think it went pretty well. Today we also had a teleconference call with COSEAR and the data management company. It was one of the longer calls we have had in a while. We went through all the sites and updated everyone on the activities occurring at each site. I was able to update a few of the trackers today. I was very busy processing MVRs and keeping up with all of my emails today. We have a new addition to our team; so I was able to meet her today and chat briefly. I followed up with a few sites after our teleconference. We are in the midst of trying to schedule all of our sites for IMV because the 400-patient deadline is Dec. 2nd. It was a busy day in the office.

11-2-05 Today was another busy day. I spent a good portion of the morning scheduling and updating the scheduling trackers. I had a visit with LaChelle, Barbara, and Tim today regarding my questionnaire project. I had to turn in my degree plan along with my proposal with all of my signatures attached. I spent most of the morning getting that straightened out. I was able to get help today with some of my filing. Todd came in and filed a huge stack. It felt like my birthday. To be

honest, I have so many miscellaneous emails I have to address, that this will take me most of the day to tackle.

11-4-05 Today has been so crazy. I didn't work yesterday so everything has been piling up. I had a ton of emails to catch up on this morning. We had a conference call at 11:00, so I needed to update all of our calendars. Our 400-patient deadline is coming up so all of our monitors are scheduling their visits. It is really time consuming arranging everyone's schedules and then tracking them in 3 different places. The conference call wasn't too long today so that was nice. I was able to send out 3 meeting minutes today. I also received the screening logs today from the data management company. I processed them, in addition to, sending out reminders to those sites who did not send in their screening logs on time. I chatted with a couple of sites to schedule visits. I also processed and sent out 4 MVRS. It has been crazy today. I haven't had a chance to update the Angio. and IVUS trackers. I will need to do this sometime tomorrow, in addition to finishing the minutes for this week. It really has been busy, but it has also been fun.

11-7-05 Well, I have spent almost the entire day doing a ton of paperwork. I had a huge stack of MVRs and associated documents that needed to be stamped. I also decided to process, stamp, put into TrialWorks, and give almost 15 MVRs to Tim. Maybe that will give you some idea of the volume of papers that cross my desk. I spent most of the morning and most of the afternoon doing this. I have not pulled emails out of the COSEAR database in a while, so I did that for almost an hour. I didn't come close to finishing. Lots of scheduling today, I received 4

monitors/COSEAR representative schedules, so I updated our calendars and associated trackers. I was also able to sit down with Tim today and finalize my questionnaire I will be sending out to the company. I have an appointment on Wednesday with training to discuss the final draft and send it out to all pertinent employees. I was surprised that I didn't have 50 emails waiting for me from the weekend. I think there were only around 10. For the most part, this was not too busy of a day. I was really able to make a dent in my paperwork without too much distraction. Hopefully I will have more of this tomorrow.

11-8-05 Today has been pretty busy day. I had one last stack of MVR packets that I needed to get into TrialWorks so that I could pass them onto Tim before our teleconference. I am having a hard time working around the glitches in the system especially pertaining to the lab field, but Tim and I talked through a few things today. I chatted with Tim about a few items in central files that will need to be re-filed when the study slows down. Either I initially filed them incorrectly because I didn't know to do different or I understood the initial directions incorrectly. Either way I will need to go back at some point and rearrange some of the papers filed in central files. We had our conference call at 11:00 today. There was a lot discussed pertaining to CRFs. Since I don't work closely with the CRFs, I usually find these discussions a little over my head. I think if I sat down and really paged through the CRFs I would be fine, but time doesn't really permit that right now. I spent most of the afternoon doing meeting minutes for 3 teleconference calls. Minutes seem like the easiest thing to forget about or push

back, but they are important and need to be done. I finished the day working with disseminating screening logs. I am not sure I will get to sending out email reminders to those sites who did not send in their faxes or not, but I will give it a shot.

11-9-05 My project manager was gone today. He was sick with the flu. Today was sort of a laid back day. I was able to spend a lot of my time updating some of my patient trackers. It had been a while since I had done that so I had 50 or so patients to plug into each tracker. I actually didn't get a chance to finish, but I at least caught myself up some. Wednesdays I send an updated visit list to our data management company. I sent off three MVRs, and also inputted a small stack of regulatory documents into TrialWorks. Scheduling is a daily activity for me, so as usual I did some scheduling. I was able to sit down with training today and go over my questionnaire. This will be interesting if it works. She is going to go through it and then pass it my way for final approval.

11-11-05 Coming back from my day off I found myself with a whole lot of work waiting for me to do. Bill sat our team down today for a little chat about how the project was going, and also to update us on some new news. One of our monitors will no longer be working on our project for reasons I cannot mention. This will make scheduling very tight for our project. My project manager and I also had a conference call today. The usual…site updates, monitoring updates, CRF questions, etc. Since we are incorporating so many new monitors into our trial we are needing to have additional available training materials. Bill actually had a

binder of his own so I added to his and made a study packet. Hopefully this will be useful in the future. Lots of scheduling changes and arrangements needed to be done today. I also did a few things in Tim's tracker and in TrialWorks. It has been a pretty busy day. Training sent back my questionnaire for me to give them the final approval. It looked good so we sent it out. I will be throwing a few prayers up to make sure I get some good feedback.

11-14-05 Central files, central files, central files. This is what I did today. I think I spent about 6 hours in there cleaning up some of the files along with filing other pieces of information. I spent the early part of my morning updating all the patient trackers. My project manager has been teaching me a few tricks on Microsoft Excel, so this process is becoming more and more streamlined. We are up against a whole lot of scheduling conflicts for our 400-patient deadline. Basically it feels like our people are going to be stretched very thin in order to accomplish this deadline. I know it will work out, but it will take a whole lot of "extra" teamwork from the company. My project manager and I have been going back and forth about the schedule most of the afternoon. I think we were able to do some great brain storming for the deadline.

11-15-05 It has been a very steady day today. I usually receive my screening log information on Tuesdays. This means that I email all the sites that did not turn in their logs and ask them to turn in their logs. I also email the monitors whose sites did not turn in logs so they can follow-up with their respective sites. My project manager sent me a long list of changes to the schedule today; so I spent

a good deal of time going back into TrialWorks and Tim's tracker to adjust to these changes. I also had to update TrialWorks and Tim's trackers regarding those visits that had been completed. In reference to tracking the status (scheduled, pending report, completed, cancelled) monitoring visits, it is really important to keep on top of things because the "status" of each visit changes on a regular basis until the visit is completed. My project manager and I had a long teleconference today. Around deadline time we always get obnoxious requests from the data management company and/or our Sponsor. We have already scheduled all of our visits and now COSEAR wants us to change 2 or so of our visits to earlier in the week. They are telling us that the data management company is going to need the CRF information earlier, because the DSMB meeting will be held earlier than originally thought. I spent a good portion of the afternoon talking to sites, monitors, project manager, Sponsors, etc. trying to coordinate these changes in the schedule. All in all it was a good day. My project manager and I had a good chat over lunch. It is always nice to work for a boss you really enjoy and respect.

11-17-05 My project manager is gone today so I am managing project requests. I was able to update all of the patient trackers. Some of the techniques that my project manager taught me are coming in so handy. I think I am able to do the patient trackers twice as quick now. I updated the calendar and 400-patient tracker with new email correspondences I received today. I sent out the calendar today so that I wouldn't forget for tomorrow's teleconference. I have actually spent

most of the day putting information into TrialWorks, in addition to, stamping all the documents. My huge pile went from needing to be stamped into needing to be put into TrialWorks into my "need to file" stack. There is nothing like rearranging papers into different stacks. A monitor of mine requested monitoring notes to be sent to her. I actually spent quite a bit of time tracking those down only to find out that we don't have any more. It was somewhat comedic. I chatted with a few sites today about SIVs to their sites. As usual, I had a plethora of emails to attend to.

11-18-05 Today I did my first "solo" teleconference call. Both Bill and my project manager were out on the road and not accessible to a telephone. I had a lot of fun. It was a little nerve wrecking at first, but it went fine. I should be used to these by now. I sit in on them twice a week. This morning I updated a few of the trackers before my teleconference. I also updated TrialWorks and Tim's tracker to reflect the most current status of all the visits. I spent most of the afternoon answering emails and doing minutes. I managed to write 3 meeting minutes reports for my project manager. It feels good to get those out of the way. I chatted a while with one of our monitors regarding tracking information. She sent me a few trackers to have me look over and see what I thought of them. I will be using this information for my thesis project. I had a CRF question by a monitor that I wasn't too sure how to answer so I sent the question to COSEAR to have them follow-up. All in all, lots of delegation went on today to people

who know how to answer questions and know more of what is going on than myself. I had a really fun day.

11-21-05 Today has been a pretty low-key day given it is a Monday. Yippee, it is a short week this week due to the Turkey Holiday. I spent a good portion of the morning going through my emails and following up with about 15 different matters. I made a ton of copies today of our training manuals. We have a gentleman who is helping us out with monitoring and he needed all the documents to read up on for our study. I fedexed everything overnight to him. My project manager and I chatted a while about the schedule. One of our sites, canceled their visit tomorrow; so I spent a good deal of time communicating with the site, our monitor, and the rest of our monitors to make sure we have a body at every meeting. One small change like that has a domino effect on so many other things. I was able to kind of relax and do a few of the things sitting on my desk for a good portion of the afternoon. All in all, it was a good day.

11-22-05 Today was a really busy day. I am only working 2 days this week, so I had a lot to catch up on. My project manager and I spent a lot of time trying to figure out how to juggle all of the schedules to accommodate our 400-patient deadline. Things are constantly changing and we are trying to be flexible. For some reason, there were quite a few questions by monitors that needed to be answered today. I sent a myriad of emails to the Sponsor Company requesting clarification on these questions. I contacted one site in order to schedule an SIV. The coordinator is out for a while so I was unsuccessful at this. My

project manager and I had a conference call today. It lasted a little longer than normal, but it was still informative. I sent off a few MVRs today as to not be late with our reports over the holiday. The day ended with my project manager and I chatting about the game plan for the Turkey Holiday along with specifics for the 400-patient deadline. This will be a challenging deadline, but very doable.

11-28-05 Today was a busy day of catching up over the weekend. I received a ton of emails requesting that I update the calendar with new visits and change old visits. Many of our monitors will be out the rest of this week retrieving CRFs for our 400-patient deadline, so I was busy getting them miscellaneous information they requested. There is a very definite process to how CRFs actually get to the data management company in order to reach a deadline. I chatted with a few sites regarding outstanding issues that seemed to be ongoing. I called 10 sites today to remind them to use the correct consent form and make sure that the two different arms of the study don't get confused with one another. One of our sites has made the mistake of consenting subjects with the wrong study consent form. This has caused a chain reaction of problems. We spent a good portion of the day remedying this issue.

11-29-05 Luis is gone today so I am left to "man" the office for our team. I had a teleconference call today. I was a little nervous today because I don't usually do the teleconference calls by myself; but since my project manager and Bill are out I was on my own. It went fine. I felt like I represented Company A well. It

was a fairly short conversation covering issues such as: our deadline, OUS sites, satellite sites, CRF questions, etc. I also participated in my first "deadline" conference call. This went great. I chatted with the Sponsor Company, in addition to, the data management company. We went over the 400-patient tracker for the deadline. I actually went line by line and told them what they should have in-house, what they will be receiving tomorrow, and what they will be receiving the next day. It was a great conversation. What was even better was that our numbers matched. I am going to go out on a limb, but this occurrence would probably be categorized as miraculous in nature. We ended the call by scheduling another call for the next day. I spent the rest of the day responding to a legion of emails from monitors who needed things faxed to their sites and/or needed me to call the company who randomizes our enrolled patients. Once in a while a patient's initials will be incorrectly inputted into the system and therefore corrections need to be made as soon as possible. All in all, it was a busy day.

11-30-05 Well, our deadline is quickly approaching us. We found out that the data management company wants us to try and get as many CRFs into them by 1:00 Eastern time tomorrow. This definitely created a frenzy. Technically we have until Friday, but they are requesting the information 2-days earlier, so changing our deadline at the last minute has caused a minor ruckus. My project manager and I called all of the monitors and asked them to fax in all pertinent CRFs to the data management company by 1:00. Needless to say, I think the data

management company's fax machine must have been burning. We ended up getting more into them than they thought they would have time to enter in the system. This definitely was a big score for us. I was able to sit down with Tim, Barbara, and LaChelle today and talk about my project. It was nice to finalize a few things. I will be sending out my second questionnaire in about 2 weeks. Busy, busy, busy. I participated in another "deadline" conference call. This one also went great. Oddly enough, it was kind of short. The Sponsor Company was not represented, so it was just the data management company and myself. This definitely made life much easier. The data management company updated me on what had been faxed to them and what they hoped to get fedexed to them. We rounded out the conversation by saying we will chat again tomorrow. I spent most of the rest of the day responding to emails and phone calls from the monitors. It was a really busy day!

12-2-05 Well, today is our data deadline where all applicable patient information was requested to be into the data management company. Oddly enough, the deadline day itself isn't too busy. It is usually the days leading up to the deadline that seem so busy. I caught up on a few trackers, and then updated the calendar for our conference call at 11:00. The conference call was a little longer than normal, but it was short enough that I was able to catch the tail end of the stress management in-service that was provided. I had a good bit of paperwork to catch up on; so I spent quite a bit of my afternoon doing this. I tried to schedule two sites for SIVs, but unfortunately I didn't have any luck

coordinating everyone's schedules. With the holidays creeping up on us, in addition to, the 400-patient deadline, I am finding it difficult to coordinate the monitor, sponsor representative, and site schedules. I will follow up with the sites on Monday to finalize dates. No MVRs sent out today. Next week will be a busy week with MVRs. I sat down with LaChelle and my project manager today to chat about my future with the company. It has been an awesome time here and I love the people, but the drive has been really tough. We will be discussing this topic further in the future.

12-5-05 Today has been a very steady day. I have not updated the patient trackers in a short while so I took most of the morning to update the trackers. I think I had almost 100 patients to enter in. Needless to say, it took a while. I was also able to contact all the sites who did not turn in their screening logs last week. There were a whole lot more than normal, so that took a while. I sat down with LaChelle today and chatted about my thesis schedule. My thesis schedule is creeping up faster than I thought. Over the weekend I accumulated a surfeit of emails in my box to respond back to. So today I responded back to them all. I called two sites to try and schedule SIVs. I updated the study calendar. My project manager and I chatted about the total number of SIVs that had been completed. Our Sponsor has allotted only so many SIVs to be conducted throughout the study; so we wanted to make sure that they weren't getting too close to going over. I think that covers it. I have quite a few meeting minutes I need to work on tomorrow; so I will feel accomplished after I am finished with

that. For the last part of my day, I spent a good hour or so pulling emails out of the COSEAR database.

12-6-05 I spend quite a bit of time updating the trackers today. I was hoping to get to some of my meeting minutes, but there were so many random interruptions that I wasn't able to finish them. However, I did have another conference call today. They officially announced our next deadline, which will be in January. It seems like our deadlines are one on top of the other. I think our monitors and their sites are getting a little tired and frustrated with all of these deadlines. I processed a couple of MVRs and sent them off today. It was a pretty steady day. I was told on the conference call to schedule another site for an SIV. I spent a good portion of the afternoon playing phone tag with the coordinator at that site in order to schedule the visit. However, we were finally able to chat and finalize a date. I have two other SIVs that I will need to finalize this week. It is tough having SIVs on top of deadlines, but that is how the Sponsor Company is running the show.

12-10-05 SNOW DAY OFF

12-9-05 I updated the calendar today. Oddly enough, there were a lot of changes to the schedule so that took quite a bit of time. We had our conference call today with both the Sponsor Company and the data management company. We did the usual OUS updates, site updates, monitoring updates, and scheduling. The teleconference call was only an hour long so that was really nice. I talked with one of the monitor's who is a new monitor on the study. She is really trying to

figure out the ropes, and as a result, I am running around copying everything I can find for her. She will be a great monitor for us, but in the meantime, it will be work trying to catch her up to speed. I fedexed her a large packet of information pertaining to the study. I think that is her 4th fedex from me. We had a standard operating procedure (SOP) training today on performing monitoring visits. The SOP trainings are actually very informative for me. I get to hear things that I don't normally get to hear because I am an in-house CRA, not a traveling CRA. I stayed late today because the Christmas party wasn't until 7:00. I had so many emails to answer and file. I rounded off the night by pulling emails out of the COSEAR database for a while.

12-12-05 Today has been really busy. I had a whole lot of emails waiting for me so I spent a good portion of the morning responding back to various emails such as: scheduling SIVs, coordinating schedules, updating schedules, scheduling visits, changing visits, and everything in between. Jonathan will be taking over some of my duties when I leave so I started training him today on some of the trackers. We were only able to get into that a little, but it was a good start. I was able to finish two of my meeting minutes today. Hopefully, I will be able to get to one more before the day is over. I was able to process and send off two MVRs today. Jonathan and I worked together a short while this afternoon. I was able to pass off to him a huge stack of TrialWorks information. Mondays are always crazy with a million loose ends to follow-up with. I have two potential SIVs that I am trying to finalize, so that has been hectic trying to get

everyone on the same page. I sat down with Tim, LaChelle, and Barbara and went over my thesis questionnaire today. Tim and I are going to need to sit down later this week to discuss the specifics, but hopefully I will be able to send out my second questionnaire sometime this week or early next week. I am looking forward to seeing what kind of responses I receive back. I will probably go door to door to make sure everyone fills out their questionnaire.

12-14-05 I had the day off yesterday so there were many emails to catch up with. I am in the midst of training Jonathan so my time seems a little stretched. I was able to finish all of my meeting minutes that I have been back-logged with. It feels so good to get those out of the way. Bill asked me to update the MVR tracker with all my fedex numbers, so I spent a good portion of the morning performing that task. I had quite a few emails from one of the monitors on the team who was requesting additional information for the study. She is a new monitor, so she feels the need to make sure that she knows everything that she can before she actually goes to a site. I processed one MVR today and sent it off to the data management company. Tim and I sat down in the afternoon to go over my second questionnaire. Hopefully, I will be able to send it out on Friday to everyone. We will see. It is more difficult than I thought thinking of questions for this questionnaire. Jonathan and I sat down and went over how to update the patient trackers, fedexing MVRs, the MVR tracker, and a few TrialWorks issues. I am currently trying to compile a binder of information for new monitors who join the study. This binder would be a quick reference tool for us

to give our monitors so they would have the opportunity to jump on board as soon as possible. We have had a few problems making sure that all of our new people are staying in the loop; so hopefully this binder will help.

12-15-05 Busy, busy, busy. Luis is back today so I spent a lot of time catching up with him and looking into miscellaneous matters with a couple of sites, in addition to, a major question that the sponsor asked us. Today I also had a huge stack to put into TrialWorks. I started off the day by sitting down with Tim and Bill. I am working on my second questionnaire, so we spent quite a bit of time brainstorming questions. I still have a lot of work to do on the questionnaire, but it is slowly taking shape. Jonathan and I spent quite a bit of time going over IVUS updating, Angio. updating, screening logs, answering questions from sites after sending screening log reminders, entering information into TrialWorks, etc. I did quite a bit of changing around of the calendar. As usual, about 10 miscellaneous things came up that required follow-up: ensuring that pre-post visit checklists and device dispositions were received, sponsors were notified of visits, etc. I was able to schedule a SIV today for the early part of January. This one has been in the making for a while; so it was nice to finally get it scheduled. What is even better is that the designated sponsor representative was actually available to go the day that I scheduled it. It doesn't always work like that. All in all, it was a very busy day, but a good one.

12-16-05 I absolutely adore Fridays. This is the last day of a full week that I have with Jonathan. We will have one day next week, and a couple of days the week after

that and then that will be it. Time is winding down. He and I went over a few screening log questions. We were also able to go over a few "random" scenarios that periodically come up in my job position. This seems to be a very large part of my internship duties, dealing with miscellaneous pieces of information, and in turn, knowing exactly who to direct the question to in order to resolve the question at hand. It is all about understanding what people are asking and making sure you connect them with the right person to answer their question. Today was Loraine's retirement party in the afternoon. I will really miss her. I can tell she has made quite a few friends in her 7 years here at Company A. She will be greatly missed. I ended the day by sending out a couple MVRs that I had processed. We have quite a few MVRs to send out next week; so I wanted to make sure that I got as many out this week as possible. All in all, it was a busy day but also a good one.

12-19-05 Well, this Monday felt like a typical Monday. I had a whole lot of emails to attend to when I arrived back in the office after a great weekend. This morning I was able to send out a large bolus of meeting minutes, in addition to, a large bolus of electronic MVRs to our Sponsor Company. It really felt good getting to make a few very large check marks off of my list. I spent a good portion of the morning entering into TrialWorks. I also sat down with Tim, Barbara, and LaChelle to go over my second questionnaire. I think the second questionnaire will be really good, and on top of that I think it will actually give Company A a good "look" into what the employees of Company A like and dislike regarding

document tracking tools. I had quite a few visits to add to the calendar today. We have a teleconference tomorrow; so I wanted to make sure the calendar was updated before I sent it out to all of the "minutes" recipients. Jonathan was in-house today so we went over a couple of things to make sure he was caught up to speed on a few items that he will be taking over when I am gone. The last part of my day was dedicated to making sure that an "almost late" report made it out into the mail. I am happy to say we were successful.

12-20-05 I spent a good portion of the morning putting information in TrialWorks. I have a very large stack that continues to get larger and larger, so I thought it would be a good idea to make a dent in the stack. My project manager and I had a teleconference call at 11:00. It was a longer call than normal. A few personnel changes are going on at the Sponsor Company; so much discussion was had about that topic. We are also inching closer to another deadline; so everyone is slowly metamorphosing into a rare form of CRF deadline species. One of our monitors had quite a few questions about CRFs today. Unfortunately, it is always a challenge pinning the right person down at the Sponsor Company or the data management company that has the authority to make any "final" decisions on what exactly needs to be done. I was able to go out to lunch today with LaChelle. It was a really good time of discussing the field of clinical research along with my future clinical research. I realize that in this field it is so important to talk to all of the people who have gone before you in order to really get a good picture of what is going on. The clinical research

picture is so large that one person's career path could not exhaustively cover all the potential possibilities that are encompassed within this field. I ended the day updating the calendar and trackers with visits.

12-21-05 What can I say... I am trying to do as many things as I can before I leave for the Holidays. I started off today by doing my usual weekly screening log copies, emails to coordinators, emails to the monitors telling them the coordinators who did not turn in their screening logs, stamping, and filing. I also spent a huge part of the morning trying to make smaller the large stack on my desk to put into TrialWorks. I feel pretty accomplished for the amount of time that I spent on it. I also updated Tim's tracker with the most up-to-date information on fedex tracking, etc. My project manager was looking at it and wanted to make sure everything was caught up to date. I had a whole lot of random emails to reply back to today. Some of the issues included demographical updates such as: personnel demographics, new trainees, SOP training, new site coordinators, change of mailing addresses, etc. all came up through email. It is amazing the wide range of topics that can be covered in one day. I am also working on processing 3 MVRs in order to get them out today.

12-28-05 Boy 'o boy back from the Christmas holiday. I officially had 52 emails waiting for me at work. It was nice to get back in the move and groove of things. I wanted to make sure that I tied up as many loose ends as possible today. I have not done any "official" SOP training, so I read up on all the SOPs and sent them into training. About 25 emails had me going every which direction to resolve. I

also spent around 2 hours "pulling" emails out of the COSEAR database. I really need to keep up with that on a daily basis. I was also able to update the MVR tracker today. I wanted to make sure that this tracker was updated before I headed out. Having our reports in on time is a must! I worked with my project manager and Jonathan a little with the small things of the "transition." I was able to process and send out two MVRs today. I updated a few demographics, and ended the day by cleaning out some of the emails in my mailbox. I think that covers it!

12-30-05 I found out today that my internship practicum will be extended at Company A. I spent a good part of the day archiving in central files. I have such a large stack on my desk that I wanted to make sure that it was getting smaller instead of larger. It is amazing how time flies when you are filing... ha, ha. I spent quite a bit of time following up miscellaneous topics on the email. Today was kind of the low-key day in terms of work. Since I was hired on, I had a lot of "chats" with managers and human resource personnel today. I left a little early today because I wasn't feeling well. I think that covers it. Cheers!

1-3-06 Today I had too many emails waiting for me after a long weekend. Happy New Year... 2006. I spent most of the morning catching up and following up with all of my emails. I sat down with my managers and our team lead to discuss what study related responsibilities will be delegated to whom since we have now instituted a project lead on the COSEAR study. My project manager and I had a conference call at 11:00. It was nice to get caught up to speed after a week or so

away. Looks like we are right on target. After lunch, I started in on the screening logs. Because of the Holidays things seem to be a little disorganized at the data management company. I received two sets of screening logs this week. We will see. I spent the last part of the day filing a few thing into central files. Today was my first official paid day at Company A.

1-4-06 Today was my first day working from home. It went really well. It is amazing how much work one can get done with no interruptions. I emailed about 30 coordinators today to remind them to turn in their screening logs every week. I also received about 4 emails back saying that they had. Somewhere there is a discrepancy. I was able to update the contact sheet. I spent most of my time stamping a very large stack of papers in order to be archived into central files. I sent the data management company the visit numbers today. As usual a bunch of random things came up today such as: chatting with our randomization company to get confirmation pages for specific enrolled patients, chatting with the data management company regarding being sent re-order forms, chatting with monitors requesting site contact information, and delegating pre-post visit checklists to their respective monitors. I think that covers it.

1-5-06 Today was a day of running around with my head cut off. For some reason there were a lot of random questions from the monitors and even more questions to follow-up with on the email. I think I spent most of the day chasing these rabbits around. Quite a few of our monitors, my project manager, and myself spent a good bit of time trying to figure out what exactly the screening logs were asking

the sites to fill out. It is the most confusing form I have personally ever came across to. It almost feels like a waste of paper because of its lack of usefulness due to poor verbiage. Ah, the day and the life of a CRA... oddly enough I love it. The end of the day I spent cleaning up my office. This has been a much needed task, but I haven't had a half hour of time to dedicate to this. It looks beautiful. I finally have a place for everything. Lets see how long this lasts.

1-6-05 Can we say the word "central files?" I spent the whole morning in central files listening to my IPOD and filing regulatory documents. I was feeling "low-key" today, so I decided to spend half of my day filing the largest stack of papers that I had ever seen on my desk. One of the monitors had a few things that he wanted me to fax to his site, so I managed to do that in between filings. I went to our in-service today; it was about the outcomes from a questionnaire sent out to personnel regarding their opinion of the usefulness of past in-service presentations. It was interesting to hear what everyone had to say. I processed and sent out two MVRs today. I updated my calendar and corresponding trackers with new visits. I updated all of the trackers to make sure that their "status" was up to speed. I spent the last part of the day making myself a little bit more familiar with the protocol. Since I haven't had a grave need to know the specifics of the protocol, my time spent on performing this task has been minimal. However, I am seeing that I need to actually read the ENTIRE protocol...91 pages. All in all it was a good day.

1-9-06 Today was kind of a laid back day. I spent most of the day answering a ton of emails and following-up on issues before they became problems. One of our field monitor's found out that her laptop keyboard was broken. Well, this wouldn't be a problem if we didn't need to send her information for an SIV and 2 IMVs. I spent a good deal of time getting all of her documents together to be faxed. Luckily, Jonathan was in-house where he could fax everything. The remainder of the day was spent writing meeting minutes that ended up getting lost somewhere in Cyberspace. Needless to say, I wasn't too happy. I almost had a heart attack over this issue. I will try to get to them again sometime later this week.

1-10-06 Today was a really busy day at the office. I had quite a number of emails that I had to follow-up with in the morning. We also had a conference call today. During the teleconference I was assigned 3 more sites to go ahead and schedule SIVs with. After receiving this request, I spent a good portion of the afternoon trying to get the demographics for the sites I was requested to schedule. A few other in-house CRAs and myself spent a good deal of time in central files. We were asked to do some "re-arranging" of our files in central files in order to make room for new studies. Needless to say, I have a whole lot of paper cuts after that experience. The day also consisted of stamping a few documents, faxing about 7 articles throughout the day, finding training documents, and sitting down with Accounting for a short while to get my time-sheet set up. It was a busy day.

1-11-06 I think I started the day off running. I wanted to make sure that I scheduled the three SIVs today. At least the day started off with good intensions. My first site

on the list I was able to confirm a date right away. The second site I was not able to schedule because the coordinator was not going to be back for another day or so. The third site caused me much confusion. It was kind of a tricky site because it is an off-shoot of a pre-existing site, so the Sponsor Company and I went back and forth trying to figure out if they actually needed training and if so what kind of training specifically. After much discussion, they will be taking care of all training at this site. I spent a good deal of time tallying up SIV totals with my project manager today. I also updated all of my calendars and spreadsheets with the most recent visits I received. I emailed the data management company the visit numbers. Jonathan and I went back and forth on a few issues regarding TrialWorks information, faxing documents to other monitors, IVUS machines, etc. It has been a crazy day. I am hoping to finish one of my meeting minutes before I call it a day.

1-12-05 Today I spent a large part of the morning sorting out all of the screening logs. Quite a few sites did not turn in their screening logs. I emailed all of the coordinators, in addition to, all of the monitors to inform them who did and did not turn in their screening logs as of 1-10-06. Like usual, I received a plethora of emails back saying why they did or did not send in their screening logs. I also spent a good portion of the day settling issues that randomly had come up with regards to information kept in central files. I was able to put quite a few MVRs into TrialWorks today. I also was able to update the "status" of all the visits for this week. I finalized one of the SIVs I was asked to schedule and found a

monitor to conduct this visit. All in all it was a very busy day, but extremely productive.

1-24-06: Today I had a very full day of human resource training. There were two new employees who participated in the training with me. It was a full day of going over a ton of information that I am already pretty familiar with; however, it was a good reminder for me. I was excited to finally get this day out of my way. I have a lot of work accumulating on my desk, so it will be nice to be able to get to some of that.

1-25-06: I worked from home today. I felt like I had a ton of scheduling to update on all the trackers and the calendar. I also had a couple very large stacks of screening logs that I went through. I love getting this task out of the way for the week, because it is a lot of busy work that can just pile on top of itself. It was a very consistent day with my paperwork, in addition to, following up with emails.

1-26-06: Today I had my second and last day of human resources training. Fortunately, it was only a half day. I learned how to complete an expense report correctly, in addition to, setting up different folders within the Company A database to find documents and forms very quickly and efficiently. This definitely will come in very handy. I was also able to sit in on training that my project manager headed-up regarding the anatomy and the physiology of the heart. I have heard of this training before, but for whatever reasons I have not ever been able to attend. All in all, it was a great tutorial. I wish I had taken it a little earlier, but nonetheless I will use the information presented within the tutorial.

1-27-06: Today I arrived into work a little late, so I hit the pavement running. I spent a good portion of the morning stamping some information for central files. I always like to make sure that all of our MVRs get sent out by the end of the week. I went on a rat race trying to figure out who sent a particular report. I never found an answer. We had an in-service today. It was from Pegasus Travel. Probably one of the more informative in-services I have attended. I emailed around 25 coordinators today regarding their absent screening logs. I spent the last part of the day on the computer (answering and forwarding a ton of emails), in addition to spending about 3 hours in central files. I can't believe it, the pile of my desk is almost gone. What an accomplishment. I better enjoy it while I can.

1-30-06: This has been the most productive day of my job to date. I think I inputted about 15 MVRs into TrialWorks before lunch. I stamped a pile of regulatory documents that were probably close to 6-7 inches in height. I also finished another stack of screening logs. Today was also an additional day of following up on random email issues that have been outstanding for a while. I feel very accomplished today. It is nice to actually accomplish what you put out to accomplish. I will finish the day updating a couple of my calendar/trackers, and probably following-up with about 20 or so emails before I close down for the night. Tomorrow is a teleconference day, so I will be sending out the calendar today.

1-31-06 I spent a good portion of the morning updating the MVR trackers. I usually like to let it go a bit before I catch everything up. That way I am not opening up the

tracker multiple times a day. We had our conference call today with COSEAR and the data management company. It went a bit long, but not too bad. We found out during the conference call that there was going to be a web cast later on that day. As a result, a few other monitors and I listened to the web cast later that afternoon. After the web cast, I processed and sent out two MVRs. I also spent a good portion of my day settling a few email questions that I received.

2-1-06- Today I worked from home. I spent a good portion of the morning working on meeting minutes that had accumulated over the course of the past week or so. After I finished the meeting minutes, I forwarded them onto Luis for a final look through. I spent the remainder of the day reading up on a few study related materials, answered random emails, forwarded site demographic information, talked with Jonathan and my project manager regarding monitoring visits and MVR reports. We had two MVRs that needed to go out yesterday; so I stayed in contact with my project manger to ensure that everything was sent out on time. All in all it was a pretty busy day.

2-2-06 Today has been a really busy day. I started off the day by sending off 4 faxes. Three of the faxes I sent to monitors and 1 of the faxes I sent to the Sponsor Company. I also spent a good deal of the morning updating the schedule. I received quite a few emails in the past few days, from monitors, updating me of their newly scheduled visits. I had a short meeting with my on-site mentor regarding a different position within the company. I also had a short meeting with the other in-house CRAs regarding central files rules/regulations, and a brief

introduction to a new addition to the in-house CRA team. The last part of the day was spent resending 3 out of the four faxes. The last part of my day I used for "pulling" emails out of the COSEAR database. The last part of my day was updating the "status" of the visits on the MVR tracker.

2-3-06 My committee approved my defense date on April 18th. I officially completed the required on-site time for the internship. I will be collecting, analyzing, and summarizing the data acquired during my internship practicum, for my internship research topic, "Project Management in View of Increasing Sponsor Demands." I will be working nights and weekends over the next few weeks to write my internship practicum report and prepare for my thesis presentation.

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