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Sponsor Accrual of Investigative Add-On Sites

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Meeting enrollment goals in clinical research trials has become increasingly more difficult due to heightened regulations and more stringent study protocols. This practicum report explores some of the reasons why sponsors in clinical research trials occasionally need to enlist the aid of investigative add-on sites, and highlights some of the unique opportunities that are presented to prospective add-on sites. Advanced Care Research Centers (ACRC) Trial's current involvement in a contraceptive study, as an investigative add-on site, provides this report with a case study, where observations and the analysis of enrollment data can appraise their success as an add-on site. Past trials are also assessed in order to supplement other themes raised in this discussion.

SPONSOR ACCRUAL OF INVESTIGATIVE ADD-ON SITES

Eli Arbov

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SPONSOR ACCRUAL OF INVESTIGATIVE ADD-ON SITES

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For the Degree of
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By
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SPONSOR ACCRUAL OF INVESTIGATIVE ADD-ON SITES

I. Introduction

This practicum project and report was completed during a 6-month internship at Advanced Care Research Centers (ACRC) Trials. ACRC Trials is a Site Management Organization (SMO) that manages and conducts Phase II-IV clinical trials for pharmaceuticals and medical devices. An SMO is different from a Contract Research Organization (CRO) in that they assume the obligations of the clinical investigator rather than the obligations of a pharmaceutical company, as Clinical Research Organizations (CRO) and industry sponsors do. ACRC Trials has five different offices in Texas, including two offices in Plano, and one office each in Austin, Carrollton and Allen. Due to the lack of available literature, this practicum project investigated and considered why study sponsors chose to enlist the help of additional investigative sites onto a study long after the study has already been initiated. This practicum project also discusses an initiative for the investigative add-on sites that is rarely examined. After being invited to partake in a study as an add-on site, these investigative sites find themselves in a demanding circumstance, having a shortened period of time to recruit, enroll and randomize patients into a study, while often experiencing the same pressures of the primary sites. However, there are also added benefits to being an add-on site, many which tend to be overshadowed by the stresses that are involved with pleasing the sponsor.

To put the discussion of this report into relevant terms, a contraceptive study that the Austin location was recently asked to join as an add-on site was be followed. With 2 months left for enrollment, the sponsor reached out to ACRC trials after almost 8 months of poor enrollment. Using the database software Clinical Conductor, the progress of recruitment, enrollment and randomization was tracked. Communication with the research director, research coordinator,

and the analysis of relevant sponsor communications like newsletters, are used to illustrate, in real settings, certain points of the practicum report. Clinical Conductor was also be used, along with ACRC Trial's in-house records, to discuss local studies that help to demonstrate specific discussions that are tabled in this report.

II. Study Aims and Methods

This practicum serves as a general discussion of why sponsors occasionally need to enlist the assistance of additional investigative sites during the enrollment period of a clinical trial. Additionally, this practicum report examines the incentives that an investigative site may gain when agreeing to partake in a study, along with the stresses that may ensue.

Aim 1: To explain, through examination of relevant literature, why the process of clinical trials has become so time-consuming and so costly during the last half century. Many sources agree that failures in enrollment have become one of the biggest obstacles towards progression and subsequent generalization of a study. This practicum examines why sponsors fail to meet their enrollment goals and consequently need to implement remedial actions, like extending their original deadlines or enlisting the aid of secondary investigative sites.

Aim 2: To consider, through the perspective of the investigative add-on site, the difficulties of keeping pace and fulfilling commitments during a shortened clinical trial period. This practicum reports on several potential benefits that an add-on site may exploit and benefits that are often not available to a primary investigative site. Since there is a lack of research on this particular aspect of investigative research, the discussion will provide prospective add-on sites the ability to view their opportunity in a different light. By considering the many advantages, companies may look beyond the inevitable stresses that are inherent to being an add-on site, to help them make a more educated decision that will prove to enhance their future with the sponsor and in their field.

Aim 3: To identify, through analysis of current and previous clinical research trials, how a secondary site is able to accomplish their goals and enjoy the rewards of an enduring relationship with a sponsor. By examining available data from ACRC Trial's database along with various

sponsor communications (correspondence, newsletters, protocol amendments, etc.) this practicum will document how problems in enrollment can be confronted, and how a sponsor and an investigative site can complement each other and cement a beneficial relationship in future trials.

III. Background, Significance and Discussion

The conduct and management of clinical research has changed dramatically in the last twenty years. As more is learned about the field of clinical research, regulations governing its conduct subsequently become more stringent, and pharmaceutical companies and their sponsors are seeing the developmental process become lengthier and more costly. As recent as 2013, it was estimated, on average, to take between 10 to 15 years for a new medicine to complete the journey from its initial discovery to the marketplace [14]. Each new drug must pass through key developmental phases and two regulatory stages (Investigational New Drug application and New Drug Application) [14]. As soon as the bench work for discovering a new compound is complete, pharmaceutical companies must file an Investigational New Drug (IND) application before any clinical testing on humans can be conducted. During this phase of the developmental process, companies will also apply for a patent, which grants them with 20-years proprietorship to their specific formulation of interest. This patent is of critical importance because it provides the company with market exclusivity, exclusivity that guarantees generous economic rewards for the pharmaceutical company [15]. During this 20-year patent term, the company holds a monopoly over the pharmaceutical formula, enabling them to "capitalize on the new drug before generic competitors are able to enter the market [1]." Starting with this patent filing, the pharmaceutical company races to get their products through the clinical pipeline and approved by the FDA, so products can enter the market well before generic competitors are able to flood it with generic equivalents, effectively eroding the developer's market share [1].

Bringing a new drug into the market is a very costly process, one that has become even pricier during the past 15 years. Research and development (R&D) costs have skyrocketed, causing pharmaceutical companies to invest more than ever before on their initial expenditures

[16]. On average, R&D costs for each new medicine, including ones that failed to obtain FDA approval, is around "$1.2 billion…with more recent studies estimating the costs to be even higher [14]." Many factors contribute to the high costs associated with introducing a new therapy to the public, but none are more prevalent than the costs that clinical trials demand. According to *The Investigator's Guide to Clinical Research*, "clinical trials are the single largest item component of the [sponsor's] budget, accounting for as much as half of all expenditures [16]." This is a logical figure considering the number of personnel that are actively involved during this stage: employees of the pharmaceutical company, Clinical Research Organization (CRO) and sponsor, regulatory institutions, site investigators and coordinators, and most importantly, the research subjects themselves. Aside from being the most costly phase of a drug's journey to market, the clinical trial phase also constitutes the greatest share of the developmental timeline, lasting anywhere between 6 to 7 years to complete [14]. While a 20-year patent term may appear at first to be sufficient, the lengthy clinical trial process with its stringent regulations make it so that companies "generally only have around only seven years of exclusive rights to its developed product after it reaches the market [16]"; it comes to no surprise that pharmaceutical companies are finding any possible means to lessen the time that a drug is actively on trial [1].

Due to the large impact that time has on the success of a study, and hence the profitability of a drug, pharmaceutical companies are constantly seeking the quickest and most efficient setting to conduct their clinical trials [2]. It is considerations like these that have the industry experiencing an impulsive shift in the delegation of clinical research responsibilities. In the year 2000 for example, Academic Medical Centers (AMCs) conducted only 50% of all industry-sponsored clinical trials, down from 80% in 1995 [2]. This trend has continued almost every

year since as industry-sponsored clinical trials are increasingly leaving AMCs and moving into private settings, such as Site Management Organizations (SMOs) and similar outlets which have the dedicated infrastructure to meet the demands of larger and more regulated clinical trials [2]. SMOs have become "increasingly visible over the last 10 years," because their particular capabilities are ones that sponsors routinely seek [16]. SMOs have become an attractive alternative to traditional AMCs because they are able to contract multiple investigative sites, with each one specializing in a different therapeutic area of medicine. This provides the sponsor with the capability to procure multiple trials through the use of one central organization. Contracting through one central entity ensures the "standardization of sites and gives for better and more consistent enrollment," two elements that are ideal when considering the success of any clinical trial [16].

Subject Enrollment

Meeting enrollment goals is conceivably the greatest obstacle in the advancement of a clinical trial. Many in the clinical research industry regularly identify that not meeting enrollment numbers in a timely way can cause a clinical trial to "lose momentum [13]." Industry sponsors denote poor patient enrollment as the "number one reason that clinical trials finish with delays or even fail," plaguing the sponsor with weighty setbacks that cost pharmaceutical companies money both in the immediate and long term [16]. Delays within a trial's defined timeline can create a shortened interval between the drug's market approval and patent expiration, which effectively reduces any potential earnings that a company will earn during their narrow window of exclusivity [3]. Unfortunately, patients also fall victim to the consequences of delayed clinical trials as they become deprived of access to innovative medicines and alternative treatments.

Failure to meet enrollment goals can be attributed to many different aspects of clinical research, some which are preventable while others are unavoidable. An example of the latter can be demonstrated using following scenario. There are so many medicines available on the market today that already target certain common ailments, such as diabetes, hypertension, constipation or uncomplicated influenza. With treatments like these flooding the market, past research has paved the road for pharmaceutical companies to investigate "more personalized medicines," that take into account certain contraindications and have them looking for a "specific patient population to use in the trials [4]." Clinical trials that were once investigating a treatment for diabetes are now investigating treatments for diabetes in patients who exhibit moderate to severe cardiovascular risk (specifically those who have had a stent implanted or have had previous bypass surgery *without* ever suffering from a myocardial infarction). Similar 'tailoring' of treatments are seen in the trials of nearly all other therapeutic areas. Trials like these are designed with "narrow eligibility criteria for participation, and purposely eliminate many patients who might have the disease" but do not meet the limitations of the underlying conditions [5]. Studies for these niche therapies have lengthier protocols and more defined eligibility criteria that are often too restrictive, leading to increased difficulty during the enrollment period [17]. This trend towards tailored therapies impacts the ability of investigative sites to identify and enroll patients in a defined timetable, impacting enrollment cycle time while also impeding the progression of the study [6]. It is important to recognize, however, that even though restrictive enrollment is often necessary for a trial, especially for a therapy designed to treat those with certain underlying conditions, modifications to the study design are often made by the sponsor in order to confront any lingering impediments.

Example of an Amended Study Design

Examining a current study that Advanced Care Research Centers (ACRC) Trials is presently conducting for the treatment of uncomplicated influenza, a demonstration of the types of alterations done to a study, as described above, can be seen. The study, which is entering its 5th year of phase-two trials, has experienced several protocol amendments, due in large part to the limiting nature of its exclusion criteria. Every year that the trial failed to meet its enrollment targets, new provisions to the protocol were made, specifically by broadening the exclusion criteria that previously created a bottleneck on patient enrollment [18]. For example, if a study protocol specifies that a potential subject must be screened within 48 hours of contracting the influenza virus, and this timeframe is deemed too limiting (because many investigative sites are encountering too many individuals who have an onset greater than 48 hours), then the next year's criteria might require a more lenient time frame for screening. With this most recent flu season just beginning, it will be a few months before the outcome of the pharmaceutical company's decision to ease restrictions on enrollment can be evaluated.

While the preceding discussion represents a situation where the indication itself may cause barriers in patient enrollment, the ensuing paragraph discusses the more preventable aspects involved with poor enrollment during clinical research trials.

Recruitment

Effective recruitment of potential research subjects leads to effective enrollment. Selection of investigators who are well trained in the area of recruitment and enrollment is a critical part of the success of a clinical study. With the clinical research industry expanding at such a rapid rate, sponsors now have a strategic ability to chose between tens of thousands of

investigative sites, enrolling an abundance of prospective subjects, and effectively shortening the amount of time spent between the pre-clinical phase of research and market approval by the FDA. Unfortunately for sponsors however, not all sites that they enlist to participate in the trial will enroll patients. According to Ken Getz, director of sponsored research at Tufts Center for the Study of Drug Development (CSDD), "patient recruitment and retention are among the greatest challenges that the clinical research enterprise faces today, and they are a major cause of drug development delays [7]." The same institution reports that while "nine out of ten clinical trials worldwide meet their patient enrollment goals, reaching those targets typically means that drug developers need to nearly double their original [trial] timelines," an unsettling statistic considering that the trial timeline is one that sponsors continually attempt to shorten [7]. While these statistics may be more promising today, it is paramount to recognize the problems that are present within the process of clinical research. How are the problems at hand identified, and how are they fixed?

> The International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (GCP guideline) provides a general standard on investigator selection:
> "The sponsor is responsible for selecting the investigator/institution…Each investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial…[the investigator/institution] should have adequate recourses to properly conduct the trial for which the investigator is selected…The investigator should be able to demonstrate a potential for recruiting the required number of suitable subjects within the agreed recruitment period…[9]"

Because these guidelines are still very generic, the ICH definitions merely supply a means to an end. These parameters still "give sponsors sufficient room to apply their subsets of criteria in the

selection process," criteria that focus highly on subjective observations, such as the past successes (in recruitment, enrollment, randomization, etc.) of an investigative site [10]. Although examining an investigator's previous record may be an effective tool in finding a favorable site, practice shows that this is not always the case because having success in one particular trial or indication may not mean succeeding in another. Clinical trials may struggle with subject enrollment because of the way that the business of clinical trials has evolved. Due to an erratic increase of new investigative sites into the field of clinical research during the last decade, a competitive nature has begun to appear in the industry, creating an environment that demonstrates the dual result of aiding while also hindering the sponsor. This competition between sites also impacts the general integrity of the clinical research field. Although sponsors are able to capitalize on the plethora of investigators by negotiating cheaper study contracts and enjoying the competitive interest towards involvement in their clinical trials, they are also being left with unfulfilled promises from the investigators. In an industry where "having patients in large numbers is a resource that is clearly needed by sponsors," it has become common practice for investigative sites to inflate their projections during the selection process [16]. To appear as competitive as other well-established sites, investigative sites who have historically average or below average records of recruitment and retention often tend to generously overestimate the number of subjects that they expect to enroll, in anticipation that they will cement a lucrative partnership with the sponsor in the current and future trials. It is not surprising that many sites fail to meet their target. Analyzing enrollment numbers in the United States (restricted to the original timetable of a study), a 2010 report funded by the National Institute of Heath (NIH) estimates that "among U.S. investigators participating in clinical trials, nearly 27% fail to enroll any subjects, with 75% failing to enroll the target number of subjects [8]." Unfortunately,

sponsors cannot gauge whether the trial will meet its enrollment deadline until long after the trial timeline and enrollment period has already begun. The sponsors are often left with the need to take corrective action. Options available to the sponsor are few; the sponsor can enlist secondary investigative sites into the trial to help increase enrollment, so the original study timeline can be kept, or the sponsor can prolong the trial timeline until the proper enrollment numbers are met using the original number of investigative sites. While both of these paths add additional expenses into the study, the more economical of the two involves enlisting the aid of investigative add-on sites. Pharmaceutical companies will incur costs associated with site initiation and study-start up, affecting them in the immediate term, but these costs pale in comparison to the potential earnings they could reap in the long term. Every day that a company gains by not extending their trial timeline is another day that the company is potentially able to enjoy market exclusivity, which will "bring a pharmaceutical company millions of dollars in additional revenues" in the long term [16]. While it is indisputable that cost is important to any industry, it is meeting timelines like this and the need to beat patent expirations that make clinical research precisely the industry where "time is more important than cost [16]."

Enlisting Add-On Sites

Enlisting additional investigative sites during the enrollment period of a clinical trial is a common occurrence in today's industry, as it is an effective approach that sponsors use to compensate for under-enrollment [11]. Because sponsors encounter the need to compensate for under-enrollment all too often, a shift in industry operating procedures has become apparent, as sponsors have begun to implement preemptive strategies in stages as early as their site selection process. Sponsors will often select 'primary sites,' investigative sites that have made it past the sponsor's stringent review, who will begin the study. 'Secondary sites' will also be selected

during the sponsor's initial site selection process; albeit their utility is only employed when enrollment is in jeopardy and the need arises to implement additional sites. Pharmaceutical Product Development, LLC (PPD), a prominent sponsor in the industry, is a leader when it comes to employing such preemptive practices. By closely monitoring a study's progress, PPD proactively identifies any enrollment concerns as they occur during the timeline of a study, and preemptively enlists additional investigative sites from which they have selected during their earlier review [12]. This strategy allows the sponsor to anticipate any potential snags in enrollment and act promptly, in order to meet their original enrollment timelines, effectively increasing the span of time that a company will benefit from market exclusivity and the absence of generic competitors.

While being selected as an add-on site puts added pressures on the investigative sites themselves, it also provides the add-on sites with many prospective advantages that should carefully be considered. Recognizing the opportunity to be an investigative add-on site as an advantage rather than as a handicap can successfully present a site with the opportunity to enhance their status in the industry. Ignoring the pressures that naturally occur when a site is enlisted late into the study timeline, the site can use the potential advantages as a drive to complete their study expectations, which will enhance the experience for both the sponsor and the site and may lead to an enduring relationship with the sponsor in future trials. Since a sponsor will usually seek an add-on site only when absolutely necessary, the site often times has the power to negotiate a more attractive contract [13]. Sponsors are usually aggressive during contract negotiations with investigative sites, attempting to lower study budgets and patient compensations, and because of the competitive nature made from the surplus of investigative sites, contracts are often finalized in favor of the sponsor's requests. However, during

negotiations with add-on sites, investigative site executives say that contracts are quicker to be met, and are more often in favor of the sites' demands [13]. While the investigative site in question is able to enjoy more favorable contract negotiations and more lenient compensations for their participation in the study, these monetary gains are only valuable for the immediate term. A greater return for the investigative site emerges when the site is successful in meeting their enrollment goal, albeit the shorter enrollment period, when they are able to use this opportunity to create a long-standing relationship with the sponsor.

ACRC Trials experienced being selected as an add-on site, and can serve as an example to demonstrate the benefits of this relationship. In early 2014, an industry leading sponsor that ACRC Trials had never before worked with, approached ACRC Trials regarding a study with an indication of chronic idiopathic constipation. ACRC Trials was enlisted as an investigative add-on site for this study and quickly met their enrollment goals, even in the reduced timeframe given. Enrollment opened for ACRC Trials at the end of June of 2013, and was closed by December 2nd, 2013. During this abridged period of enrollment, 36 patients were originally prescreened, with 19 of the 36 patients actually coming into the clinic for their screening visit. Even though 13 of these screened patients ultimately failed to randomize (3 screen failed and 10 run-in failed), ACRC Trials was still able to meet their assigned goal of six patients. Ever since their initial partnership with this sponsor, ACRC Trials has procured its place in four new studies, as ten primary sites, with additional studies already in the course of initiation. This local illustration demonstrates just how productive succeeding as an add-on site can be; sites are able to provide supportive services during a vulnerable time for the sponsor, which can give them a favorable assessment in the eyes of the sponsor and warrant consideration for future trial participation.

Investigative sites are often skeptical of accepting the role as an add-on site because they are afraid that they may not meet their enrollment goals, and may appear under-qualified to the sponsor and undependable in meeting their obligatory goals. After interviewing ACRC Trials executives, including the Research Director and Contracts Manager, along with multiple industry sponsor Clinical Research Associates (CRAs), these reservations about becoming an investigative add-on site appear to be well warranted. Although there are those who believe that a sponsor's expectations of a secondary site's obligations should be more lenient, this belief is misguided since both sites are essentially held to the same standards. Sponsors recognize that secondary sites have considerably less time on a study than a primary site does; less time to familiarize with the protocol, build up an effective recruiting campaign, train on all related equipment, etc. Still, it is improper to suppose that these add-on sites receive a theoretical 'justification' for underperforming during their abridged involvement in a clinical trial. After all, a signed contract is a commitment, and for this reason, site discretion is absolutely necessary. Sites should contemplate joining a study as an add-on site just as they would as a primary site, by performing chart reviews, referencing their patient database with the indication of interest, and determining if they will be able to meet their enrollment goals based on the prospective patient population that meet the study criteria. Sites should also consider whether they have the dedicated infrastructure necessary to conduct the specific study of interest. Even though secondary sites are expected to perform like their primary counterparts, the draws for a secondary site to succeed are marginally greater. Just by meeting the sponsor's expectations, a secondary site may demonstrate more utility and dependability than a primary site that had a longer period of enrollment, yet only managed to meet a similar outcome.

Another aspect that should be considered when given the opportunity to become an

investigative add-on site is the benefit of involvement in the trial. According to the Research Director at ACRC Trials, enlisting as an add-on site can be a worthwhile effort as it affords the site the opportunity to gain more experience, especially experience with new indications [18]. This practicum will discuss this opportunity in the ensuing section, which covers ACRC's progress as an add-on site for a new contraceptive study, their pilot study with this indication. Participating in a trial for a new indication gives the investigative site some added benefits because it provides the company with an opportunity to expand their competencies and give them broad range of therapeutic areas in which to work in. During the first stages of the site selection process of a new study, sponsors typically send out feasibility surveys to potential investigative sites that ask about any previous trials that sites have conducted under the same indication. Sites who can show that they have prior experience with a certain indication may appear as more resourceful, to the sponsor, since the site may be more familiar with aspects of the study, and contribute with less uncertainty to the demands of the trial.

The enrollment target that a sponsor requests from a site is also a decisive factor, when an investigative site considers the value of joining a study as an add-on site. The Research Director mentioned that when ACRC Trials is confronted with an opportunity to enlist as an add-on site, the company takes every element into consideration: the amount of time left in the enrollment period, the number of patients requested by the sponsor, the contract and budge terms, available in-house resources, current active or enrolling studies, etc. [18]. Although ACRC Trials has a favorable stance on investigative add-on sites, this stance will only materialize into action if such an opportunity acts in the best interest of the company. For instance, if the company is going to invest its time and resources into a study, then the goal at hand should mirror a comparable amount of fiscal return. No matter how short of an involvement a site has in a study, their

involvement requires commitment from a dedicated infrastructure; a Recruitment Specialist to create campaigns and pre-screen potential subjects, a Contracts Manager to negotiate terms with the sponsor and compensations with other parties, a Regulatory Specialist to submit to the Institutional Review Board (IRB) and manage regulatory documentation throughout the study, Investigators who assess patients and bear the full responsibility of the clinical trial, and Clinical Coordinators who conduct study-specific elements and complete all necessary study-related documentation. If a sponsor were enlisting a site only to randomize two subjects, then a company's time and efforts would be better suited towards another trial in which they have a greater obligation and thus a greater return on investment [18].

ACRC Trials: A Case Study

During the writing of this practicum project, ACRC Trials concurrently became enlisted as an investigative add-on site in a trial for a revolutionary birth-control medication. These coinciding events allowed this practicum to follow the experiences of an investigative add-on site in real time, thus allowing for a more perspective discussion. The practicum project proactively followed the progress of the study, examining the study timeline, the recruiting/enrollment/screening numbers, and the overall study success compared to other regional sites. The practicum analyzed the resources that ACRC Trials allocated towards this trial, and its success relative to other studies in which ACRC Trials is a primary site. Because ACRC Trials was initiated into this study with only two months remaining in the planned enrollment period, in contrast to the primary sites that were initiated with eight months remaining, sponsor correspondence and sponsor newsletters discussing the overall progress of enrollment were used to evaluate the efficiency of ACRC Trials relative to other national sites. ACRC Trials had their site initiation visit on June 17th, 2015, and enrollment official opened for the study the following day. Originally, the enrollment period was planned to last only two months; however, with other sites falling further behind on enrollment, the enrollment period was extended for an additional three months.

Recruitment efforts for this study were not as concentrated on the part of ACRC Trials, since the sponsor had initiated their own central recruitment campaign for the study. For their main recruitment campaign, commercials for this trial were broadcast on a major social media platform, where interested subjects could call and be directed to the investigative site closest to their location. Because of this central recruitment campaign, ACRC Trials was able to better allocate their resources, since not as much time was spent on campaign planning and regulatory

approvals. This central campaign proved to be extremely effective, as it accounted for nearly 35% of all incoming patient referrals.

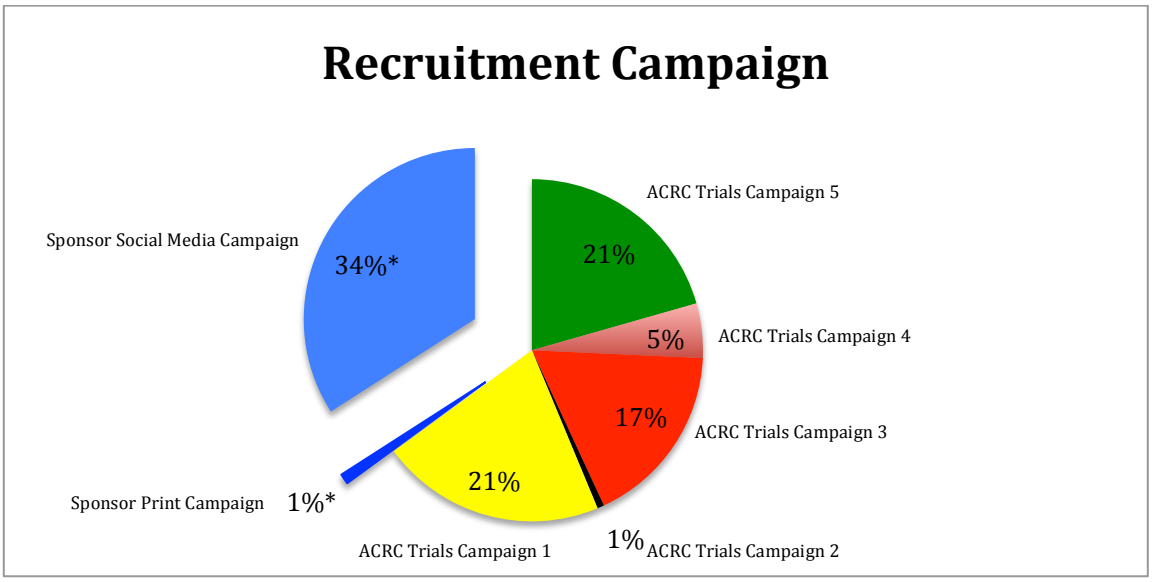

Fig 1.1- Recruitment Campaign Efforts

For the contraceptive study, a total of 311 patients initially expressed interest in the trial after learning about the study from one of the seven recruitment campaigns. Out of these 311 potential subjects, 109 (35%) of them were recruited from the sponsor's two central campaigns, as can be seen from the two detached sections of the pie chart in figure 1.1 (shown in blue).

Due to the proprietary nature of the enrollment results, a complete list of all national sites and their final enrollment efforts were inaccessible. Fortunately, for this discussion, the lead CRA for ACRC Trials was able to provide enrollment data for 12 other regional sites that were all under the observation of the same CRA. Out of the 12 other regional sites, 3 were primary sites that were on the trial since the beginning of the enrollment period, and nine were secondary sites that entered enrollment at the same time as ACRC Trials. This mixture of data from primary and secondary sites allowed this practicum to evaluate ACRC Trial's successes relative to both cohorts.

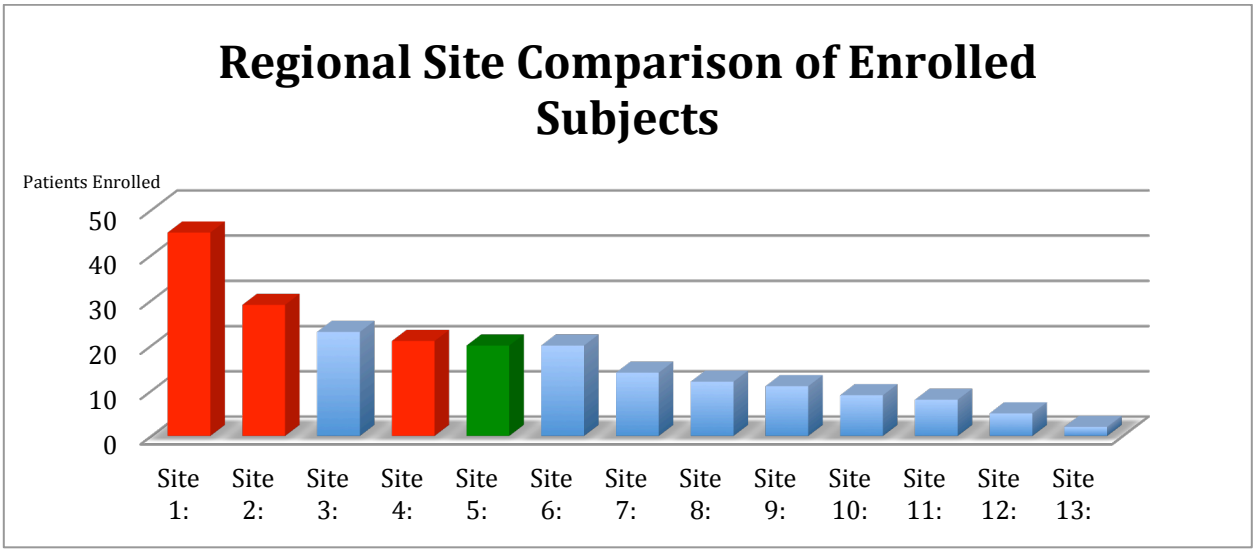

Fig 1.2- Regional Site Comparison of Enrolled Subjects

Figure 1.2 provides an overview of the number of subjects enrolled at each site. Each red bar (Sites 1, 2 and 4) represents an investigative site that was on the study as a primary site, whereas each blue bar represents an investigative add-on site. The green bar (Site 5) represents ACRC Trials. This graph shows how ACRC Trials performed in relation to both primary and other secondary sites. It can be seen that ACRC Trials performed significantly better than most other secondary sites by enrolling 20 subjects. ACRC Trials also performed considerably well in comparison to one of the primary sites, which enrolled only one more subject (21) than did ACRC Trials during their extended time on the trial.

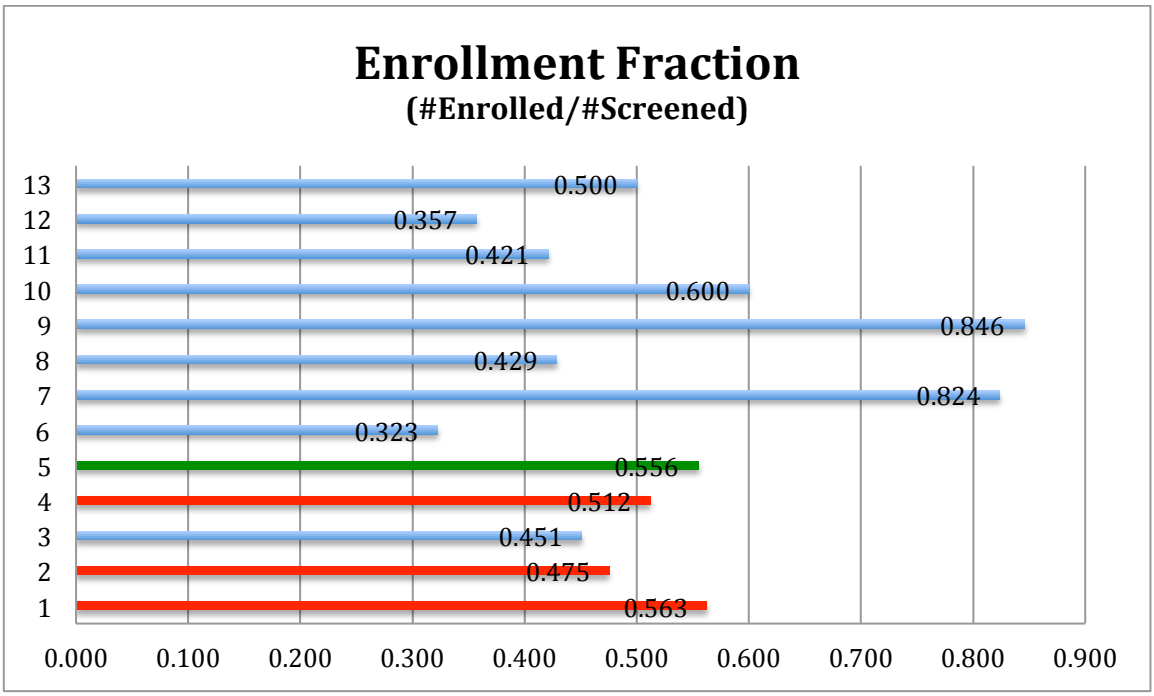

Fig 1.3- Enrollment Fraction (#Enrolled/ #Screened)

Figure 1.3 shows the enrollment fraction for each of the 13 regional sites. The enrollment fraction is the number of patients enrolled divided by the number of patients that were screened at the site. Enrollment fractions are important to the sponsor, because it provides information about the efficiency of the screening process and reliability in retention. A higher enrollment fraction is more favorable because it shows that a higher percentage of subjects that were screened were eventually enrolled and randomized into the study. This means that resources are more efficiently used, since less time and effort are spent towards subjects who will inevitably be considered ineligible for the study. Although ACRC Trials (green bar) attained an enrollment fraction of 0.556, which is less than other secondary sites, ACRC Trials remains the most efficient secondary site, as analysis will later show. Overall, ACRC Trial's enrollment fraction is higher or at level compared to the primary sites.

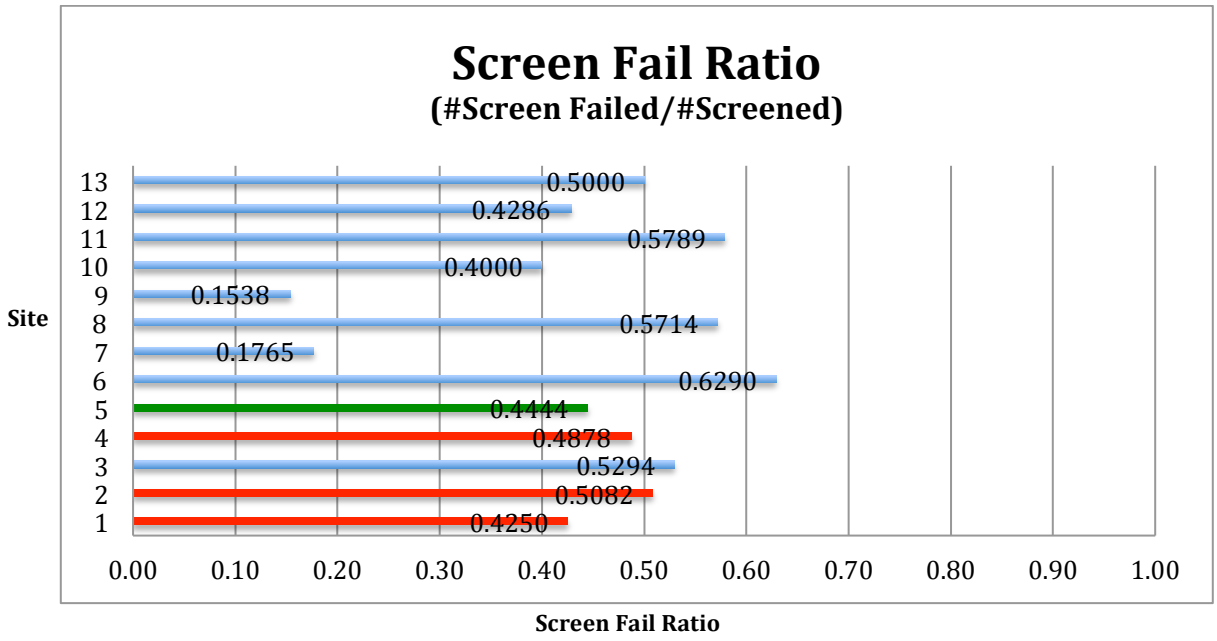

Fig 1.4- Screen Fail Ratio (#Screen Failed/ #Screened)

Figure 1.4 shows the screen fail ratio of each of the 13 regional investigative sites. The screen fail ratio is the number of patients that screen fail divided by the total number of patients screened. Screen failures are very important for an investigative site to consider because in many studies, a sponsor will permit an investigative site a predetermined proportion of screen failures, after which they will no longer be compensated for. It is imperative that the screen failure ratio be kept to a minimum because if too many patients screen fail, the company will ultimately incur costs due to uncompensated visits and investigator oversight. The screen fail ratio is also important, because it is an indication of the site's due-diligence in recruitment and pre-screening processes. Having a firm understanding of the study criteria will help a site select the most eligible and suitable subjects, and will help keep the screen failure rate to a minimum. ACRC Trials ended its enrollment period with a screen failure ratio of 0.4444, which is more encouraging than a majority of the other regional sites. Although other sites, e.g., Site #9, have a much lower screen fail ratio (0.1538), the number of patients that they initially screened is significantly less (by approximately 2.7 fold) than ACRC Trials, which greatly weakens the

comparability of the two site's results. When comparing ACRC Trial's screen fail ratio to those sites that screened a number equal to or greater than ACRC Trials, it can be seen that ACRC Trial's screen fail ratio is on par and in most cases considerably better than those comparable sites.

CONTRACEPTIVE STUDY						
	Total Screened	Total Enrolled	Total Early Terminated	Percent ET of Total	Total Screen Failures (SF)	SF Ratio
Site 1:	80	45	8	17.78%	34	0.4250
Site 2:	61	29	4	13.79%	31	0.5082
Site 3:	51	23	1	4.35%	27	0.5294
Site 4:	41	21	3	14.29%	20	0.4878
Site 5:	36	20	1	5.00%	16	0.4444
Site 6:	62	20	2	10.00%	39	0.6290
Site 7:	17	14	0	0.00%	3	0.1765
Site 8:	28	12	6	50.00%	16	0.5714
Site 9:	13	11	1	9.09%	2	0.1538
Site 10:	15	9	1	11.11%	6	0.4000
Site 11:	19	8	0	0.00%	11	0.5789
Site 12:	14	5	1	20.00%	6	0.4286
Site 13:	4	2	0	0.00%	2	0.5000
Average:						
All Sites (13)		16.8461535		11.95%		0.4487
Secondary Sites (10)		12.4		10.95%		0.4412
Primary Sites (3)		31.6666667		15.29%		0.4737

Table 1.1- Regional Site Data for the Contraceptive Study

Table 1.1 shows all data obtained for the 13 regional investigative sites on the contraceptive study. Sites in red (Site1, 2 and 4) are primary sites that were on the study since the beginning of the enrollment timeline, while all of the other sites are secondary sites. Site #5 represents ACRC Trials. Towards the bottom of the table, shaded in grey, are averages that have been calculated for various enrollment categories. The number of enrolled subjects has been averaged for both the primary site and secondary site subgroup, as well as for all of the sites combined. As can be seen, ACRC Trials enrolled 20 subjects, which is greater than the average of enrolled subjects among the secondary sites (12.4 subjects), and greater than the combined average of enrolled subjects among all 13 regional sites (16.84 subjects). Although the average of enrolled subjects for the primary site cohort was 31.66 subjects, evaluating the figures allows for a more meaningful number. Site #1 enrolled 45 subjects, which is roughly 33% more than the second highest enrolling site (also a primary site), an outlier that skewed the average of subjects

enrolled. If Site #1 were omitted from the calculation, Sites 2 and 4 would average 25 enrolled subjects, a number that is more comparable to ACRC Trials. Taking this extreme deviation into consideration, it is clear that ACRC Trials fared consistently with the other two primary sites, considering the 4-month advantage they had over ACRC Trials.

Looking at the values from the most competitive and highest enrolling secondary site, site #3, a comparison of between ACRC Trials can be made. Although site #3 enrolled three more subjects than ACRC Trials did, the number of patients they initially screened is much greater (51 subjects v. ACRC's 36). Evaluating the enrollment fractions for the two sites, it is can be seen that ACRC Trials had a significantly greater enrollment ratio, enrolling 55.6% of screened patients compared to Site #3's 45.1%. Analyzing the screen failure ratio between the two sites also gives ACRC Trials a competitive edge; ACRC Trials had a 0.444 screen fail ratio, compared to Site #3's .5294 screen fail ratio. Considering these parameters, it can be determined that although Site #3 enrolled more subjects into the study, their resources were not used as efficiently as ACRC Trial's resources, since a greater percentage of subjects who screened with Site #3 were not eligible for the study and ultimately screen failed (depending on the sponsor and the time of screen fail, a screen fail can mean the following: dropped, loss to follow-up or failed during run-in). By analyzing the enrollment data, a sponsor may deduce that ACRC Trials is a more reliable and more resourceful secondary site.

IV. Limitations

Limitations on Study Data

This practicum was faced with certain limitations that made it difficult to directly assess some of the central themes discussed in the report. A limitation that was mentioned previously was the absence in the literature about sponsor accrual of investigative add-on sites. Although the current literature discusses poor patient enrollment, it does so in regard to its ability to jeopardize the clinical trial timeline and incur the pharmaceutical industry additional unnecessary costs. This practicum's aims were to investigate one of the solutions to this problem, particularly the utility of an investigative add-on site, both to the sponsor and to the site itself. Because of the scarcity of published media on this topic, interviews with industry workers, including but not limited to CRAs, industry sponsors and SMO executives were used to give credibility to various points raised in this discussion.

Another limitation of this practicum report came with the proprietary nature of the enrollment figures themselves, which would have normally given an illustrious comparison of a secondary site's successes (ACRC Trials) relevant to those of a primary site. By not having an exhaustive list of all of the national sites and their respective enrollment figures, the generalizability of ACRC Trial's successes as an add-on site may not be as great. Fortunately, ACRC Trials was given pertinent data points for 12 other regional investigative sites, which all share the same lead CRA, and this data was enough to form an adequate analysis on their performance when compared to other primary and secondary sites.

This practicum report was intended to analyze the resources that ACRC Trials allocated towards the contraceptive trial and compare them to other trials where ACRC Trials was a primary site; however, because the sponsor initiated their own central campaign, and one that

proved to be so significant, recruitment efforts were not as complete, and thus, comparison to a another trial would not have proved to be generalizable.

V. Conclusion

Investigative add-on sites have become a more involved and more efficient safeguard in today's clinical research industry. As regulations in clinical research trials persistently become more stringent, pharmaceutical companies will continue to be faced with snags in their enrollment timelines. This inevitably leaves the sponsor with the need to take corrective actions, such as enlisting the aid of investigative add-on sites. As previously outlined, these secondary sites are given an opportunity to help a vulnerable sponsor meet their lagging timelines, and in return, are able to make an impression on the sponsor, opening the door for future involvements.

ACRC Trials has demonstrated how further opportunities can arise when a secondary site successfully meets their study goals. In 2014, when ACRC Trials was enlisted as an add-on site and quickly met the sponsor's expectations, they were soon invited to four new studies as a primary investigative site, and cemented a continuing relationship with the sponsor. Presently, ACRC Trials is involved in a contraceptive study as a secondary site and has performed very well compared to many of their regional counterparts. Although it is too early to see whether ACRC Trial's involvement in this study will materialize into a lucrative partnership with this sponsor, the commendation that ACRC Trial's has already received from the sponsor remains encouraging sign.

While there are obvious draws to why an investigative site should consider joining a study as an add-on site, this report is only meant to enlighten prospective sites. Of course, the ultimate discretion lies with the site itself.

Description of Internship and Site Activities

Internship Site

Advanced Care Research Centers (ACRC) Trials is a Site Management Organization (SMO) that conducts phase II-IV clinical research trials of pharmaceuticals and medical devices in a variety of therapeutic areas. ACRC Trials has been managing sites in the Plano area since 2006, and has five branches across four major Texas cities. Partnering with many physicians who specialize in differing fields of medicine, ACRC Trials is able to conduct clinical trials across a vast array of different therapeutic areas, giving them a highly competitive edge over other SMOs.

ACRC Trials utilizes a dedicated infrastructure that enables them to efficiently and seamlessly manage and conduct clinical research trials. ACRC Trials employs a Research Director, Regulatory Specialist, Recruitment Specialist, Contracts Manager, Principal Investigator (PI) or Sub-Investigator (Sub-I), and Clinical Coordinators, with each individual contributing immensely to the success of each trial.

As an SMO, ACRC Trials assumes the obligations of the Principal Investigator, who under law, bears full responsibility for the conduct of the clinical research trial. ACRC Trials conducts all contract negotiations, completes and submits all necessary regulatory documentation, performs all visit elements (excluding PI or Sub-I assessments), dispenses and collects investigational product, processes and ships laboratory specimens, corresponds regularly with the sponsor and CRO, interacts with and accommodates on-site monitors, and recruits and screens potential study subjects. It is because of this extensive foundation, and their verifying track record, that ACRC Trials has the ability to procure multiple trials across a broad range of therapeutic fields.

Journal Summary

Throughout my internship I was able to work closely with each part of ACRC's management team, and gained valuable insight into the many important aspects of the clinical research field. I began my internship by sorting through and filing regulatory documents into study-specific regulatory binders, a responsibility that I believe was crucial to my understanding of the documentation that is required to initiate and maintain a study. Since each regulatory binder contains copies of all relevant documentation pertaining to a specific study, my time sorting through these documents allowed me to familiarize myself with many of the essential components in a trial, such as the delegation of authority log, FDA form 1572, Financial Disclosure Forms, Confidentiality Agreements, CVs, sponsor newsletters, monitor correspondence, etc. These are all components that I would later find myself encountering as I became more involved in studies.

I also worked closely with our recruitment specialist, where I learned to navigate our database software, Clinical Conductor, and familiarized myself with the process of patient recruitment. Recruiting patients showed to be fundamental in helping my understanding of each study's protocol, because in order to properly inform prospective patients about our current studies and properly pre-screen them, I would need to be familiar with each study's specific criteria. Performing these duties gave me the knowledge that I would later need in the clinical setting, as I began to see patients and perform visit-specific elements.

I soon began to be included in the delegation logs for certain studies, which allowed me to perform coordinator duties and interact with patients directly. Initially, I would perform visit elements with another coordinator present, but as my experience reinforced my capabilities, I began to see patients without supervision. During patient visits, I would assess the patient's

compliance with their electronic and dosing diaries, collect and dispense the IP, perform vitals, EKGs, process labs, and coordinate the physical exam and medical assessments with the Principal Investigators. I would complete all sections of the source document and then transfer the records onto the electronic data capturing system (EDC), and answer any queries that might result.

Throughout my internship, I kept a journal where I would document all of the activities that I did each day. The journal entries that follow this report provide a view into my internship experience, and illustrates the progression of my duties in the office.

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Appendix A: Daily Journal

University of North Texas- Health Science Center

CRM Internship Daily Journal

ACRC Trials

NOTE: It is important to note that each diary may not specify every activity that occurred that specific day. While at ACRC Trials, there are many common activities that I performed each day, which may or may not have been included in that day's entry. For the most part, every day I was engaged in some form or another in the following activities: Patient recruitment, calling patients for their follow-up phone calls or calling patients who are on one of our surveillance studies to remind them of their study obligations (for example: a study where the patient takes home the Investigational Product (IP), and only begins to use it when they start feeling symptoms, like a cold sore), preparing source documents for the next day's patients or making new source documents for screening patients, ensuring subject eligibility by assessing compliance with diaries and/or IP, regulatory documentation and regulatory submissions, and performing visit-specific elements.

Day 1: 6/1/15

-I began the day at 8:00 AM, H.M. was not present today. I met R.L. for the first time today and reacquainted with the other staff that I met when I first came to see the office. I also met Ma.S., a UNT-HSC graduate who gave me many tips on what to expect. Today I was mainly on the computer, mostly for *IATA and OSHA* Training, which I completed. Thanks to the UNT-HSC curriculum, I already had my CITI training and did not have to complete it again. I also got my desk and phone assigned to me. I setup my voicemail and my email signature, and I also created an outlook email distribution list, which will allow me to email the whole office by selecting just one group.

- I reviewed folders with outdated forms and looked through the company server to see if updated forms existed. If they did, than I would recycle the older forms. However if no updated form existed, than we would transfer the forms to a different part of the office, where the forms are usually kept.

-I reviewed the Company's SOP (standard operating procedures) binder to familiarize myself with the company's standard of operation. I also read through 3 current study protocols, all dealing with some sort of dermatologic ailment. I took notes on these protocols so I could understand them fully when I begin to work with these studies in the near future.

-I organized different investigator study binders that needed to be filled with loose paperwork. I took the loose papers (correspondence, regulatory documents, protocols, certificates, etc.) from the filing bins and began to sort them out by study and place them under the correct tabs in the study binder. It took me a lot of time at first, since many of these papers I have never seen before, but after a few hours of looking at the binder's organization, I began to find the right spot quicker.

Day 2: 6/2/15

-Today I arrived at 8:00 AM. I spent the first few minutes of the day reviewing the many ACRC Trial sites. The company has sites in Plano, Allen, Carrolton, McAllen, and Austin. Although it is a lot to remember,

writing the locations out helped me map them in my head.
-I met another intern who will be interning with us until the end of August.
-I reviewed ACRC's SOP on phone operations. This SOP explained how to work the phone system (i.e. how to greet the caller, a script for ACRC trials company description, and how to ask for a patient's information if he or she is interested in a trial).
-I continued to work on organizing more free leaf paperwork into study binders.
-I learned how to use Clinical Conductor (CC) to search for patients and their upcoming scheduled visits. I can now get their source documents printed and put in their charts a day ahead of their visit so that the staff can quickly retrieve their charts. I also learned how to navigate the software to see patients files from different clinical sites and to find their screening number, which will help me obtain their respective chart in clinic.
-I scheduled myself for 2 introductory sessions on CC. One will teach me how to enter criteria for a patient and how to direct enroll a patient into a study, the other session teaches me how to search for groups of patients with specific criteria, how to use the call center, how to make and use call lists, and how to use web recruitment.
-I learned how to find source documents for each specific study on the companies "S" drive.

Day 3: 6/3/15
-Today I filed more miscellaneous paper work from the filing cabinet into the study binders.
-I helped gather complete paperwork for a study that is being closed out. I helped log returned drugs from the study by looking at patient return logs in the study binder. I gathered temperature logs and made copies of the missing logs to get a complete month by month log from the study's first shipment to the study's ending shipment.
-I went through boxes of filed with patient charts and logged when the patient received their investigational product (IP) and when they returned their IP. I logged the date returned and the amount of units returned. If there was a discrepancy with the paperwork, I would go check our drug storage cabinet and see if the patient had in fact returned the drugs, and the date in which they did.
-I was given a copy of my CV to sign, that will be used for when I am assigned onto a study as investigational staff.
-I searched CC to find and log patient's screening numbers, DOB, date of 1st (Consent) and 2nd (baseline) visits, and if the patient failed to screen- the reason why they did.
-I had a meeting with H.M., discussing my future duties as an intern. We also talked about our upcoming meeting with the committee members on June 22 and what I may want to write about on my thesis. I was also told to go to Carrolton this Friday to get to know the ACRC site there. I already met the lady that works there when she came into this office earlier this week, she is very nice and welcoming.

Day 4: 6/4/15
-Today I went through SAR (serious adverse reaction) documentation from a recent study and filled out a "safety letter receipt log". In order to find these documents, I had to log onto an online database and download and save many forms onto our company's "S" drive. This process of downloading links and saving them to the proper drive took the majority of the time I spent on this task.
-From 1pm-2pm, me and another intern participated on the online Clinical Conductor (CC) training session. We learned how to add a new patient into the system, and how to enter all of their criteria. We also learned how to direct enroll a patient into a new study, and how to schedule a patient.
-After our training session, we sat down with J.T. and she showed us how to do other tasks on CC. This was a bit more interactive than our online training session, which was nice since we were able to be more "hands on". She taught us how to navigate through CC, how to create and manage call lists, how to add a new patient into a prospective study and how to phone screen a patient. She also taught us

how to transfer calls to others in the office.
-I learned how to scan documents using the software "paperport".
-I was tasked to call patients who are currently on a study that requires them to call the office whenever their particular symptoms occur. Since this study is ongoing, and only requires the subject to come in when they start to feel symptoms, we need to call the subjects every 2 weeks to remind them that they are in the study. I would either talk to the subjects directly, or if they didn't answer, leave a message reminding them to apply the Investigational Product within an hour of feeling symptoms and to call and schedule an appointment without office within 24 hours of feeling any symptoms. After calling, I would complete their "visit requirements" on CC and would reschedule them for another "reminder call" 2 weeks from the date. I also filled in the proper paperwork in their charts, describing that we called them and reminded them of their duties in the study.

Day 5: 6/5/15
-Today I will not be going to the Carrolton location. I was told that it would be more beneficial for me to stay at this location so I can learn more and learn quicker. I agree with this decision.
-I sat down with R.L. and she taught me how to log onto different sponsor's portals to search updated IND Safety Reports and how to acknowledge that they are read. She also taught me about some of our "Surveillance studies", and how to contact patients from them. Since these patients just call us only when they are experiencing certain symptoms, it is our duty to call them every so often to remind them not to miss their daily/weekly reporting etc. I called a couple of patients to remind them to contact us, and I also checked up on a few patients who previously contacted us with some complications (to make sure that everything was fine now).
-I learned how to use *CPS Client* to perform a search query for possible patients to enroll in one of our new studies. I filtered the search based on the specific study's inclusion/exclusion criteria and other protocol descriptions. I am currently working on a chart review so that we can start finding patients when our study enrollment and screening opens up.

Day 6: 6/8/15
-Today I was sent to the Carrollton site to work with M.E.. I was shown around the office and was introduced to much of the staff.
-I filed loose paperwork and put the paperwork into their respective studies regulatory binders, as I have been doing in the main office, to help get the binders organized for our monitor that is coming tomorrow. Doing this has helped me get to know the different paperwork that is needed for clinical trials.
-M.E. had me email one of our regulatory employees to ask and confirm new stipend for one of our new study subjects.
-I was taught how to ship study materials (body fluids, hematology, urine specimen, blood chemistry) and how to prepare them for shipment (centrifuge the blood and transfer the serum into another vile). I learned how to schedule pickup by FedEx and how to properly pack a specimen to be shipped using an airbill.
-Verified a patient's stipend payment on Clinical Conductor.
-Completed patient visits and scheduled patients in the future on Clinical Conductor.
-Corresponded with staff from main office on matters that this site needed (for example, asking for more toner for the printer and arrA.C.ng an order)
-Learned how to navigate sponsor sites, view and respond to Queries.
-Rescheduled patients on Clinical Conductor.

Day 7: 6/9/15

-Today I made new patient charts by hole-punching and inserting source documents and other documentation into the folders.
-I called patients that are currently on one of our studies. These patients need to call daily to report certain conditions, and these calls are meant to remind the patients who forget to call daily, to call. I also asked them if there were any particular reason that they didn't call (either they forgot their access number, etc.) and offered any assistance.
-M.E. gave me a couple of charts of subjects in the study that is being monitored today, and asked me to go through the paperwork to see if anything is missing (pages, signatures, dates etc.)
-I unpacked some expired study materials before throwing them away. I took out urine collection cups, safety needles, and other materials that can still be used.
-I organized the filing cabinet in the coordinators office and placed different study kits on different shelves and in order by their visit dates.
-Participated in Session 3 (my second lesson) of Clinical Conductor- learning how to filter patient databases and how to use call center, make call lists and recruiting.
-I made new patient charts for any new patients that may be enrolling in this specific study. I made copies of the source documents and put them into the folders.

Day 8: 6/10/15
-Today I am working at the Allen site with M.E. Elena.
-I began the day my making new study charts for when we do enroll patients. I had to copy source documents and informed consent forms, along with other relevant documentation and place them in correct order into the charts.
-I wrote an email to a previous study subject, per monitors request, to explain to them a situation in which one of their documents had the date missing, an issue that needed to be fixed. It was just a precautionary email explaining why we needed to replace a page of their informed consent form into the chart.
-I helped label (for easy identification) and organize the investigational product supply closet.

Day 9: 6/11/15
Today I met M.E. Elena at the Carrollton site to pick up some important signed documents that need to be taken to the main site. I met her and picked these up and discussed other important things that need to be done while I'm at the main site (need to complete some regulatory queries that involves me retrieving documents from the S drive and getting some original documents that are kept in the regulatory investigator binder at the main site. Done things I need to speak with R.B. about at the main site)
-I will also be picking up toner, folders with tabs to make the study files, and extra fasteners for the charts.
-I sat through a 1a visit for one of our new studies (new patient screening) and learned what is involved in a screening visit (follower through with the protocol list of events that take place on the first screening visit)
-at the main site, I dropped off documents that needed to be scanned and filed into regulatory binders. The scanned documents were uploaded to the company's S drive.
-I picked up stamps, petty cash, filing folders, and prong fasteners for the Carrollton site. I also had to change laptops because my previous one didn't have the remote connection that I needed to access the company's a drive from the Carrollton site.
-I went through each of the monitor's queries with R.B. (the regulatory specialist) and completed then one by one until there were no more outstanding queries on this study, I am taking all copies of these completed queries back to the Carrollton site so they can be filed into the investigator binder.

-I sat with H.M. and we discussed my thesis and went over possible topics. We will be meeting next week sometime to further investigate what I want to write about. So far I am thinking about either recruitment, loss to follow up, or informed consent processes. I also may want to create a questionnaire that will allow me to conduct a "sub study" within our studies-particularly to either assess the ICP or to see why patients chose to enroll in clinical studies (actual benefit, financial benefits, etc.)
-I called a few patients to let them know that they have been pre-screened and scheduled them for their first visits in clinic. Some I had to leave messages, one patient decided that she no longer wanted to be considered for the study, and the other was scheduled.
-I studied the protocol for a current study and will have to familiarize with it to help with queries on the EDC on Tuesday, and also to help screen patients.
-I helped M.E. scan documents from the regulatory binder (requested by the monitor) and sent them via email to the monitor.
-I used VHP (a database) to start a chart review for an upcoming study that we will begin enrolling patients in.

Day 10: 6/12/15
-Today I worked in both the Carrollton and Allen sites.
-In the Carrollton sites, I prepared the materials needed for a screening visit (visit 1) and a randomization visit (visit 2). This required me scanning and placing the proper source documents into the patients charts, dispensing the proper study medications, and setting up the electronic diary. For the randomization visit, I also had to prepare the supplies needed for the blood draw and urine collection. After M.E. drew the blood, I centrifuged the sample and collected the serum for the blood chemistry tube. I also had to perform an hCG urine pregnancy test, and transfer some urine into another vile for a urinalysis. I then packaged and contacted FedEx for a scheduled pickup.
-At the Allen site, we had to randomize a subject for another study. While M.E. performed the EKG and took the subjects vitals, I copied the proper source documents (for visit 2) and placed them into the patient's chart so that M.E. could fill it out. I also copied other important visit documents that needed to be in the folder. I learned how to randomize the patient and dispense the investigational product by using the sponsor online site. I learned how to navigate through this site to complete study visits and other important study procedures.
-Everything I did today required me to really understand the protocols for the studies. I have been reading up on the studies and I think today really showed how much of a good understanding I had for them. For one of the studies in our Carrollton site, M.E. had me explain to the subject (with her in the room next to me), exactly how and when to take the investigational product. I also answered any questions that the patient had, with M.E. confirming my answers. It was nice to interact with patients and explaining to them how the study works and how to be compliant with the study procedures.

Day 11: 6/15/15
-Today I had a meeting with Dr. P.G. at 10:00 AM in Ft. Worth. Due to this, I worked a half day. Dr. P.G. and I talked about my thesis proposal and possible topics. We also spoke about the meeting that we will be having next week at ACRC trials. I told her that I will probably write about the importance of understanding and minimizing loss to follow up, although there may not be that much that I can research. She gave me some good advice on who to ask or previous papers written about similar topics.
-When I got to ACRC trials (around 11:45), I spoke with H.M. and updated her on my meeting with Dr. P.G., as well as a little recap of what I did last week with M.E..
-I entered in a patients visit and their diary information onto the EDC, and completed the visit requirements. I will be inputting this information onto this sponsors EDC for the remainder of this week. I also scanned source documents for the patients next visit and put them in the patient's chart.

-I printed an updated version of a study's source documents and replaced them with the older version that was still in the filing cabinet. I also received an email with an updated page from another study's source documents, and I went ahead and printed this update and replaced the page in the investigator site binder and its proper place in the filing cabinet.
-I called patients that were scheduled to be called today for a surveillance study. I reminded them of the protocol of the study and to call if they have any questions regarding the study etc. I then completed their visit and rescheduled them in 2 weeks, when the next reminder phone call should be placed.
-Continued to work on a chart review for a new study we have coming up, searching the network database to filter patients based on the protocols inclusion/exclusion criteria. I exported the patients information to excel and it will be used to get patients for the study.
-R.L. showed me how to access a list of all of the patients in our database and how to export the list to excel. After I exported the list to excel, I looked or the screened or randomized patients and looked to see which patients have had their last visit, but have not been scheduled for their next. I would see why the patients weren't scheduled, and I would either write a note for their coordinator to go back and look, or if i could schedule them, I would schedule them depending on which visit they needed.
-I updated the temperature log to correspond with all of our current studies. I had to look through the Investigative Brochure (IB) and/or Protocol of each study to find the proper temperature range the Investigational Product (IP) and the other medications had to be kept at.

Day 12: 6/16/15
-Today I worked with M.E. Elena at the Allen site. I went there primarily to help her work on queries for one of the studies that are being held there. To work on these queries, I needed to log onto the sponsors EDC site and go through each patient's queries. Since they had patients listed by their randomization number, I had to either look at the patients corresponding screening number on clinical conductor, then search for their chart in the filing cabinet, or I could have found some of the patients just by using their randomization number (those who had the number already written on their chart). I then read the query and looked for the proper information in the chart. All together, today we finished all of the queries (I think it was around 40-something).
-I broke down old study boxes and retrieved materials that we decided to keep to give to the walk in clinics. Usually, to keep a good relationship with them, we give them syringes, test tubes, masks, gloves, swabs, etc. to help them keep stocked up. There were near 100+ boxes that needed to be looked through. I sorted all of the materials into different bags to be taken to the clinics.
-We had a screening patient today, and I helped get the patient started by talking with them about the new patient info sheet, and retrieved their ID to take a copy of. I also spoke with them shortly on the study (visit #s, compensation, a little on the ICF) and answered any general questions that I could answer myself).

Day 13: 6/17/15
-Today I recorded the daily temperature log on the three locations in the lab (RT, fridge, freezer), and them reset the daily reading.
-I logged onto to one of our studies portals to search for either a IB or Protocol to print and put in the regulatory binder. I also need it to look for the temperature range in which we need to store it.
-Called 5 patients that are on one of our surveillance studies to remind them about their duties to call in and schedule within 24 hours of feeling any symptoms. Documented conversation in their chart and completed their "call" on Clinical Conductor. After, I scheduled them for another call in 2 weeks.
- I sat in with R.L. and S.C. on a "Site Initiation Training Visit" with the study monitors and went through an hour+ discussion over the whole study. Signed training forms and delegation logs. Spoke with the sponsor about the study and received study related material to look over. We went over the protocol,

source documents, sponsor guidelines, study drug, etc.
-I went with R.L. to one of the physicians that we partner with in the building. The physician thought that one of his patients were good for one of our new studies. I went with her and I saw how she spoke to the patient about our study and how she went over the Informed Consent Form (ICF), for when I begin to consent patients. I got to meet the staff at the office, so now I can begin to see people there.
- I called patients who missed their daily diary assessments (that are required for one of our studies) and reminded them to complete them every day before noon.

Day 14: 6/18/15
-I took the daily temperature recording and inputted the information into the log. I had to print off a temperature log off of the company's "S" drive because we were missing one for the "room temperature" recordings. After writing in the log, I had to reset the daily temperature min/max, so we can have a 24 hour reading tomorrow.
-Today I continued the work I did yesterday, filling out what patients charts were missing. I also organized the filing cabinet where we keep the patients charts, according to how S.C. wanted it done. I figured out which patients we are missing charts on and which ones we still need their medical information on.
-Printed study synopsis sheets that sum up the study on one page- these will help me access and explain each study on a moment's notice (i.e. when I answer the phone and someone asks about a specific study that our site or another site is currently enrolling).
-Called 2 patients who are currently on one of our surveillance studies and reminded them of their obligation as a participant. I then completed their "phone call" on CC and scheduled them for their next phone call 2 weeks from today. One of the patients had an inactive phone number, so I emailed them and asked them to update their information.
-I continued and finished the chart review for one of our upcoming enrolling studies. I exported the spreadsheet and saved it to the company's "S" Drive.

Day 15: 6/19/15
-I started the day recording the temperature of the cabinet/fridge/and freezer onto the temperature log, and then I reset the thermometers for tomorrow.
- Learned how to process the labs for our studies here, and how to properly pack and send them.
- Called 2 patients on one of our surveillance studies to remind them of their duties in the study. I put extra source documents in their charts to be filled out, and also completed and rescheduled their "phone call" for two weeks from now.
-I printed a few ICFs for our new studies so I can practice what I need to say to patients and how to present the ICF to them.
- I learned how to navigate CC to get to patient appointment reminders, so I can call them the day before their scheduled visit and remind them of the time and any other pertinent information regarding their visit (I.e. if they should fast before a blood draw, or what to bring, etc.)
-I spoke with H.M. about my thesis topic and perhaps going to our Austin site for a week. I think that this would be an awesome opportunity to see the other site and how they navigate through their studies. Since I am very familiar with the Austin area (I went to UT for undergrad), I feel like getting to know the company in that city would be a great opportunity for me. I also have a few good ideas of what we may be able to do there as far as recruiting and advertising, since I am familiar with the "hot spots" and "high volume traffic" areas.

Day 16: 6/22/15
-Recorded in the IP temperature log and reset the thermometers temperature reading so I can read

them tomorrow.
-Got around 15 charts ready for one of our PIs to sign later today. Since we don't want to take too much of their time, I needed to go through each chart and make sure that we have notes sticking out ONLY on the pages that we need signed.
-Set up the log-in information for two of our doctors and one of our coordinators on the sponsor portal site.
-Today we have an SOP (standard operating procedure) workshop that will last most of the day. We will be training on our company's standard operating procedures (an annual training) that required all of our staff to know how to conduct trials according to GCP and sponsor regulations.
-I met Danielle, the CRC at our site in Austin. After speaking with H.M. about my proposed thesis topic, I may go to Austin for a week or two to observe the site and perhaps get some ideas on what to write about in my thesis. Since it may be on the factors of being an add-on-site to a study, the Austin site will be a great example of this (since that site has just been added onto a new contraceptive study). This will teach me the differences between an add-on-site versus a normal site that has ample time to recruit and setup for the study.
-Checked to see if patient's medical records have been released either on the "S" drive or in their charts. If the patients had no records released, I needed to fill out a "note to file" per monitors request.
-Met with Dr. P.G. and Dr. Gatch with H.M. today and discussed my internship activities thus far. Also discussed the two topics that I am thinking about writing my thesis on. The first is on "loss to follow up" and the second topic is about sponsors adding an "add on site" to a study (which makes the time frame of enrolling/initiating etc. much shorter than a normal site). I do not yet know which one I will be picking, but I am leaning towards the latter. We also signed the proper paperwork that is needed for my degree plan and thesis proposal.

Day 17: 6/23/15
-Recorded in the IP temperature log and reset the thermometers temperature reading so they can start a new 24 hour reading for tomorrow.
-I began to look through source documents to see when patients on this particular study were diagnosed with a condition of interest (for inclusion) into the study. If patients did not have medical records released by their PCPs, documenting their diagnosis, I needed to look in their chart to see if they had mentioned the specific diagnosis themselves. If they confirmed the diagnosis themselves, without proper documentation from their usual doctor, I needed to file a "notice to file" document in their source document that contained the start date of their said condition and any related medications that they might be taking, per monitor request.
-Today was day 2 of our "SOP" (Standard Operating Procedure) site training. We had the first half of today's training in the office, then we moved to a conference room in the building to finish. To help us stay involved, we each switched off reading from the screen. One interesting subject that we reviewed today were the procedures involved for when there may be an FDA auditing visit.
-I replaced the toner in the printer and saved the old toner cartridge, labeled it so we do not use it, and stored it with the other old toners in the storage closet.
-I helped J.T. process a new IP kit shipment. I checked that we had all of the proper supplies by using the enclosed packing list. After confirming that everything that was supposed to be in the box, was there, we stored the materials according to their specific locations in the lab.

Day 18: 6/24/15
- Recorded in the IP temperature log and reset the thermometers temperature reading so they can start a new 24 hour reading for tomorrow.
-Sat in on a conference call with Danielle from our Austin site. She had a SIV (site initiation visit) with

one of the new sponsors that will be conducting a study at the site. Since we are helping her recruit/enroll patients, she went over the protocol and inclusion/exclusion criteria with us so we can phone screen patients.
-Continued to look through patient charts and medical records released to document if the patient has been diagnosed with a specific condition of interest, and what medications they have been taking for the condition.
-I went with R.L. to the NTXFM site (North Texas Family Medicine) site that is located in Plano. This was my first time at this site. I helped her see a patient who was being screened. I saw the process of informed consent, the setup of the daily diary, the EKG, physical examination, and other study visit procedures. I also acquainted myself with the PI of the site, the staff, and the facilities. I Also helped R.L. get the regulatory binder ready for the study monitor that will be coming tomorrow. I hope to frequent this site, as the staff is very friendly and the office atmosphere itself is very welcoming.

Day 19: 6/25/15
-Today I recorded the daily temperature logs in the lab and reset min/max back to zero, so we can have an accurate 24 hour reading tomorrow.
-I called a patient who started a study yesterday, who had begun experiencing side effects of the rescue medications. I reminded him of the procedure and protocol and reminded him of his scheduled visit for visit 2 (randomization). Also reminded the patient to remember to complete their daily diary log.
-Helped M.E. Elena with some patient reminder calls and left messages for those who didn't answer. These were reminder calls to complete their daily diary for their specific study. I also helped her find suitable patients for a new study that is coming up. Since this is a similar study to one which just ended, I looked at the previous study's completed patients and began calling or emailing them to ask if they were interested in joining the new study. I scheduled them for next week after making sure that they passed the pre-screening eligibility criteria.

Day 20: 6/26/15
Today I went to the Allen site to help M.E. with Queries for one of the studies. She had a patient at the Carrollton site at 10:30, so she left me at the Allen office while she did her duties at Carrollton. I spent the whole day catching up on the queries, which really helped me understand what the monitors are asking when they flag something down on the EDC. It also helped me really understand the protocol for the study. Since the office in Allen closes at 3, I had extra time to work. I drove to the Carrollton site and brought M.E. Elena back her laptop and when I got to the site, I helped her enter some appointment completions into CC. I separated out the charts that still need to be called, and she will either finish the calls tomorrow, or I would do it on Monday when I get back to work.

DAY 21: 6/29/15
-Today I was out sick.

Day 22: 6/30/15
-Recorded the daily temperature logs for the drug cabinet/freezer/fridge. Printed July temperature log for the RT drug cabinet, and filed the June temp log in the ACRC filing binder with the rest of the temp logs.
-Called a patient to remind them to call for their daily diary assessment after receiving a notification from out automated system.
-Logged onto the diary portal for one of our studies to check for patient compliance and eligibility or one of our current studies. Called a patient who has not been completing their diary (phone was out of service), so I emailed the person asking them to update their contact information.

-Called a patient on one of our surveillance studies to remind them o their responsibility with the IP, and to schedule an apt with us within 24 hours of feeling any symptoms.
-Assisted during a patient visit (Visit 3 – dose administration)

-Learned how to set up and perform and obtain a reliable spirometry at VHP
-Took the patient's vitals (BP, HR, RR, temp)
-I then escorted thepatientto our ENT provider, where the provider assessed the pre-injection site and initialed some paperwork (Source documents and spirometry reading).
-Watched R.L. administer the dose of IP, and then sat with the patient for 30 minutes to make sure no adverse reaction occurred
-After 30 minutes, PI re-examined injection site and evaluated and wrote interpretations on the SD.
-I escorted the patient back up to VHP exam rooms and took another set of vitals. The patient also needed another spirometry reading.
-Began calling patients on our call lists and from our recruitment prospects list (i.e. people who have emailed/qualified from out site), and spoke with them about the studies that they expressed interest in. I went over a synopsis of the visit and any pertinent information, I then updated their status on CC, and scheduled them if they ended up meeting our phone pre-screening criteria.

-I called patients who needed to be informed of either new blood draws, new visits, or termination visits that needed to be scheduled.

Day 23: 7/1/15

-Recorded daily temp logs, and reset the temp reading for tomorrow. I also needed to print a new refrigerator log for July, and put the June log into the ACRC files.
-Today I Called patients who are on our recruitment page and spoke with them about their interest in our current studies. I went over the synopsis of the study with them and answered any questions that they had over the IP or study procedures. I Ma.S.ed our conversation on CC and input the patients into CC. I went through the phone screen with patients who were interested in seeing their eligibility.
-I went through charts that need to be signed by one of our PIs here. I will be going to his office at 12:45 to get him to sign the papers (we arranged this time last week, since this time is most convenient for him to sign papers). Since we have over 90 patients that need more than one document signed in their charts, we have been bringing papers in bulk to his office.
-Answered company calls, and assisted the subjects with their questions/rescheduling, or transferred them to the appropriate employee.
- R.L. did a skin test on me today, testing my reaction to Histamine (a study sponsor wanted the skin test done to someone in our office for comparison). I also did a cat and cockroach allergy test, and found that I am not allergic to cats, and only slightly allergic to cockroaches.
-Scheduled a few patients for their screening visit in Austin for a study that we are quick enrolling, after I prescreened them over the phone.
-Called patients to remind them of their appointments for tomorrow (at all the sites), and told them what they needed to bring to the visit (or do before the visit; like fast if drawing blood, etc), so they can be prepared for the appointment.

Day 24: 7/2/15

-Today I recorded the daily temperature logs in the lab and reset min/max back to zero, so we can have an accurate 24 hour reading tomorrow.
-Called patients on one of our surveillance studies to remind them to apply the IP within an hour of feeling any symptoms, and to call our office and schedule an apt within 24 hours of any symptoms.

-Checked patient eligibility and diary compliance by logging onto the sponsor portal and looking through the submitted reports. I then called any patients who haven't completed their diary assessment within the last day and reminded them the need to fill them out every day.
-Went to Dr. A site with R.L. to assist in a patient visit. I got the electronic diaries ready (charging), I set up the EKG system, and dispensed the rescue medication to the patient. I also guided the patient through the diary training and got the PI for the physical exam. I also obtained the urine sample from thepatientand performed a pregnancy test. After the patient visit, I completed the visit on CC and scheduled the patients next visit (visit 2) on CC.
-I looked over one of our new Austin study's Source Documents and compared them to the protocol to see if there are any things that
-Ha.M. asked me to make an excel sheet with the physician reimbursement values on it. He gave me a sheet of paper from CC that listed all patient visitors the past two months, with the specific study, the PI an the physician who presided over the visit. I needed to sort the visits by study and specifically find out how much compensation each PI, physician, or ACRC got buy computing the appropriate percentages using the values given from the sheet. I then created a summary spreadsheet which states the total amount that each physician should receive.
-I then went to the Carrollton site to help M.E. Elena organize her study drug cabinets, and help make some charts and file some regulatory documents. Since she will be gone a few days next week, this was important to do before since we have a Monitor coming to that site at the beginning of the week.

Day 25: 7/6/15
-Recorded temperature log for drug cabinet/freezer/fridge, and reset the daily min/max temp recording.
-Searched on the study portal for patient e-diary compliance. If the patient has not completed their daily diary within the last 2 days, I called them and talked with them/left a message to comply daily with the diary.
-Called patients on our recruitment list and informed them about the study that they were interested in. I gave the perspective patients a synopsis of the study, and went through the eligibility criteria, seeing if they were a good candidate for the study. Once I pre-screened the patients successfully, I scheduled them for their screening visits.
-Send email reminders to patients who have their appointments coming up.
-Called patients who have been on previous studies, that expressed interest in being contacted for new relevant studies.
-Went to the other Plano site (NTXFM) and helped R.L. complete a patients screening visit. I presented the informed consent form to the patient, and answered any questions that the patient had regarding the study procedure. I also got their paperwork ready and got the computer ready for the EKG reading etc.
-I will be going to the same site tomorrow, by myself, and completing the screening visit on my own. By this point, I feel very comfortable with this study's procedure and visit details. I know how to prepare the patients chart and new information sheet, how to complete the visit requirements, and how to present the ICF. I also know how to set up the patient's electronic diary and get it ready for their use. I also am very comfortable with the physicians and other staff at this site, so I feel like I will be more than ready to tackle on the visit by myself. I needed to get on the delegation log for my duties that I will be performing (since I will be writing in the Source Documents), so today before I left the site, R.L. had me sign the delegation log and training log.

Day 26: 7/7/15
-Today I recorded the daily temperature log for the drug cabinet/refrigerator/freezer.
-I called patients that expressed interest in some of our studies from one of our recruitment sites. I

entered their information (name, number, email) into our system, and added the patients to our recruitment call lists for the specific studies that they were interested in. After calling and either talking or leaving a message, I updated their status on the call lists so we know where we last left off with the patient. After discussing the study with the perspective patients, I phone screened them and made sure they met eligibility. If they did, I scheduled them or their first screening appointment. One of our studies (constipation) is ending enrollment this Friday, so it is imperative that we schedule all who we can by the end of the day Friday. This is an important deadline that we must meet, so we are trying to recruit and schedule as many patients as we can by then.
-R.L. had me fill out the templates of the FDF, FDA 1572, and site checklists for the three sites that we are getting set up for a new study. I needed to download the forms, and input the correct study number, site number, PI, Sub-I, addresses for the lab, IRB, clinic, etc. (saved the documents onto the "S" drive under each respective PI).
-Went to our other Plano site (North Texas Family Medicine) and performed a patients 1st (screening) visit. I presented the Informed Consent, took vitals, and performed the EKG. I also went through the inclusion/exclusion criteria, and performed a pregnancy urine test. I also set up the electronic diary, and input all of the patient information into the EDC for the visit. I explained to the patient how to use the electronic diary. I spoke with the physician (PI) about the patient, and the PI confirmed that the patient met the inclusion/exclusion criteria. The PI performed the physical exam, and I got signatures from the PI where needed (ICF, EKG, PEx, etc).

Day 27: 7/8/15

-Recorded daily drug cabinet/refrigerator/freezer temperature log
-Began calling patients that are on our recruitment call lists and also people who expressed interest in the studies from various internet sources. I explained the study protocol to them and scheduled screening appointments if they were interested (assuming they passed the pre-screen).
-Retrieved all of the documents that one of our PIs need to sign. We arranged that every Wednesday and Friday that he will be able to see us at 12:45 to sign relevant study papers. I believe that after Friday, we will be done with all of the signatures that we will need. To make it easier on the doctor, I decided to take out all of the papers that he needs to sign from the patient charts (since bringing 20+ charts to his office takes up A LOT of space and time). We realized that taking the papers that need to be signed out of the charts allows us to take A LOT more papers to get signed without it even seeming like it is that there are more. The doctor also thinks that it makes signing more manageable.
-Answered phone calls and relayed the calls to the appropriate person, or explained the study to the callers who were calling about a specific study.
-Rescheduled patients on CC
-Logged onto the Biomeds site to see if patients currently enrolled in a study were keeping up with their E-diary. If they weren't, I called them/left them a message reminding them to complete their assessments daily.
-Visited Dr. G's office to get his signature and date on a few documents.
-Met with Dr. P to sign study documents

Day 28: 7/9/15

-Today I woked a half day, coming in at noon time, so I could spend the beginning hours of the day working on my thesis draft and proposal.
-When I came in at 12, I began calling patients on our "recruitment prospects" page, and informed them about the studies that they inquired about. I was able to schedule a few patients for screening next week, after confirming their eligibility criteria.
-Around 1pm, me R.L. and S.C. called into to an online conference meeting with one of our sponsors, to

go over the EDC system. The meeting took about an hour, and we went over how to respond to queries, how to input the CRFs into the EDC, and how to navigate other aspects of the EDC.
-I logged onto one of our sponsors e-diary portals to view the eligibility of current study participants. I looked at the log of their reports, and called patients who haven't completed their daily assessments for the last two days. I reminded them to keep up with their diary daily, and gave them information on what to do before their next office visit.

Day 29: 7/10/15
-Today I recorded the daily temperature logs for the drug cabinet/freezer/fridge.
-I checked one of our studies gateway site to see the patients eligibility and e-diary compliance.
-I called patients on our "recruitment prospects" call list and explained to them about the studies that they were interested in, and scheduled them if they passed the pre-screening eligibility.
-I rescheduled patients who are scheduled on Monday, since many of our CRCs will not be in the office.
-I reviewed the protocols and ICF of a few new studies that we will be participating in. I read them to understand them in more detail and know how to pitch them to prospective candidates.
-I saw a few patients in Dr. D's office today. It was quite an experience. There were two perspective patients who ended up not being eligible for the study, and they caused quite a scene after being told they did not qualify. Luckily, after a few minutes of talking, and giving them a small compensation for their gas, we got the patients outside of the clinic, where they could no longer make a scene. The other patients that we saw there were on their 2nd and 3rd visits, and were compliant with the study. It was a nice change of scenery after the complications with the first patients.
-I was asked by R.L. to go to Dr. A office (our Plano location) to complete a patient's withdrawal visit. I need to give the patient a new ClinCard (the debit card that we give them or compensation for the visits), and I need to enter his stipend amount in the system. I also need to collect and reset the electronic diary, and collect the rescue medication we gave the patient.

Day 30: 07/13/15
-Today I recorded the daily temperature log for the drug cabinet/refrigerator/freezer.
-I called patients that expressed interest in some of our studies from one of our recruitment sites. I entered their information (name, number, email) into our system, and added the patients to our recruitment call lists for the specific studies that they were interested in. After calling and either talking or leaving a message, I updated their status on the call lists so we know where we last left off with the patient. After discussing the study with the perspective patients, I phone screened them and made sure they met eligibility. If they did, I scheduled them or their first screening appointment.
-H.M. was back in the office today, after having to miss 2 weeks. I was able to talk to her about my thesis topic, and we arranged a meeting for later this week to discuss the outline. I also spoke with J.T. about recruitment campaigns, and she gave me valuable information on the process of recruitment and advertising.
-Went to VHP (village health partners) to get the signature of a few doctors and sub-investigators. I was able to meet some of the staff there, and acquaint myself with their offices.
-Ha.M. gave me access to the financial/budget aspect of the studies, in order to help him input some of the contract terms into Clinical Conductor. I learned about how contracts are worded, and how they are input into CC so they can be billed (for each visit/procedure/etc).

Day 31: 07/14/15
-Today I recorded the daily temperature log for the drug cabinet/refrigerator/freezer. The freezer temp log was full, so I printed off a new blank sheet and filed the filled sheet in
-I called patients that expressed interest in some of our studies from one of our recruitment sites. I

entered their information (name, number, email) into our system, and added the patients to our recruitment call lists for the specific studies that they were interested in. After calling and either talking or leaving a message, I updated their status on the call lists so we know where we last left off with the patient. After discussing the study with the perspective patients, I phone screened them and made sure they met eligibility. If they did, I scheduled them or their first screening appointment.
-Escorted a patient to one of our PI's offices, and instructed them to fill out the 'New Patient Information' form.
-I presented the Informed Consent Form to a patient who was on their 1st (screening) visit today. Since the patient was a minor, I made sure to print the Assent form as well, which needed to be signed by the guardian.
-Called one of our patients that are on one of our surveillance studies, to remind them to apply the study medication within 1 hour of feeling any symptoms, and to call and schedule an apt within 24 hours of feeling those symptoms. I then updated the patients chart with this reminder, and scheduled the patient on CC for their next phone call visit (2 weeks from today).
-Registered for a SIM (Study Initiation Meeting) that will be held for one of our upcoming studies.

Day 32: 7/15/15
-Today I recorded the daily temperature log for the drug cabinet/refrigerator/freezer.
-I received an email from one of our studies portal sites and I was able to activate my EDC account. I needed to log on (using the generic password given to me), and then I need to make my own password. I now have access to the EDC.
-I met with H.M. in her office and spoke briefly about my thesis proposal. She helped me formulate a good outline with some key points. We will meet again tomorrow and discuss the outline in more detail. -I went to our other Plano site (NTXFM) to assist a patient in their 3rd visit on one of our studies. Duties include:

-Print and enter information into visit 3 source document
-Review ConMeds and Adverse events
-Access electronic diary completion
-Vital signs & EKG-Collect and analyze and ship laboratory samples (Hematology, Chemistry, Urinalysis).(Since I cant draw blood myself, I filled out a requisition form so the phlebotomist at the practice can draw the blood for me. I called fed-ex and arranged a pickup time for the specimens.)
-Dispense Study Medication
-Schedule the next study visit to occur 56(+/- 2 days) after visit 3.
(The subject ended up having an abnormal test result, which led to the PI wanting to discontinue the patient in the study. Instead of doing a visit 3, I needed to perform a Early Termination visit, which required more paperwork and a physical exam. We will be following up with the patients PCP)

-Participated in a call-in Study Initiation Visit for one of our new ragweed studies that we will be starting in the near future. The study went over the basics of the Protocol, inclusion/exclusion criteria etc.
-When I came back to the Main site, I filed loose paperwork into two study binders that will be checked tomorrow when we have our monitor closeout visits.

Day 33: 7/16/15
-Today I was at the Plano site all by myself. I saw three patients in total (their visit 3). I asked about any changes in medical history or ConMeds. Performed vitals, and performed their EKGs. I assessed their diary compliance and their study medication compliance. I collected their study meds and dispensed new study medications. The on-site phlebotomist took their blood, however I centrifuged the samples

and processed them. I also collected urine samples and processed them. I packed the lab samples according to IATA regulations and coordinated FED-EX pickup. I completed all visit notes, progress notes, and source documents. I also input all of their information onto the EDC. R.L. came for a little to help with a patient's visit 2, which included some extra tasks (mainly assess eligibility and randomize). She left as soon as the patient was done, and had me process all the labs and enter all relevant documentation in the EDC.

Day 34: 7/17/15
-Today H.M. allowed me to take the day off in order to work on my thesis proposal. I was able to go to the library and use academic sources to cite in my paper. I got a lot of progress done, and feel confident in my subject.

Day 35: 7/20/15
-Today I recorded the daily temperature logs for the drug cabinet/fridge/freezer. And reset the values so an accurate 24 hour reading can be made for tomorrow.
-I needed to print Screening/ScreenFail confirmation emails (per sponsor) from the study's EDC/Portal site. Many of the charts in this study were missing relevant documents that the monitors wanted inside them. To retrieve them, I needed to log onto the portal and find the subjects number and their appropriate visit to confirm failure.
-I called patients who were on the recruitment call list, as well as patients who expressed interest through studykik (a website that recruits potential patients). I called many different patients and explained to them about the studies that were of interest to them. I pre-screened them and ultimately scheduled them or their appointments.

Day 36: 7/21/15
-Today I recorded the daily temperature logs for the drug cabinet/fridge/freezer. And reset the values so an accurate 24 hour reading can be made for tomorrow.
-I needed to print Screening/ScreenFail confirmation emails (per sponsor) from the study's EDC/Portal site. Many of the charts in this study were missing relevant documents that the monitors wanted inside them. To retrieve them, I needed to log onto the portal and find the subjects number and their appropriate visit to confirm failure.
-I called patients who were on the recruitment call list, as well as patients who expressed interest through studykik (a website that recruits potential patients). I called many different patients and explained to them about the studies that were of interest to them. I pre-screened them and ultimately scheduled them or their appointments.
-H.M. asked me to organize the lab. I took out most of the materials from the cabinets and drawers and organized them according to use. I threw away any old/broken/expired materials, and made the cabinets more manageable. I also put little labels on the outside of the doors so you can see what is inside the cabinet. I also did the same thing to the drug cabinets.
-We received three sets of study binders for each of our three (PIs) sites. I printed all the relevant communications and announcements from the company's CPAP site, and printed enough for all three binders to have. I also set up the binders with the appropriate CVs, Certifications, and 1572s. The site investigator binders were important to get set up early, especially with so much loose-leaf paper building up.

Day 37: 7/22/15
-Today I recorded the daily temperature logs for the drug cabinet/fridge/freezer. And reset the values so an accurate 24 hour reading can be made for tomorrow.

-I called patients who were on the recruitment call list, as well as patients who expressed interest through studykik (a website that recruits potential patients). I called many different patients and explained to them about the studies that were of interest to them. I pre-screened them and ultimately scheduled them or their appointments.
-I had a small talk with H.M. about my future roles with the company. I asked her if I would be able to see more patients while at main site. I have been doing a lot of patient interaction at our other site (A) but have yet to see that much action while working here. I have a lot of responsibility with recruiting and enrolling patients into studies, but I think that my talents will also be used well in the coordinator aspect o trial duty.
-Saw a few patients for their study visits and dispensed their study medication with instructions on when and how to use.
-I added information about a new potential study onto CC. This includes inputting the study name, any relevant contact information (Sponsor, monitor, etc), the stage of the trial, the company name and sponsor name, etc.

Day 38: 7/23/15
-Today I recorded the daily temperature log for the drug cabinet/freezer/fridge, then reset the thermometers so we will have an accurate 24 hour setting for tomorrow.
-I continued to call patients about our various studies and pre-screened them/scheduled if they met eligibility and were interested.
-I was sent to out other plano site to see a patient who ended up being ineligible for the study. I collected their rescue medication and electronic diary, screen failed them in CC, and disabled their electronic diary. I also gave them their ClinCard and copied the account number so we can have in our files.
-I created a spreadsheet for the screening patients in one of our studies, and listed when we last saw them, when their next visit needs to be done by, and all that we are still missing from the patient (i.e. lab results, dust kit reports etc.). I had to call the lab to ensure that their reports were done and to send them to us, so we can continue scheduling the patient for the study.

Day 39: 7/24/2015
-Today I recorded the daily temperature log for the drug cabinet/freezer/fridge, then reset the thermometers so we will have an accurate 24 hour setting for tomorrow.
-I continued to call patients about our various studies and pre-screened them/scheduled if they met eligibility and were interested.
-I delivered a study kit and an electronic tablet to R.L. who was visiting with a patient at VHP.
-I called patients from a previous interest group to see if we could round up enough patients for a particular study at our Carrollton site.
-Called many patients on one of our call lists regarding a cold sore study.
-Created an excel spreadsheet for Danielle at our Austin location to help her keep track of patient's pending results (labs/procedures) as well as scheduling dates. Since this study requires monthly visits with a timetable of 28 days (+10 days/ -7 days) I programmed formulas in Excel to help estimate visit intervals.

Day 40: 7/27/15
-Recorded the daily temperature logs of the drug cabinet/freezer/fridge, and reset the thermometers so they can have a accurate 24 hour reading tomorrow.
-Called patients study call lists and on our recruitment database and scheduled patients who were interested and who qualified for the studies.

-Saw a few patients with S.C., particularly those who are currently enrolled in our few dermatological studies. I am learning the study visit procedures so I can soon start to see them myself.
-Worked on the close-out procedures for one of our studies. Went through the regulatory binders and searched for specific paperwork that we will need to send to the sponsor for the close-out routine.
-Called patients who are on one of our surveillance studies (cold sore) and reminded them of their study obligations. I also took out their charts and gave them to J.T. so she can write an update in their source documents. I also completed their TC schedule and scheduled them for another one in 2 weeks.

Day 41: 7/28/2015
-Recorded the daily temperature log for the drug cabinet/freezer/fridge. Reset the thermometers so we can have an accurate 24 hour temperature range for tomorrow.
-Continued calling patients on our recruitment lists to screen for potential studies. I also used Tutenberg (a recruitment site from one of our sponsors) to pre-screen patients for our Austin location studies, and managed to schedule many of the patients on the list.
-Called patients on one of our surveillance studies and reminded them of their duties as a subject participant.
-Called Copernicus IRB to see the status on one of our Closeout reports for a recently closed study. I was informed that we submitted the wrong company form, and found the right one on the "S" drive and filled it out for R.L. to submit again. Scanned all relevant closeout documents and uploaded them to the "S" drive and also onto CC under "closeout documents."
-Scanned a previous study's IP Return Log for per sponsor request, and uploaded the forms onto the "S" drive so R.L. could access them from another site.

Day 42: 7/29/2015
-Recorded the daily temperature log for the drug cabinet/freezer/fridge. Reset the thermometers so we can have an accurate 24 hour temperature range for tomorrow.
-Continued calling patients on our recruitment lists to screen for potential studies. I also used Tutenberg (a recruitment site from one of our sponsors) to pre-screen patients for our Austin location studies, and managed to schedule many of the patients on the list.
-Called patients on one of our surveillance studies and reminded them of their duties as a subject participant.
-Began assembling closeout documents for two more studies (I am trying to have them done by Friday so me and R.L. can go to the storage and take the many boxes that we have lying around the office).
I will look through regulatory binders, server documents, and sponsor portals for necessary documents.
-I helped Ha.M. create an excel spreadsheet with February, May and June's physician reimbursement for all of their study visits. I sorted the compensation out depending on the physician oversight, consulting physician, and PI oversight.
-I called a recruitment office and spoke with their representative about the fees for their services (per H.M.'s request).
-Saw a patient at our dermatology clinic for their Visit 2. I assessed their eligibility based on their diary compliance, and randomized them on the EDC so I could administer the right study medication number. I went through the source doc with the patient and called the physician when their duties were needed (assessing the patient's application site etc.)

Day 43: 7/30/15
-Recorded the daily temperature log for the drug cabinet/freezer/fridge. Reset the thermometers so we can have an accurate 24 hour temperature range for tomorrow.
-Continued calling patients on our recruitment lists to screen for potential studies. I also used Tutenberg

(a recruitment site from one of our sponsors) to pre-screen patients for our Austin location studies, and managed to schedule many of the patients on the list.
-Called patients on one of our surveillance studies and reminded them of their duties as a subject participant. Then pulled their charts out for J.T. to document that we called them.
-R.L. had me look through two study's regulatory binders to see if we had sent back the study materials to the sponsor. R.L. received an email asking about a certain lot number of materials, and I looked in both the correspondence section and in the shipment return section. We found out when the supplies were shipped, and also which ones were never returned, and communicated the findings with the sponsor to clear up any issues.
-I saw a patient with S.C. today at our ENT physician's office. We went over the ICF and past medical history etc. There was also blood work that S.C. took, and we gave the patient a dust collection kit to take home, along with a diary that she will bring back to the next visit, after we find out if she qualifies or not.

Day 44: 7/31/15
-Today I recorded temperature logs for the drug cabinet/freezer/fridge, and reset the max/min values to have an accurate recording on Monday.
-Saw 4 patients with S.C. at our Dermatology office. Helped him fill out source doc's, dispensing study medication, and activating patient stipends.
-Called some patients from one of our studies to inform them (per sponsor), how to upgrade the software of their e-diary.

Day 45: 8/3/15
-Recorded the daily temperature log for the drug cabinet/freezer/fridge. Reset the thermometers so we can have an accurate 24 hour temperature range for tomorrow.
-Continued calling patients on our recruitment lists to screen for potential studies (Tutenburg/Studykik/CC).
-Saw patients with S.C., to get my used to each study visit in our Atopic Dermatitis and Actinic Keratosis studies.
-Went to Dr. P's office to have him sign documents for the study that he is PI of. Documents included source documents, lab results, conmed/AE pages etc.

Day 46: 8/4/15
IN FORT WORTH FOR MEETING WITH DR P.G.
-Time spent on proposal/thesis/relevant documents

Day 47: 8/5/15
-Recorded the daily temperature log for the drug cabinet/freezer/fridge. Reset the thermometers so we can have an accurate 24 hour temperature range for tomorrow.
-Continued calling patients on our recruitment lists to screen for potential studies.
-Continued to see patients with S.C. in our dermatology studies (Atopic Dermatitis, AK). Interacted with patients and learned what needs to be done during the specific visits involved in these studies. Today was a pretty busy day, so most of the morning and some afternoon was spent with these patients.

Day 48: 8/6/15
-Recorded the daily temperature log for the drug cabinet/freezer/fridge. Reset the thermometers so we can have an accurate 24 hour temperature range for tomorrow.
-Called patients on our dust mite allergy study who recently screen failed, and scheduled an

appointment time for them to come retrieve their ClinCard (compensation payment) and return their dust collection kit and their screening diary.
-Called patients on one of our surveillance studies and reminded them of their obligations as a study participant. Completed their TC visits on CC, and scheduled them for another TC two weeks from today. I also retrieved their charts and put the necessary documents needed for J.T. to record the visit occurred.
-Got H.M.'s signature for my thesis proposal form.
-Prepared for the weekly phone call that I will be having with a sponsor representative for our contraceptive study from Austin. I will be be collecting recruitment data, screening/enrollment data, and SAE/AE information from either CC, Danielle, or other sources, to answer any pertinent questions the sponsor may have about our progress.
-Spoke to J or around 30 minutes discussing previous data, and answering any other questions she had on the study. Also relayed pertinent information to Danielle regarding her (and the PI's) pending responsibilities etc.
-I am helping R.L. complete the Research Site Submission Forms for 3 of our sites, for a new upcoming study.
-Printed documents from various sponsor portals that needed to be filed in the regulatory binders.
-Filled out "site submission reports" that will be sent to the IRB for one of our new studies. It required filling out information about the PI/SubI/research staff, with appropriate contact information and addresses, as well as answering questions about the physical facility, as well as regulatory. I filled out 3 different forms (for the 3 different PIs) and saved them to the "S" drive, under their appropriate site.
-Helped S.C. enter in patient visits onto the paperCRF forms for one of our studies.
-Spoke with a representative of CRF-Health to track down a shipment that we made (e-diaries and other study materials). Received an email with pertinent information regarding the shipment supplies and date/tracking number. Once it was confirmed that the shipment had never arrived at the facility, we contacted other parties that may have been shipped the materials by mistake (sponsor facility etc). Will follow up with these parties tomorrow morning.

Day 49: 8/7/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-I helped the office with some regulatory documentation, regarding new studies.
-Helped perform basic visit specific elements with S.C.
-Helped recruit potential patients.

Day 50: 8/10/15
-Today I was at the Carrollton site helping M.E. Elena see patients during her SIV meeting. I helped her see 2 patients, processed their labs (centrifuge, separation, packaging, and shipping through FedEx), and input their visit info into the EDC.
-I called patients that are on our surveillance study and updated her charts and updated CC on what patients have been called, need to be called, etc. And filled it out in her charts.
-Filed paperwork from her filing bins into the necessary regulatory binders.
-Worked on closing out a study, by finding the necessary closeout documents on the EDC, IRB Portal, and in the regulatory binder. Submitted a PI Site Closure Report to the IRB in order to receive an IRB confirmation email.
-Went to main office during lunch to get signatures from site staff there, that the monitor at the SIV needed.

Day 51: 8/11/15

-Recorded daily temp log for the drug cabinet/freezer/fridge.
-Entered 2 patient visits into the EDC for one of our cold-sore studies.
-Saw an end-o f-study patient with S.C., and entered their information into the paper CRF.
-Started working on a EDC training for an upcoming study.
-Today we met our enrollment goal of 15 patients in one of our dermatology studies. It was a great relief since we got the company their bonus from the sponsor by randomizing that many patients. It was a hard run for me, J.T. and S.C.… that PAID OFF!

Day 52: 8/12/15
-Recorded daily temperature log for the drug cabinet/freezer/fridge.
-Transcribed patient chart data onto the paper CRF for one of our studies.
-Filled out the weekly Subject Enrollment and Subject Screening logs for two studies that we are supposed to update every week and send to the sponsor. Filled out the new information by looking up the study on CC, and seeing what new screened/randomized patients we have had since the last week's submission. Scanned them and sent them to the sponsor.
-Called a patient for his follow up phone call for one of our current studies. Just asking about his adverse events (if any), any new changes to his medications etc., and overall health since last visit. Then input the information onto the eCRF.
-Went to VHP to get a few signatures that we needed for FDF/1572s etc. Then sent the papers through FedEx, by putting them into a manila envelope, and fixing the sending label onto it. Scanned the original 1572s and saved a copy on the "S" drive, along with a printed copy in our Investigator binder.
-Replaced patient Adverse Events pages into their charts after being signed by the PI.

Day 53: 8/13/15
-Today I was sent over to our other Plano office to see 4 patients that are participating in one of our current studies. I am seeing the patients alone, and will be completing all visit elements, including entering the data into the EDC.

> -For each patient, I needed to logon to the sponsor portal for the E-diary and see their compliance with filling out the diary, taking their medications, etc.
> -During the visit, I followed the source documents and took vitals, asked about adverse events/new medications, assessed e-diary compliance and drug compliance, performed an EKG, took urine and lab samples, collected and dispensed new study medications, completed their visit on the e-diary (as well as on the e-diary portal), processed labs and shipped them using fedex.
> -After the visit, I entered their data from the visit into the EDC. I entered the new visit and input all relevant data into the EDC. I answered any queries that were given.

-Got a confirmation email from the IRB of one of our close-out studies. On Monday I submitted a final site closure report, and today we received the IRB's confirmation of the site close out. I logged onto the IRB's site and downloaded the IRB Confirmation Report, saved it onto the "S" drive, and uploaded the document onto CC under the "archived study" under study documents as a "closeout document."
-Alphabetized new patient information charts and faxed medical history charts in the filing cabinet on-site.
-I was supposed to have a call with one of our monitors for our Austin study, however she was unable to talk at our arranged time. We rescheduled for tomorrow morning, to go over screening/enrollment/randomization numbers etc.
-Came back to our Main site after lunch and helped organize our study documents that the monitors have been using the past two days. I also filed some site closeout letters into the Home Depot Boxes that are archived.

-I dropped off papers to be signed by Dr. P, since we will not be here tomorrow (we are going to Main Event at 11-4 for our birthday celebrations (Me, S.C., J.T., R.B.).

Day 54: 8/14/15
-Recorded the daily temperature logs or the drug cabinet/freezer/fridge and reset the values.
-Called patients on our surveillance study to remind them of their duties, and updated their visits on CC, scheduled their next visits, and updated their charts.
-Emailed doctors using their practice's EMR. Looked at a chart review that we made for an upcoming study, found their patients on the EMR, and "flagged" their respective doctors explaining the study and that we think their patient would be a good candidate. Sent them a short synopsis of the study, exclusion/inclusion, and asked them to email us back if they do not want us to continue pursuing the patient for the study.
-Saw 2 patients with S.C. today, one was a end-of-study visit, while the other was a visit 2 (post treatment). Both were at the dermatology clinic.
-Activated a clincard for a patient and approved their stipend, sent an email to Ha.M. to activate the card through the CC company.
-Entered the two visits that we saw today in the EDC. One study was in the eCRF, and the other was on paper CRF.

Day 55: 8/17/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge, and reset the thermometer values so we can get an accurate 24 hour reading tomorrow.
-Picked up a stack of signed documents from Dr. P's office, that we had him sign this weekend as the PI for one of our studies. Put the documents back into their respective charts.
-Entered 2 patient visits into the EDC for one of our current studies. Entered their visit from the source document, and input their diary information.
-I will be going to our other Plano site to see a patient by myself for one of our constipation studies. I will be filling out the source (visit 3), taking vitals, EKG, blood and urine samples, and sending the samples through FedEx express. I will also enter the information, along with the information of a patient that R.L. saw this weekend, into the EDC.
-Called a patient for his follow up phone call for our AK study. Asked about any adverse events, any deviation from the protocol, and any ConMeds since start of study. Recorded the conversation and updated his chart and CC.

Day 56: 8/18/15
-It is me and S.C.'s Birthday today!
-I recorded the daily temperature logs of the drug cabinet/freezer/fridge, and reset the thermometers values so we can get a new reading for the next 24 hours.
-I went through loose paperwork of archived and closed-out studies that we still have in the office, and sorted them into folders so we can take to the storage unit and store them in the correct boxes.
-Me, S.C. and R.L. are going to the storage unit where we have all of our archived studies and will be transferring 100s of boxes of study charts/investigator binders/ etc., to a new storage unit that is in the same building. Since we have a smaller storage unit now that barely fits the boxes that we currently have, we need to transfer all of the banker boxes/home depot boxes into a bigger storage unit.
-R.L. had me sign a delegation log for a new upcoming study. I will be a research assistant.
-Called patients from one of our media outlets that expressed some interest in joining one of our studies. Explained the study to them in more detail and went through eligibility questions to see if they were able to participate.

-Called 2 patients for their follow-up phone calls in one of our studies. Asked them about any adverse events, if they have added/changed/discontinued any medications since their last visit, and reminded them o their next appointment. Updated their charts and the eCRF.
-Began gathering close-out documents for one of the MDVI studies that is closing. When I came back from our other Plano site after seeing patients the other day, I brought back a box filled with study documents, and will be looking for site visit logs, subject screening/randomization logs, and sponsor close-out correspondence. I will scan these documents and save them to the "S" drive, so I can upload the documents to CC when closeout begins.
-Today we got a huge shipment of boxes for a new upcoming study. Me and J.T. went through the package list and checked off that we received everything. After, I had to clear out some space in the lab/storage room, to make room for all of our new supplies. I kept materials that we could reuse (screens, blood draw kits, pipettes, etc.) and threw away other things from older studies.

Day 57: 8/19/15
-I recorded the daily temperature logs of the drug cabinet/freezer/fridge, and reset the thermometers values so we can get a new reading for the next 24 hours.
-S.C. asked me to go to VHP and ENT to gather signatures from various physicians and PAs for our training log.
-Entered a patients source document onto the EDC.
-Logged onto VHPs Centricity portal to see if the doctors that I emailed last week regarding some of their patients had requested that we not reach out to their patients. After receiving no dissents, J.T. and I began calling patients to see if they would be interested in this new Diabetes study.
-R.L. asked me to look through regulatory binders and filing cabinets at the main office (she is at our Allen location), and try to find an original copy of the protocol signature page to upload to the "S" drive.
-Input patient information into the EDC, per sponsor request. Updated the EDC with patients ConMeds and Adverse Events.
-Prepared tomorrows charts by printing the proper source documents for tomorrows visits.
-Updated and faxed in one of our studies screening and enrollment logs to the sponsor.

Day 58: 8/20/15
-I recorded the daily temperature logs of the drug cabinet/freezer/fridge, and reset the thermometers values so we can get a new reading for the next 24 hours.
-Entered a patients source document onto the EDC.
-Went through closeout reports to see what boxes we can go ahead and store. Two studies will be closing out later this month, so I put those aside for when we can start collecting the closeout documents. There was one study that was already packed up in boxes that I needed to put back into the filing cabinet (since it is a 10 year follow up study).
-Called patients that we have gotten notifications over, and reminded them to complete their daily diary assessments for the studies that they are enrolled in with us.
-Logged onto our BMS Gateway portal to check subject compliance with their daily diaries.
-Finished the new VHP EDC portal training. I had 2 modules left over from a few weeks ago, and was able to finally get the computer to be compatible with the flashplayer. I printed the certificates and uploaded them to the "S" drive. I also printed them out and put them in my file in our companies training/certificates binder.
-Had my weekly telephone call with J from our contraceptive study. Discussed research progress etc.
-R.L. logged me into her email and asked me to send out emails to all of the CRA's and Monitors that are working with us on many upcoming studies. I emailed them asking about standard study start up information (about third parties/IRB/staff training/documentation etc.)

-R.L. asked me to log onto the different IRB websites and email the
-R.L. had me go through our company "S" drive and look for everybody's CV to see if they are the most up to date signature that we have. Now the sponsors request that the CV's are updated every year (instead of every two years). I wrote down the dates of all of our employees and doctors that we work with (PI's and SubI's) and took notice of the CVs that we need to get re-signed. I then looked on the "S" drive for the original copies of the updated CV's (the ones without signatures) and printed them for them to get signed again by the doctors/staff.

Day 59: 8/21/15
-I recorded the daily temperature logs of the drug cabinet/freezer/fridge, and reset the thermometers values so we can get a new reading for the next 24 hours.
-Entered a patient's source document onto the EDC.
-Filed study documents from our filing binds that needed to be put into the investigator binders.
-Logged onto various sponsor's portals to retrieve important study announcements, acknowledge their reading, save them to the "S" drive, and print them and place them in their respective study binders.
-R.L. tasked me with creating the source document for a new upcoming IBS study. I looked at the upcoming study's protocol, SIV slides, and eCRF guidelines to give me an idea of what needs to be on the source document. I also looked at a previous study we had with the same sponsor to see if I could retrieve anything of value towards the new SD.
-Sent in a new patient stipend.
-Learned how to work VHP's computer and log onto a new patient visit. Learned how to calibrate the spirometry machine. Learned how to administer the study dose to patients through the injection site.
-Looked at our source documents and compared them to the information that is currently in the EDC (to make sure that we are not missing any information for when the monitor comes on Monday).
-Saw one of our Dermatologypatients with S.C. (eczema 2) and randomized the subject. I transcribed the chart (source document) into the paperCRF after the visit.

Day 60: 8/24/15
-I recorded the daily temperature logs of the drug cabinet/freezer/fridge, and reset the thermometers values so we can get a new reading for the next 24 hours.
-I went through loose paperwork and sorted them into their respective regulatory binders.
-Saw a patient on their end-of-study visit, by myself. I coordinated the visit with the PI and approved the patients compliance and stipend.
-I filled out a few accelerated CVs or our current staff and PI's.
-I continued working on the source document for one of our upcoming studies, and will pass it by R.L. to see if it needs any adjustments.
-Continued to call patients to see if we can enroll them before the period ends (next week). I called back patients who we had previously left messages for.

Day 61: 8/26/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge, and reset their values.
-Gathered updated CVs that have been signed by the provider, scanned them onto the "S" drive, and filed them into the appropriate binders.
-Input two patients' charts into the EDC. One of the patients was a new patient (visit 1 screening), so I had to put in the medical history and ConMeds (which often takes a while longer than a normal visit).
-Helped Ha.M. prepare spreadsheets for the provider reimbursement for the months of April-June. I went through CC's notes on patient visits with their respective PI/physician oversight/and consulting oversight, and divided the compensation among the responsible parties. Created a spreadsheet from

this information and summed up all of the reimbursements owed to each of the physicians.
-Continued working on the source documents for one of our upcoming IBS studies. R.L. approved my visit 1 (screening) SD, and I will continue to work on the rest of the scheduled visits.
-Completed a Nasopharyngeal Specimen Collection video for one of our upcoming studies. I then signed the training log stating that I saw the video.
-I called many of M.E.'s patients to remind them of their study duties on one of our "surveillance studies".

Day 62: 08/27/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge, and reset their values.
-Filled out new study forms for H.M., for two sites that we will be initiating. Filled in the PI's information, and set up file folders for the two PI's so H.M. can present them with the documents to sign.
-Made an account with Dun&Bradstreet, and then searched our providers D-U-N-S number by inputting their information into the database and requesting the proper information.
-Went to Dr. P's office to get some signatures for study documents.
-Completed my weekly phone call with J, the monitor for the contraceptive study that we are doing. We talked about enrollment/screening numbers, run-in status, queries, protocol changes etc. She also gave me information on our sites status.
-Saw one of our AD (Derm) patients and completed their visit. I recorded their visit documentation (from the source document) into the paper CRF. I also spoke with Dr. D while in the office, and asked him for some signatures and some information on prospective study enrollments for two upcoming dermatology studies.
-Continued to call patients on our call lists and through our recruitment platforms.

Day 63: 08/28/15
-Today I was off of work, visiting relatives in New York.

Day 64: 08/31/15
-Today I arrived to work around noontime, since my flight came in this morning from New York. Although I was extremely exhausted, I came to work ready to make up for lost times. I was kept very busy. I initially came to the main office, where I helped Ha.M. reimburse physician stipends for their visits the last 3 months. I also helped recruitment calls.
-I was sent over to our other site in Carrolton, where I helped R.L. see a patient and prepare for the work that will need to be done this week. I helped file some free paperwork into regulatory binders, made new labels for new patient information (manila folders), made reminder calls to patients that are on various studies at the site, filled out confidentiality logs/screening&enrollment logs/ and IP return logs for a finishing study that have not been updated yet. (to do this, I had to go on CC and look at the study folder and see the patient list and visit summary. I also had to coordinate the information I saw on CC to the patient charts). I also had to organize these patient filed by what they were missing (i.e. if patient chart had a DL copy and if the patient medical records release form was ever faxed-and if it was, did we have a conformation etc). I also had to enter in a bunch of different study charts into the EDC's for their respective study.

Day 65: 09/1/15
-I was initially at Carrolton site today, but was asked to come back to another (main) site after lunch, to help with recruitment calls since J.T. will be out of town all week. There was a lot to catch up on at main, but I made great headway.
-At the Carrolton site, I did much of the same stuff that I did yesterday. In addition to all of this, I saw a

patient on my own, that was in our cold sore study. I completed their visit and approved their stipend. I also coordinated the physician assessment with the physician.
-I emailed two different sponsor representatives with information on our different PI's. H.M. had me send (and copy her) our PI's CVs and Licenses to one of our monitors so we could get the study up and going. I also needed to find CDA forms and forward them to another sponsor.

Day 66: 09/02/15
-Updated the daily temperature logs for the drug cabinet, freezer/fridge and reset their values for tomorrow's reading.
-Filed regulatory documents into archived study binders, per sponsor request. I also charted patient files (ConMed and Adverse Events pages) that needed to be signature by the PI. Once they were signed, I had to go into the archived banker boxes and put the papers in their respective patient's chart.
-I emailed some sponsor representatives, on behalf of H.M., sending them updated CVs (addendums) that showed their current involvements in therapeutic areas that we are currently being selected for.
-Continued to do recruitment calls (and taught A.C. how to properly manage recruitment calls.)
-Listened to the company's voice messages to take down any numbers that I may need to call regarding recruitment prospects, or names that I need to give the higher management regarding study related correspondence.
-Went through some study boxes and sorted out different study materials (lab manuals, source documents, patient information booklets etc) and put them back into individual boxes for easier organization.
-Processed labwork from an earlier patient that I saw today. I centrifuged the samples, separated the serum using a pipette into the appropriate vials. I updated a freezer log, where I will be keeping two vials of the serum, and sent two other vials to the sponsor.
-Scanned a CDA for Dr. Reddy and sent it to the sponsors representative.

Day 67: 9/3/15
-Today I began at main site, where I recorded my daily temperature logs for the drug cabinet, fridge/freezer. I also did the same when I was asked to go to the Carrolton site. -At main, I entered some patients charts into the EDC, and visited one of our dermatologypatients with S.C.. -I was sent to Carrollton early to help M.E. with patients and other pressing issues. I was supposed to help build a bookshelf, but when I opened it, I saw that it was cracked- so we have to wait for a new one to get shipped. -Here, I continued to organize the many new patient information charts that we have, making labels for them, and sorting them out into groups (depending on what each folder still needs, for example, a DL, a medical history release form, or a fax confirmation of request). -I helped M.E. with documents that needed to be sent to a monitor before a COV visit. I also needed to make a note to file (NTF) document clarifying who is affiliated with the site that we are trying to get the study for. -Disassembled study kits for a study that has just closed. I kept all of the still-usable materials (pipettes, needles, discs) that we will ultimately donate to a free-clinic. -Called patients on one of our "surveillance" studies, to remind them of their obligations as a participant. (apply study medication within 1 hour of feeling any symptoms, and to call our office to schedule an apt so we can see then within 24 hours of those symptoms). -Worked on completing/answering/resolving queries on different studies. I completed the sponsors requests by looking through the diary portals and through patient charts. -I filed some loose paperwork into regulatory binders. -I processed and packaged labs for one of our patients visits (collected blood cerum, and urine).

Day 68: 9/4/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.

- Processed labs for various patient visits, and sent them via FedEx. I centrifuged some blood samples (serum), and transferred urine samples to preservation tubes.

Day 69: 9/7/15
-Off for Labor Day

Day 70: 09/08/15
-Went to VHP to get some PIs signatures that we needed before our site monitoring visit occurred today.
-Prepared the monitors workspace by spreading out the necessary study binders and charts for easy access during her visit.
-Followed up with emails regarding a certain study. I was copied on the correspondence, and answered any requests that were made by study monitors. I scanned and sent over updated and signed DOA logs, and freezer temperature logs.
-I saw 3 dermatologypatients on my own, two were end of study visits, and one was a followup assessment visit. I collected their diaries, assessed their compliance, and coordinated the assessments with the physicians. I dispensed new diaries, filled out the Source Documents, and updated their visit on CC and on the EDC (both paper CRF and online EDC). I also approved their stipends through CC.
-I got patients charts ready for tomorrow by copying SD and putting them into the patient's charts.
-H.M. wanted me to help M.E. at the Carrolton site, so I left to Carrolton at lunch time.

Day 71: 09/09/15
-Today I started off in Carrollton to pick up a few documents that needed to be signed by the PI there. After picking up the signed documents, I made my way over to NTXFM (our Plano site) to see a few patients.
-At the Plano office, I completed two end-of-study visits with patients by myself. I made copies of the relevant source document, put it in their chart, and followed the SD during the visit as my guide. I took vitals, performed an EKG, collected the IP and diaries and assessed compliance, processed labs and urine specimens, and sent off the labs appropriately according to IATA guidelines. I also scheduled the Fed-Ex pickup. After the visits, I entered all of the visit details into the EDC.
-I drove back to main after seeing these patients, and R.L had me call some patients that needed to be called, either for study reminders, or due to some other pending issues.
-Saw another end-of-study patient at main, and entered the visit details into the EDC. S.C gave me another chart that he compelted earlier, and asked me to enter the information into the eCRF.
-I called patients that are on our surveillance studies and reminded them of their study responsibilities.
-I updated our "S" drive's collection of updated CV's, by scanning newly signed CVs that we have retrieved from the staff/doctors that had outdated copies.

Day 72: 09/10/15
-I began the day by going to VHP to get signatures on some FD forms.
-I entered in subject visit data into the EDC for S.C.
-I called patients on one of our surveillance studies.
-Made new charts for one of our studies by coping the visit 1 SD, the "left" source documents that consists of a progress note sheet, ConMed sheet, AE sheet, as well as the informed consent. I also printed SD labels to place on the charts.
-I printed out SD for a new upcoming study, and placed them in sheet protectors for when we file them away.
-I scanned documents that were recently signed by one of our off-site doctors, and saved them onto the

company's "S" drive.
-I completed an FDA 1572 sheet and accompanying FD forms for one of our upcoming studies. After making the forms on the computer, I printed them and went to VHP to get the signatures that were needed. I then scanned the signed copies to the "S" drive under the appropriate folder.
-I was sent over to our other Plano site, to see a patient during their 4th clinic visit. I took A.C with me to show her the office, introduce her to all of the employees, and to have her help me with this new protocol. It was a standard visit in regard to procedures (EKG, Vitals, Labs, etc). I then drove back to main to finish some pending duties.
-Prepared the Source Documents for tomorrows patients.

Day 73: 09/11/15
-I started my day going to NTXFM to see a patient for their EOS visit. The visit was supposed to be at 8 AM, but the patient had to call and reschedule or later in the day. I documented in the daily temperature log and reset the thermometer values. I was sent back to main, and helped with regulatory stuff for our new upcoming studies. My duties included retrieving documents, scanning them, and organizing them both on the "S" drive and in the regulatory binders. Around 12:30, I went back to NTXFM to see the patient that rescheduled from the morning. Her appointment was at 1. After setting up for the second time (getting the EKG machine, setting it up, getting the lab kits, logging onto the computer and to the EDC/portal, etc), R.L contacted me to let me know that the patient had to reschedule for Monday. Since I was already at NTXFM, I organized some loose paperwork found some other pending work that I could do. I went back to main to help with some of the work that I left before I went back to NTXFM. I updates S.C's, R.L's, and A.C's CVs to reflect some professional skills that were previously left out of their CVs.

Day 74: 09/14/15
-Off of work due to Rosh Hashanah

Day 75: 09/15/15
-Filled out an informed consent progress note in a patients chart, confirming that the patient was explained the study procedures/protocol, and understood their participation fully.
-S.C gave me a few charts to enter into the online EDC, and a chart to enter into the paper CRF.
-Signed up for a webcast investigator meeting for an upcoming study. I will be attending this "webcast" on September 18th.
-H.M asked me to fill out previous study enrollment numbers to send to a prospective sponsor. I needed to go back to CC and find the studies, count the number of patients screened vs. randomized, and filled out a spreadsheet which I then sent to her to forward to the sponsor.
-Saw a dermatology patient for their screening visit. I presented the informed consent form, answered any questions the subject had, and coordinated the assessment and physical exam with the physician. I dispensed the study moisturizer and explained how the subject should use it, administered a pregnancy test, and took the subjects vitals. I also assessed the patient's eligibility by going through the inclusion/exclusion criteria.
-I called patients who missed their daily diary assessments, reminding them of their obligation in the study and the importance of keeping up with their daily diary assessments.
-Helped S.C. answer and unanswered queries that are on one of our sponsor portals. I looked through charts to see any discrepancies that may need to be changed.
-Had R.L. sign a site closeout report and then scanned the document to upload it onto CC under closeout documents.
-Began setting up a new study regulatory binder for our 3 sites that will participate in this study.

-Made new charts (source docs) for various studies, and prepared patient charts for those who we will be seeing tomorrow.

Day 76: 9/16/15
-Today I called two SMS companies to talk about their services and pricing. We are looking to integrate SMS messaging to our patients on CC to remind them of upcoming appointments, in attempt to increase patient retention. We are also looking to use this service as a method of recruitment, by messaging our database of upcoming studies that may be of interest. I spoke with two representatives and compared the two company's pricing and utility. One of the companies can be integrated into CC, with CC already having developed a suitable interface, so this is more appealing to us.
-I helped H.M. with some provider reimbursements for the last two quarters.

Day 77: 9/17/15
-Began the day by scanning some CDA documents on the computer to be sent to one of our other locations, for the PI to sign and send back.
-Called patients on one of our surveillance studies, to remind them of their duties as a participant. To apply the study medication within 1 hour of feeling any symptoms, and to call our office to schedule an appointment within 24 hours of feeling any symptoms.
-R.L. gave me a list of study documents that I need to retrieve from an archived regulatory binder. Documents include CVs, FDA 1572, Accountability Logs, FDFs, and refrigeration/temp logs.
-Joined a teleconference investigator meeting for one of our upcoming dermatology studies. I viewed the conference on my monitor, while listening in on my phone.
-Gathered closeout documents from the regulatory binder, and begun to scan them to the "S" drive to save on CC for archived studies.

Day 78: 09/18/15
-We started the day going to IHOP to celebrate R.L.'s birthday.
-When I got back to the office, I recorded the daily temperature log for the drug cabinet/fridge/freezer, and reset their values.
-I scanned 2 documents signed documents for the TH005 study for H.W. and sent them to his email.
-Got some CDA forms signed by two of our PIs, and scanned them onto the "S" drive, then I forwarded the scanned copies to the study monitor for approval.
-S.C asked me to add some patient visits into the EDC, and I also needed to look for missing patient eligibility pages and protocol amendment pages to print for their charts (per sponsor request).
-Continued to work on closeout procedures for one of our studies. I scanned the required paperwork (Site visit log, screening/enrollment log, IRB closeout confirmation & letter, and sponsor end-enrollment letter).
-Continued working on setting up the regulatory binders for an upcoming study (printing ICF, 1572s, FDFs, IBs, IRB approvals, etc).
-Entered more information into the EDC after R.L. visited with the subject.
-Found a discrepancy between the source document and the EDC entry requirements, so I added a note to the source document for others to see in the future. (The vital signs are supposed to be taken before the spirometry- per EDC).
-R.L. asked me to stop by Dr. A site to pick up some signed regulatory paperwork.

Day 79: 09/21/15
-Recorded daily temperature logs for the drug cabinet/freezer/fridge.
-Collected patient record charts (manila folders) for our on-site monitors today.

-Finished scanning and uploading closeout documents for one of our studies. Documents included IRB closeout confirmation, sponsor end-enrollment email, subject screening/enrollment logs, site visit reports.
-Filled out abbreviated CV, FDF, and site information sheets for an upcoming study for three of our PIs. This required me going through the "S" drive to pick our relevant information regarding the PI's past professional and research experiences, and relevant certifications. I also needed to fill out FDF forms for each sub-I associated with each site.
-Saw two patients today (one visit 3/follow up, and one visit 1/screening). During the screening visit, I presented the informed consent on my own, and performed the necessary visit elements (pregnancy test, vitals, medical history etc). I coordinated with the physician on the physical exam and skin assessments. I completed the patient's visits on CC and approved their stipend, and scheduled them for their next visit.
-Received a signed CDA for an upcoming study, and scanned the document to the "S" drive, then send it to the study representative, while copying H.M.

Day 80: 09/22/15
-This morning I went to our other Plano office to pick up a signed CTA for one of our upcoming studies.
-When I got back to main, I responded to emails.
-S.C. had me answer queries in the EDC from one of our dermatology studies, and he also had me place certified letter receipts in each subjects chart.
-Updated a few staff members and a Sub-I's abbreviated CV, got them signed, and scanned them to the "S" drive.
-Downloaded and filled out Regulatory documents for one of our site's upcoming studies. I filled our FDFs, 1572, abbreviated CVs, and other investigator agreement forms. I also downloaded the IB and protocol, along with any amendments and previous versions to save onto the "S" drive.
-Built some banker boxes for storage purposes and helped H.M & H.M organize old company invoices and receipts.
-Printed off new versions of source documents and ICFs for an upcoming study.
-Spoke with 2 company representatives regarding possible SMS messaging with patient reminders and spoke with H.M over the two services.

Day 81: 09/23/15
-Out of the office for Yom Kippur

Day 82: 9/24/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-I also helped J.T. recruit patients for some of our current and upcoming studies.
-I performed a chart review to see any potential patients in our many clinic databases.

Day 83: 9/25/15
Investigator Meeting at the Hilton Anatole DT

Day 84: 9/28/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Worked on different studys' queries on the EDC, answering sponsor requests.

Day 85: 9/29/15
-Recorded daily temperature logs for drug cabinet/fridge/freezer and reset their values.

-Filled out a Delegation of Authority log by putting in the names and titles of different study personnel, and retrieved their signatures.
-Placed signed study documents into their respective patient charts.
-Scanned regulatory documents onto the computer to be sent to study sponsor representatives in order to initiate the study.
-Went to Carrolton site today to help M.E. with some study tasks, as well as to build a shelving unit for her office. I went through a couple of boxes that were just sent from the sponsor for a new initiated study. I went through the master packing list and organized the contents into our storage room. I also called patients and updated their PC visits on CC. I also filed many loose documents into their respective study regulatory binders.
-While at Carrolton, I set up an IPAD ERT for one of our new studies. There was a problem with the device, so I had to call the IT representative and re-configure the device with them on the phone. We remotely reset the device and after, I was able to complete the duties that I needed to do on the device prior to study start.

Day 86: 9/30/15
-Recorded daily temperature logs for drug cabinet/fridge/freezer and reset their values.
-R.M. had me fix some regulatory documents that were missing some information. I updated the forms and then went to go get signatures before scanning them and sending them back to the sponsor.
-I entered in a couple of visits into the EDC for two studies. One of the studies had an ECRF and the other had a paperCRF.
-I made a few more visit charts since we were out of new patient charts. I printed SDs from the "S" drive and set up the folders for upcoming visit 1a's.
-Added a new opportunity study to CC, adding the study information/sponsor/CRA/CRO/PI/etc.
-Helped H.M make a zip file for VHP providers, including their CVs/Licenses/NIH & GCP trainings. This will make it easier for us to initiate studies with future opportunities.
-Caught up with phone calls for patient recruitment. Called patients both on our call lists and who have recently tried to contact us regarding upcoming and current studies. Went through pre-screening questions with them to see if they are eligible for the studies, and if so, I scheduled them for their 1a screening appointment.
-Saw a dermatologypatient and went through the ICF with them. After going through the process, I began the study visit elements by going through the SD (pregnancy test, vital signs, medical history/ConMeds, inclusion/exclusion, etc) and also coordinated with the PI for the physical exam and skin assessment. I also dispensed the study moisturizer and diary, and explained to the subject how to complete the diary.
-Completed this weeks screening/enrollment logs for two of our dermatology studies. Every Wednesday, I fill out the forms with new information regarding patient visits/completion etc, and fax the forms into our study representative.

Day 87: 10/1/15
-Printed new temperature logs for the month of October, and filed the September logs in our ACRC temperature log binder. I recorded today's temperature for the drug cabinet/freezer/fridge.
- After emailing one of our PIs to see if they can fit in a patient in their schedule today, and getting their response, I had to call the patient that was scheduled today and had to reschedule them for another day. Since we have 3 other patients in a one hour block, the PI wasn't able to fit in this new study patient.
-Helped S.C. look in a study's EDC to see if a few subjects charts were entered and completed into it.

-Saw 3 patients today at our dermatology office. They were all visit 4 (EOS) visits. One of the studies required a pregnancy test, but other than this, the EOS visit was short and didn't require much besides safety questions and the physician's assessment. After the visits I entered the patients data into the EDC for the respective studies.

Day 88: 10/2/15

-I scanned many regulatory documents that needed to be updated after one of the physicians left the practice. The 1572s needed to be updated to reflect this change, and then needed to be signed. I saved the signed copies onto the "S" drive under their respective folders, and also put the hard/original copy of the 1572s inside the regulatory binders on site.
-I filled out a screening log for one of our studies, scanned it then sent it to the sponsor.
-There is a problem with one of our study's EKG machines. We need to upload each patient's EKG to the computer after the visit, however the EKG machine wont transmit the files onto the computer. I already re-installed the program and tried to troubleshoot it, however the files still wont transfer. I called the technical support line, and left them a message stating my problem, along with my site number and protocol number. Once I receive a response, and am able to transmit the EKG results to the sponsor, I will be able to complete the visit elements.

-The technical support representative gave me a call back and he walked me through some configuration setup. We ultimately were able to fix the reason why the EKG wasn't transmitting, and after I was able to send the EKG's from our recent patients to the sponsor.

-Trained one of our new interns
-Updated daily temperature logs
-Went to VHP to get some signatures from our PI and Sub-I. One of the PIs was not at the office yet, so I talked with one of his MAs and asked them to relay a message to the PI about a monitor today.
-Updated a few different study documents that will be sent into the sponsor. I needed to update a confidential subject identification log, and did so by looking at all of this particular study's patients on CC, and filled out the relevant information. I also filled out the weekly screening and enrollment logs for our two dermatology studies, that will be faxed to the study monitor.

Day 89 & 90: 10/5/15 & 10/6/15

-Updated daily temperature logs.
-Watched an EDC training video for an upcoming study, and signed a training certificate certifying that I was trained on the new EDC system.
-Saw a few patients for a new dermatology study. The visits required EKGs, blood draws, vitals, and urine collection. I filled out the source documents and entered in the data onto the eCRF. I completed their visits on CC and scheduled their next appointment.
-Called patients that are on one of our surveillance studies to remind them of their study obligations. I noted the call on CC, and pulled out their charts to be filled by J.T.
-R.L. had a talk with me about increasing my responsibilities with some of our studies. She wants me to start taking full responsibility of one of our studies, to practice me how to deal with every aspect (from patients to monitors, to EDC/IVRS/AE/SAE, ordering more IP and study supplies, etc. She wants to see my potential as a coordinator, and I look forward to working hard and showing that I can be trusted with the great responsibility of being a study coordinator.
-I watched a e-caselink training DVD to train me on the EDC/IWRS system that I will be using on the new study that was assigned to me.
-I created SDs for our new study (we have 23 patients scheduled for screening in these next 2 weeks) so we needed to make many charts.

-R.L. asked me to register for an investigator meeting that will be held in Las Vegas, Nevada on October 23. I will be representing ACRC (and one of our PIs), and will travel to this investigator meeting. The last IM that I went to was in Dallas, so this one will be a different experience for me. I registered by flight and hotel accommodations, and will be spending just over 24 hours in Vegas for the meeting.
-I helped H.M. with his monthly provider reimbursement spreadsheet. We went through CC and issued checks according to study visits. I made a spreadsheet with each providers role in the study visits, and their subsequent compensation.
-Sat in during a WebEx for the EDC program for one of our upcoming studies.
-Called patients of one of our surveillance studies to remind them of their study obligations.
-Went to VHP to collect regulatory documents that I needed to be signed. Once I retrieved them, I scanned them onto the computer, saved them onto the "S" drive, and put them into the regulatory binders. Some of the documents were needed for study-start-up, and I needed to send them to the study sponsor via email.

Day 91: 10/7/15
-Updated daily temperature logs
-Went to VHP to get some signatures from our PI and Sub-I. One of the PIs was not at the office yet, so I talked with one of his MAs and asked them to relay a message to the PI about a monitor today.
-Updated a few different study documents that will be sent into the sponsor. I needed to update a confidential subject identification log, and did so by looking at all of this particular study's patients on CC, and filled out the relevant information. I also filled out the weekly screening and enrollment logs for our two dermatology studies, that will be faxed to the study monitor.
-R.L. asked me to register for an investigator meeting that will be held in Las Vegas, Nevada on October 23. I will be representing ACRC (and one of our PIs), and will travel to this investigator meeting. The last IM that I went to was in Dallas, so this one will be a different experience for me. I registered by flight and hotel accommodations, and will be spending just over 24 hours in Vegas for the meeting.
-I helped H.M. with his monthly provider reimbursement spreadsheet. We went through CC and issued checks according to study visits. I made a spreadsheet with each provider's role in the study visits, and their subsequent compensation.
-Sat in during a WebEx for the EDC program for one of our upcoming studies.
-Called patients of one of our surveillance studies to remind them of their study obligations.
-Went to VHP to collect regulatory documents that I needed to be signed. Once I retrieved them, I scanned them onto the computer, saved them onto the "S" drive, and put them into the regulatory binders. Some of the documents were needed for study-start-up, and I needed to send them to the study sponsor via email.

Day 92: 10/8/15
-Today I took the day off to work on my practicum report.

Day 93: 10/9/15
-Went through an IWRS training for an upcoming study.
-Helped S.C. to answer queries since we had an in house monitor today. I sat with the monitor and made a list of duties that needed to be done before she left for the day. I called patients to confirm their ConMed and AE information (only on patients that information was missing or incomplete). Overall, the monitoring visit went well.
-Processed labs from some screening visits throughout the day. This included centrifuging the blood samples, filling out requisition forms, and preparing shipping materials for FedEx to pick up.
-Entered many source documents into the EDC system. (from various different studies).

Day 94: 10/12/15

-Recorded daily temperature logs for the drug cabinet/freezer/fridge.
-R.L. is at our other office today, and she needed me to get signatures from one of our PIs before he left the office this morning. When I got to the office, I went to get the charts and regulatory documents signed by the PI.
-Called patients that are currently on a "run-in" period in one of our new studies. I am keeping up with their e-diary completion, and if they miss more than a day, I need to call them to remind them of the importance of completing the diary entries every day (because if not, they can be screen failed).
-Made new patient charts for today's visits. This included printing source documents, medical history forms, and ICFs.
-I needed to call the medical monitor for one of our studies since we submitted an EKG last week that came ended up flagging an alert to the sponsor. We received the alert and now we need to see if the sponsor wants us to discontinue the subject from the study (screen fail) or if they want us to just refer them to a specific doctor, and continue them with the study.
-Called patients on one of our surveillance studies to remind them of the study protocol.
-Saw a patient for their screening visit (visit 1) for one of our new dermatology studies. I went through the ICF and answered any questions that the patient had over the study. The study was interested in participating, and after she signed the form, I began going through the study procedures:

-Went through Inclusion/Exclusion criteria
-Vital Signs/EKG/Blood Draw (processed labs later in the lab)
-Went through medical history and any ConMeds
-Coordinated with the physician the physical exam
-Set up the subject number and taught the patient how to complete the e-diary
-Entered visit information into the EDC

-Uploaded a patients EKG and filled out a EKG submission form with the patients screening number on it, and sent it to the sponsor representative (who will get the EKG analyzed by the lead medical monitor) and any significant findings will be reviewed

Day 95: 10/13/15

-Recorded daily temperature logs for the drug cabinet/freezer/fridge.
-Called patients on one of our surveillance studies to remind them of the study procedure and their study duties.
-Called a few patients that needed to be rescheduled, either because we won't have the appropriate staff at the location during their appointment, or because the PI/Sub-I won't be present during the appointment time.
-Input a new patient stipend to be approved, and collected study supplies and completed the EOS visit on the e-diary of a subject who decided to withdraw from a study.
-Began checking all of our close-out/archived studies, to see what we can take to storage. I filled out the inventory checklist form, and made sure that we had copies of all the relevant documents scanned and uploaded onto CC. (documents include: IRB closeout letter, sponsor end-enrollment email, study visit log, screening/enrollment logs, final site status report).
-Sent in the EKG and filled out the EKG Form for a study that requires us to send in the EKGs to the sponsor.
-Filled out a DIF (data inconsistency form) and faxed it to a central laboratory that is processing labs for one of our studies. There was a discrepancy between the collection time on the specimen and the collection time on the requisition form, so I had to clear up the correct time on the DIF.

Day 96: 10/14/15
-Went through an IWRS training for an upcoming study.
-Recorded daily temperature logs for the drug cabinet/freezer/fridge.
-Helped S.C. put in additional information in certain patients ConMed forms on the EDC system.
-Contacted one of our study sponsors after we received a query. I was forwarded the email, and responded with answering the query, and also told the monitor to start contacting me on further issues/queries. Since I have more responsibility on this study, I will be the point of contact regarding regulatory issues and other study aspects.
-Organized a regulatory binder that we just got in the mail today. We had a lot of loose-leaf paper that we have been waiting to file once we got the reg-binder.
-R.L. had me call Covance and ask them for a subjects lab results that were missing from their chart. I looked through the patients chart to find the requisition form and the information I needed to tell the support representative to find the correct lab report to send.
-Updated and emailed screening & enrollment logs for one of our dermatology studies to the sponsor.
-Saw a patient for their second visit. In this visit, we needed to measure their underarm sweat in order to randomize them into the study. They needed to sweat a certain amount of weight in a certain specified time period. Me and S.C. filled out the SD and carried out the visit elements. This was exciting since it was our first visit 2 for this study.
-Changed the toner in one of the office printers.

Day 97: 10/15/15
-Today I went to Fort Worth today to do some research for my practicum report in the UNT HSC Library. I checked out a few great books that gave me a new angle to approach my report. I also met with Dr. Gatch to get his signature on my Intent to Defend form.

Day 98: 10/16/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Made recruitment calls
-Went to Carrolton to help R.L. see a patient while she met with the PI there and the sponsor representatives during an SIV visit. I performed an EKG, vitals, asked source document questions about the study medication, and collected both the E-diary and any left over IP. I then entered the visit elements into the EDC.
-After working with R.L. in Carrolton, I had to come back to main to drop off some regulatory binders, and I also had to pick up some supplies that we will be using this weekend at our Health Fair booth. Me and J.T. will be working on Saturday at the health fair, giving out prizes and giving people information about ACRC Trials and possibly volunteering to be in a future study.

Day 99: 10/19/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Made some extra source documents for one of our studies today. We have 7 new patients that will be coming into screening today.
-Saw a patient for their visit2 (baseline/day1) visit. I went through the SD with them, and filled out any required data. I took vital signs, and took a gravimetric assessment of their underarm sweat. I used the study scale to measure the exact amount of perspiration experienced in 5 minutes (under each arm), and made sure the subject met the inclusionary criteria and randomized into the study. After, I completed the EDC and filled out the IP dispensing log.
-I began working on closeout documents for a study. I searched through the regulatory binder, and on the IRB webpage, to find all necessary documents to scan onto CC for proper closeout procedures.

-I filled up a regulatory binder for an SIV that we have next week. I needed to put in all relevant documents (regulatory etc), and print off any ACRC credentials (CV/License/Certifications).
-Requested new patient stipends to be approved.
-Had to disable a subject from their E-diary, after they withdrew consent from one of our studies.
-I did EDC training and E-diary training for one of our new dermatology studies. I had to take 2 quizzes after watching training videos, to activate my access.

Day 100: 10/20/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Saw patients with the other coordinators, and helped them with visit specific elements, documentation, entry into the EDC, and completing patient visits on CC.

Day 101: 10/21/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Filled out DOA logs for an upcoming study. The sponsor is coming to our site today, and needs these logs updated in the regulatory binder, in order to initiate our site.
-Screen failed 2 patients from one of our new studies, and updated the e-diary to reflect their screen failure, and also updated the EDC.
-We had a SIV today at Main, and I sat in during the meeting, learning a lot about the operating procedures and protocol of the study.
-Went to Carrolton, to help M.E. with some regulatory documents, and also to pick up some important documents that we needed at Main.
-After going to our Carrollton site, I went to our other Plano site to get a signature from Dr. A (to send to the sponsor, since the data was misinterpreted). I also needed to speak with the office manager to find a suitable time for the Dr. to sit in during a teleconference for a new upcoming study.
-When I returned to main, I had to fill out and submit the weekly screening and enrollment logs for one of our current studies.
-Answered important emails regarding study-start up documents and other ongoing study documents. I corresponded with the monitor and sponsor representatives to clear any pending documents, and to ensure that we are up to date on our study requirements.

Day 102: 10/22/15
-Went to Fort Worth today to speak with Dr. P.G. about my practicum report.

Day 103: 10/23/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Saw patients on our various studies, performing visit specific elements (vitals, EKGs, processing labs, coordinating with the physician for their assessments with the patients, etc.)

Day 104: 10/26/15
-Today I completed NIH GCP training and printed a certificate for my records. I will need this certification for all future studies.
-I completed various sponsor EDC/IWRS/Portal trainings and got access to multiple studies.
-Answered emails from monitors, regarding regulatory document submissions, and query resolutions from various studies.

Day 105: 10/27/15
-Updated the daily temperature logs for the drug cabinet/freezer/fridge.

-Saw a patient for their visit 3 (week 1) visit, for one of our dermatology studies. I filled out the source document, and transferred all information into the electronic EDC. During the visit, I collected the patient's vital signs, assessed their compliance via their electronic diary submissions, and performed a gravimetric assessment for their axillary hyperhidrosis.
-I confirmed my itinerary for an upcoming investigator meeting in Houston, TX for one of our upcoming dermatology studies.
-I filed some loose paperwork into the regulatory binders for a few studies that we are expecting monitors for.
-R.L. had me go to our Carrollton site towards the end of the day to see a patient. I evaluated the patients dosing diary and coordinated the physical exam and assessment with the physician. I also worked on filing regulatory documents, and also answered some pending queries regarding some study patient lab results.

Day 106: 10/28/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.

Day 107: 10/29/15
-Updated daily temperature logs for the drug cabinet/fridge/freezer.
-Worked on completing requests by the monitor who was in house yesterday. There are a few documents I need to fill out in the regulatory binder, and a few patients that I need to call for an unscheduled visit to re-check their lab values.
-Sent in weekly screening and enrollment logs for a study that we are currently wrapping up.
-Went to the Carrollton location to get a few documents signed by the PI. I also picked up a patient's chart so that I can enter the visit elements (that I completed yesterday) into the EDC. I also picked up a box that had some upcoming study training supplies (nasopharyngeal swab training).
-Sat in on a Webinar for IWRS and EDC training for an upcoming CIC study. I gained access to the system and got username and set up a password.

Day 108: 10/30/15
-Today I was out sick.

Day 109: 11/2/15
-Printed new temperature log sheets for the month of November. I took down the October temperature logs and filed them into the ACRC temperature log binder for future reference. I recorded the daily temperature for the drug cabinet/freezer/fridge.
-I checked on my emails from last week and the weekend, and attended to requests that I was unable to attend to while I was gone on Friday.
-Send an original PSP for an upcoming study by FedEx, and filled out an airbill and packaged the document, made a copy for our regulatory binder.
-Filled out some regulatory documents for an opportunity study. I filled out feasibility questionnaires for 4 of our PI's, and filled out a 1572 for one.
-Saw a patient for their screening visit. The patient ended up wanting to take more time thinking about participating in the study, so I gave the subject a copy of the unsigned ICF so they could take it home and read it again by themselves.
-Made an excel spreadsheet for one of our studies, to keep track of which subjects need repeat labs/ekg/etc. We can now update this excel spreadsheet with any pending labs or procedures that need to be done so the patient's chart and study participation can be UTD.
-Updated our EKG machine to reflect daylight savings time, and filled out a form (& emailed it) to the

sponsor, confirming our EKG unit and that it has been updated to the correct time.
-Filled out EKG forms and transmitted EKGs through the ELI-Link software, and sent them to the sponsor.
-Updated the EDC by adding 3 patient charts into it.

Day 110: 11/3/15
-Updated the daily temperature log for the drug cabinet/freezer/fridge.
-Went upstairs to Innovative Dermatology to get a signature from one of our Sub-Is. Once I got the document, I scanned it, along with some signatures that I obtained yesterday, and I send them to one of our monitors so we can begin an upcoming study. Documents that I scanned and sent include: Debarment Certification Forms, Financial Disclosure Forms, 1572s, and protocol compliance statement pages.
-Completed a follow up phone call for one of our studies. I called the subject, and asked them if they have had any adverse events or reactions since their last (final) study visit in clinic, since the stopped taking the product. The patient reported that all was perfectly normal, so I filled out the source document and approved the patient's stipend.
-Completed ERT DIARYpro training session and qualification exam, and received access to the EPX/ERT online EDC form, for one of our new influenza studies.
-Helped R.L. collect and submit pending regulatory documents. I scanned the signed documents onto the "S" drive, and printed out a copy of most of the documents so we can have it on site. I corresponded with the monitor and CTA of various studies to finalize all of the documents that I was sending.
-Went to Carrollton site to pick log in a drug shipment, and put it in the correct area.

Day 111: 11/4/15
-Updated the daily temperature logs for the drug cabinet/freezer/fridge.
-Made new charts (source docs) for one of our studies. We are seeing 6 patients tomorrow (screening visits) and needed new charts for them. The charts included the source docs, informed consent forms, progress notes, ConMed and AE Pages, and medical history pages.
-Made recruitment calls for our upcoming studies.
-Called patients that are on one of our surveillance studies, reminding them of their study obligations. I pulled out the source documents for these patients, and had J.T. write a progress note of these actions.
-Began working on collecting closeout documents for one of our off-site studies. I went through the regulatory binder and scanned relevant documents, and also logged onto the IRB portal to find IRB closeout confirmations.
à(Documents include: IRB Closeout Confirmation, Site Closeout Report, Screening/Enrollment logs, Site Visit Log, Sponsor Closeout Letter)
-Sat through a Protocol Training Webinar for an upcoming influenza study for U.S. Sites.
-Updated and sent screening and enrollment logs for one of our studies. I sent the logs to the study sponsor, as required every week.
-I sent wet-copies of a compliance page to the sponsor, as requested. I filled out a FedEx airbill, and packaged the document with a cover page, referencing the study.

Day 112: 11/5/15
-Today I went to our other Plano site to work with A.C. We screened three patients and randomized two more. We both worked together during the visits, each conducting a different part of the visit, in order to make the patient visit go by smoothly and swiftly. (While I did the informed consent form, A.C. would get the study kit and the documentation ready. I would process the urine specimen and perform the drug screens while A.C. would do the EKG and draw blood, etc.)

-After seeing these 5 patients, I was sent to the Carrollton site by myself to see a patient. I got the source document ready and conducted the study visit with the patient. I also coordinated with the PI, when they would need to complete their assessment and physical exam.

Day 113: 11/6/15
-Today I worked a half-day at Main, helping randomize subjects into one of our current visits. I left for Houston to attend an Investigator Meeting for an upcoming Actinic Keratosis study. Tomorrow, I will be joined by one of our PIs at the meeting.

Saturday 11/7/15: In Houston for an Investigator Meeting.

Day 114: 11/09/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Updated the Master Patient Log for one of our studies, filling out the log with the patient's name, address, DOB, phone number, initials, and screening number. This is used for situations where the FDA or sponsor needs to reach out to the subjects, in case there is a SAE or other event that must be communicated with the subjects after their participation in the study has ended.
-I created an ACRC Trials CV for a new employee that just joined our team. I will take their normal resume/CV, and import all of the information onto our company template, so we can have a CV that can be put into the regulatory binders.
-Made ICF binders for one of our closeout studies. I went through all of the patient's charts, and took out the ICF forms, along with the ICF progress note forms. These will be placed in a binder, and kept in storage with the other regulatory documents.
-Finished uploading closeout documents for one of our studies. I needed to look through the regulatory binder to find certain documents to upload onto CC, to complete the closeout/archiving SOP. Documents include: Subject screening/randomization log, monitor site visit log, sponsor end-enrollment email, final site status review and IRB closeout confirmation/approval.
-I saw a patient with R.L. for their screening visit. I went through the ICF with the patient, and they decided to join the study. I took the patients vitals and performed an EKG. I then took the patient to the onsite lab to get their blood work done. After collecting the blood work, I came back to our office and processed the labs (centrifuge, etc) and packaged the labs up to send through FedEx. I filled out all necessary parts on the source document.

Day 115: 11/10/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Signed a DOA document for a study that we will be initiating today, at main. The monitor is here and we will be doing a SIV once everyone arrives to work.
-I sent out EKG reports for one of our studies to our medical monitor. After each EKG that we take, we need to upload them to the computer, and email the EKG to the sponsor, so they can interpret the EKG and alert us on any findings.
-I called LabCorp to request TSH results for 3 patients that we have yet to receive.
-Worked on gathering study start-up documents for a site qualification visit that we will have later this month. I went on the "S" drive to retrieve site calibration records, current staff CVs/Licences/GCP & IATA training and certifications, along with a site clinical research experience table.
-Our whole team practiced nasopharyngeal swabs on eachother in order to complete the training for an upcoming influenza study that we have.

Day 116: 11/11/15
-I took the day off today to work on my thesis.

Day 117: 11/12/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Entered in patients charts onto the EDC portal.
-Sat through a WebEx training for the Sofia Analyzer, a device that we will be using in one of our upcoming studies to process labs.
-Sat with one of our monitors today for a SIV/training. We went over the protocol and other reporting procedures (SAE, etc.) Signed training documents and the DOA for the study.
-Saw 2 patients today for one of our Dermatology studies. Both patients were follow up visits. I collected and re-dispensed IP, and wrote down all relevant visit elements in the source document. I also put in the visit information into the EDC.
-Updated IP master logs.
-Filled out study start-up regulatory documents for an upcoming study. I saved the filled out documents onto the "S" drive, and printed the documents to have the PI sign today.
-I interviewed H.M. for my practicum project. I asked her questions to get a better understanding of how a clinical director/manager views their role in a study.

Day 118: 11/13/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-I called patients on one of our surveillance studies.
-Printed new source documents for various studies.

Day 119: 11/16/15
Today I took the day off to work on my thesis.

Day 120: 11/17/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Saw my first patient (screening/baseline visit) for a new study that I will be the lead coordinator. I went through the ICF with the subject, and once the subject signed it, I went through all of the visit elements (vitals, medical & medication history, inclusion/exclusion criteria, physician skin assessment, etc). The patient randomized and I dispensed the IP to them, and instructed how to apply it. After the visit I completed the SD, and transferred all of the information to the CRF.
-Trained on Adverse Event Reporting, ICH GCP, Inform 6.1, and Privacy Protection for access to an upcoming study's EDC. I saved and printed off the training completion certificates, and put them in the regulatory binder and also sent them to our monitor, so she could give me access to the study portal.
-Input other patient information into the EDC.

Day 121: 11/18/15
-Started the day at our other Plano location, to see a patient for their follow up (Week4) visit. I performed all study elements (vitals, drug accountability, IP dispensation, lab processing & sending, etc.) I then put all of the Source Document information into the EDC. After this patient appointment, I went back to Main office and helped with study visits and regulatory work. I went around the medical building to our various PIs and SubIs, and got their signatures, then scanned them and sent them to our monitors who are trying to initiate our sites.

Day 122: 11/19/15
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Made source document charts for one of my studies, since we are going to start seeing an influx of

patients into this study.
-I helped S.C. see patients today for one of our dermatology studies. There were many patients, most of them follow-up patients, so we had a busy morning/afternoon. I helped him put the information into the EDC, and helped him process labs.
-Went through lab reports that have been reviewed by the PI, and made a spreadsheet that lists what subjects need to repeat and recheck labs before their next scheduled visit. I called the patients that needed new lab results, and scheduled them before their next study visit.
-Entered a lot of patient charts into the EDC for their respective study. Updated all of the Screen Failures on the EDC as well.
-Had a meeting with R.M. about putting me on a few more studies as a primary coordinator. I will be in charge of most dermatology studies that we have. I was delegated many more responsibilities.

Day 123: 11/20/15
-Updated the daily temperature logs for the drug cabinet/freezer/fridge.
-Went to VHP to get one of our Sub-I's signatures on a few regulatory documents. These are the last pending documents that I needed to scan in and send to the monitor.
-Saw a patient for their week 2 treatment visit. It was a relatively short visit, consisting of vitals, application site assessment, and gravimetric assessment. I filled out the subjects IP accountability log, checked compliance, and re-dispensed IP to the subject. After the visit, I filled out all of the source document and uploaded the information onto the eCRF.
-I left main to go to our other Plano location, so I could get some signatures from the PI, and also to put away a few shipments of new study supplies (kits, diaries, etc.,) in neatly in our office.

Day 124: 11/21
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Did some more EDC/Portal/IWRS trainings for some upcoming studies. After the trainings, I needed to print the certificates and send them to one of our monitors, so I can be included in the delegation log of the study. I also needed to perform a skin-prick test for an upcoming ragweed study, where I will need to observe the allergic reaction that a person has against Histamine, glutamine, and other danders.

Day 125: 11/22
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Called patients that are on one of our surveillance studies, reminding them of their study obligations. I pulled out the source documents for these patients, and had J.T. write a progress note of these actions.
-Processed labs from some screening visits throughout the day. This included centrifuging the blood samples, filling out requisition forms, and preparing shipping materials for FedEx to pick up.
-Entered many source documents into the EDC system. (from various different studies).

Day 126: 11/23
-Updated the daily temperature logs for the drug cabinet/freezer/fridge.
-Conducted 3 baseline visits today for one of our dermatology studies. During this visit, I performed a gravimetric assessment to measure the subjects axillary sweating, to see if they meet criteria to become randomized today. I also performed vitals, asked pertinent questions regarding medical & medication history, and coordinated a physical exam and axillary assessment with the physician. Two of the three subjects met criteria, and I dispensed IP to them, and recorded the dispensing in the master IP log. I also activated clincards for each of the patients who came in for their second visit. After, I updated the source documents and eCRF.

-The monitor for one of our studies was in house today. I worked with the monitor to make sure that all of our documentation and study

Day 127: 11/24
-Updated daily temperature logs for the drug cabinet/freezer/fridge.
-Created new source documents for our new and upcoming studies. We are beginning to see a large influx of new patients come in to screen for our studies, and this requires that we have many source documents to keep up with the new patients.
-I saw my dermatology patients for their follow up visits, and documented all necessary visit elements onto the source documents. I then uploaded all of the source information onto the eCRF.

Day 128: 11/25
-Updated the daily temperature logs for the drug cabinet/freezer/fridge.
-Saw patients in our dermatology clinic who were coming in for follow up visits. Because of Thanksgiving break, we needed to see all of our Thursday and Friday patients on Wednesday, to make sure that they all stay in-window. It was a very busy day. I performed most visit elements (ICF, vitals, EKGs, dispensation of IP, etc.) and had to enter in the source document into the EDC.

Day 129: 11/30
-Updated the daily temperature logs for the drug cabinet/freezer/fridge.
-Saw a patient this morning, who came in to have their blood pressure rechecked, to see if the subject would be eligible for one of our studies.
-I saw a patient who came in for a screening visit for one of our dermatology studies. Since the patient still had to go see their PCP after this appointment, and there was a possibility that the patient was going to be prescribed a medication that requires washout, we decided to see the patient later today, after their PCP appointment, to see if the patient needs a washout or not. J.T. will be seeing the patient later today, since I will be in Fort Worth, meeting with Dr. G.
-Put in various signed documents into patient charts. Some of these documents include lab reports, signed by the PI with their assessment, EKG results, and interpretations.
-Went to Fort Worth around noon to speak with Dr. G about my thesis. I will be submitting my final draft to all of my committee members tonight.