A Comparative Analysis of Recruitment Methods used in Randomized Controlled Clinical Drug Trials

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CHAPTER I

INTRODUCTION

This practicum report and internship project was completed during a 7-month period at North Texas Clinical Trials, LLC, Fort Worth, TX. The site focuses on conducting clinical trials associated with psychological and central nervous system disorders. Currently, the site is conducting clinical trials for the treatment of Major Depressive Disorder, Tourette Syndrome, Postpartum Depression, and Essential Tremor.

Clinical trials are a crucial part of any drug development process. Pharmaceutical companies conduct clinical trials to demonstrate the safety and efficacy of investigational drugs or medical devices. However, the reliability and validity of clinical trials depends on the successful recruitment of subjects. According to National Institutes of Health (NIH) nearly 80% of clinical trials fail to meet their subject recruitment goal within a forecasted timeframe.[1] Hence, subject recruitment is an essential aspect of clinical trials.

The overall goal of this project was to evaluate the effectiveness of subject recruitment methods used in Randomized Controlled Trials (RCTs) focusing on Major Depressive Disorder and Postpartum Depression studies. Recruitment methods utilized in these trials were examined for their effectiveness in terms of recruitment return, including the number of subjects enrolled and the number of subjects randomized in the trial.

CHAPTER II

RECRUITMENT METHODS USED IN RANDOMIZED CONTROLLED CLINICAL DRUG TRIALS

Background and Literature

For decades, the US Food and Drug Administration (FDA) has defined and regulated the route of drug development and marketing approval. If a candidate drug appears promising in pre-clinical studies, a drug sponsor or investigator can submit an Investigational New Drug (IND) application. After approval of the IND, the investigational drug undergoes Phase I, II, III trials, and if demonstrated safe and efficacious in the intended population, the sponsor can then submit a New Drug Application (NDA) to the FDA. After final approval, the drug is further studied in phase IV studies, such as post-marketing surveillance studies.[2]

In the United States, new drug takes an average of 12 years to progress from preclinical testing to approval, in comparison, bringing a medical device to market takes an average of 3 to 7 years.[3] A recent study suggests that the cost of development of medical devices is in millions of dollars and the cost of bringing a new drug to market can be in excess of $1 billion.[3] Therapeutic area and phase of a clinical trial are the important determinants of clinical trial cost. On average, respiratory system, pain and anesthesia, and oncology clinical trials are the most expensive.[4] There are multiple factors that impact clinical trial cost; patient related costs such as recruitment costs and screen failure costs; site costs such as startup fees, IRB (Institutional Review Board) fees, close-out fees, and labor costs; miscellaneous costs such as travel, technology solutions, and regulatory filing.[5]

Based on the trial design, clinical trials are differentiated as observational or experimental. In observational studies, researchers observe but do not intervene or randomize participants. Observational studies can be analytical or descriptive. Analytical studies look at the relationship between an outcome and a variable. For example, investigators may observe a group of older adults to learn more about the effects of different lifestyles on cardiac health. Descriptive studies describe demographics, etiology, disease history or treatment history without determining causality between a variable and an outcome. For example, retrospective study of multiple patients with the same injury or treatment. In experimental studies, such as Randomized Controlled Trials (RCTs), researchers assign participants to a treatment or a control group.[6]

Randomized Controlled Trials are widely accepted as the gold standard for investigating the efficacy of interventions including pharmacological interventions. RCTs are studies in which participants are randomly assigned to two or more different study groups. One study group uses treatment or intervention being tested while the other group is provided with an inactive placebo, control or comparative treatment.[7] Along with randomization, blinding is also used to avoid bias in study treatment. A study can be double-blind, single-blind or open. In double-blind study neither the subject nor the study investigator knows which treatment has been assigned. If only the subject or the investigator is blinded to the treatment, the study is called single blind. A pharmacological study without blinding is called an open label study. Double blinding has been the preferred approach, particularly for placebo-controlled trials while open label studies are conducted for getting information on long term safety and tolerability of potential new drugs.[8]

There are different methods for recruitment of subjects in clinical trials including media (i.e. television, radio, newspapers), physician referrals, recruitment letters, flyers, and internet. Some methods prove more effective than others, specifically in certain populations. Some of the studies need specific population characteristics and so population specific advertising is necessary for recruitment. For example, a 19-year-old patient is probably more likely to search social media sites, where a 70-year-old patient may find information in a newspaper.[9]

Physician referrals play a pivotal role in clinical trial recruitments. It is reported that more than two third of respondents would be very or somewhat likely to participate in a trial if their doctor recommends it.[10] A physician can review the medical history of a subject and can recommend whether a subject would be eligible for the study as per the inclusion and exclusion criteria. All social media platforms such as Facebook, Twitter, Snapchat, Instagram have the potential for subject recruitment, but Facebook is most widely used in the healthcare industry. With more than 2 billion monthly active users, Facebook can target a study specific population that is interested in a particular clinical trial.[11] Clinical trial portals are new information technology tools designed to facilitate subject recruitment in clinical trials. Potential subjects usually find these portals while searching for more information about their health and learn about new trials they might be eligible for. Some portals allow subjects to create a profile for the type of study they are interested in, allowing researchers to easily match potential subjects to suitable clinical trials.[12]

Krusche A. *et al.* (2014) examined the effectiveness of recruitment methods used in 'The staying well after depression randomized controlled trial' and concluded website advertising as the most effective recruitment method in recruiting the highest number of randomized participants.[8]

Furthermore, Shere M. *et al*. (2014) reported a significant difference in recruitment for clinical trials in pregnancy after the intervention of social media platforms.[13] Statistical analysis done by Beaton S. *et al*. (2010) of the efficiency and cost of recruitment methods used in the RCT evaluating outcomes of a group and individual diabetes education reported that, a combination of mail and phone call recruitment was the most successful method.[14] The study conducted by Baquet CR. *et al*. (2006) suggested serious gaps in efforts to recruit racial/ethnic minorities and residents of rural regions in clinical trials. Their findings suggested scarcity of recruitment efforts in rural settings, among racial minorities, and among lower socioeconomic groups.[15]

A number of factors affect the recruitment of subjects in clinical trials, some of which are universal across all clinical trials, while others arise due to the characteristic of a particular disease, or the design of a trial.[16] Increasing study complexity and eligibility criteria for clinical trials is one of the factors contributing to poor recruitment and retention rates. Sometimes researchers overestimate the pool of eligible candidates which may result in lack of an appropriate recruitment plan and extension of the recruitment phase. This common error is known as Lasagna's law.[17] For instance, the number of subjects who are actually available for a clinical trial is about 1/10 to 1/3 of what was originally estimated.[18]

Subject recruitment is challenging and generally low across all RCTs. One of the reasons for low subject recruitment is that subjects may not want to be randomly assigned to a treatment and are afraid of receiving a treatment that they feel is inferior.[19] Many RCTs do not meet their recruitment targets, extending study duration and thus cost. The validity and integrity of the study

may also be compromised, which could lead to type-II error; finding no difference between treatments when one actually exists.

Retention, or maintaining subject enrollment, is another hurdle in conducting an efficient and timely clinical trial. Once the subjects are randomly assigned to the study drug or placebo, the retention of subjects is important for obtaining accurate and statistically significant data. Subjects may choose to drop out of the trial when they begin to suspect the use of a placebo due to little improvement or the lack of desired effect.[20] Other factors that may cause subjects to drop out are a distance from the study site, multiple and long visits, or inconvenient appointment scheduling. According to Forte Research, the average dropout rate across all clinical trials is about 30%.[21]

Recruitment strategies may vary depending on the type and design of the study, disease, demographic characteristics, etc. Recruitment methods used at North Texas Clinical Trials for two randomized controlled trials were onsite methods such as physician referral, flyers, social media, and an offsite third-party recruitment agency, StudyKik.

Many clinical trials fail to report the efficiency of recruitment methods used. A recent Cochrane review concluded that the impact of different strategies on recruitments has remained unclear.[24] Further research therefore is needed to investigate the efficacy of recruitment strategies for RCTs.

Research hypothesis

The total number of subject referrals provided by recruitment agency /off-site recruitment method is higher and more cost-effective than on-site recruitment methods.

Specific Aims

Aim 1: To compare the total number of subject referrals provided by recruitment agency/offsite method with on-site recruitment methods including number of subjects who were enrolled and randomized.

Aim 2: To determine the cost-effectiveness of the recruitment methods per randomized participants.

Aim 3: To compare sociodemographic characteristics of individuals recruited from different sources.

Significance

Development and implementation of a well-planned recruitment strategy is a key determinant in the success of clinical trials. Many randomized controlled trials fail to measure, report, or analyze the cost and efficacy of the recruitment methods used.[22, 23] Knowledge of efficient and cost-effective subject recruitment strategies in RCTs is essential for planning and implementing a research study.

Use of any one single recruitment method alone may not result in a representative sample, but a greater understanding of these methods will enable researchers to target a specific population. Optimization of subject recruitment strategy may provide a steady stream of potential subjects,

that are eligible and likely to complete the study without the mounting costs of extending trials into subsequent phases.

A detailed recruitment strategy should be developed before beginning the trial taking into consideration the study population, costs of the recruitment methods, and the specific research question. Comparative analysis of recruitment methods could provide insight for other researchers in choosing recruitment strategies for future studies.

Research Design and Methodology

Two multicenter randomized placebo-controlled trials conducted at the North Texas Clinical Trials were selected for this project. With the purpose of understanding efficacy, and cost-effectiveness recruitment methods used in these trials were evaluated.

Study design

Major depressive disorder study

This study was a randomized, double-blind, placebo-controlled study of an investigational drug as an adjunctive therapy in Major Depressive Disorder (MDD). The study consisted of three parts. Part one was a double-blind, placebo-controlled study. Levels of depression were monitored throughout this period using clinically approved assessment scales. After three weeks of administration of either study drug or placebo subjects were moved into part 2A which was an open-label trial period for 8-16 weeks where study drug was administered to all subjects. Depression levels were monitored throughout the study and subjects who achieved treatment response stability (i.e. not relapsed) were again randomized into double-blind part 2B of the study wherein they were assigned to drug or placebo to assess length of treatment response or symptom remission. If subjects never achieved stability, then they were enrolled into part three of study which was an open-label, long term safety study.

The target sample size for this study was approximately 700 across 35 study centers in the United States. The target enrollment goal for the site was 16 subjects.

For enrolling into the study, a subject had to meet all inclusion criteria and no exclusion criteria as stated in the protocol. For example, a subject had to be at least 18 years of age, but no more than 65, meet DMS-5 (Diagnostic and Statistical Manual of Mental Disorders) criteria for MDD, a minimum MADRS (Montgomery-Asberg Depression Rating Scale) score of 25 or above at screening visit and baseline, and have no more than partial response to ongoing typical antidepressant treatment and a normal physical examination. MADRS is a 10-item diagnostic questionnaire used to measure the severity of depressive symptoms. The exclusion criteria included the presence of psychological disorder such as anxiety, schizophrenia, bipolar disorder etc., history of substance abuse within 6 months before screening visit, history of antipsychotics or anticonvulsant use, suicidal attempt or hospitalization within 6 months of screening visit, lack of psychotherapy for depression within 3 months of trial and falling outside of the 40 kg to 125 kg weight range on the day of screening.

Postpartum Depression study

The Postpartum Depression (PPD) study was a randomized double-blind study for adult female subjects with severe postpartum depression. This study consisted of 14 days of double blind treatment period in which subjects received either study drug or placebo followed by a 30 day of follow up period. During the treatment and the follow up periods, depression levels were assessed using clinically approved depression scales.

Eligibility subjects were ambulatory females between 18-45 years of age. They could not have clinically significant findings as determined by the investigator on physical examination, ECG, or laboratory tests. Subjects had to be less than or equal to 6 months postpartum with a negative

pregnancy test at screening visit and day 1 prior to the start of study drug administration. Subject must have had a major depressive episode that began no earlier than the third trimester and no later than the first four weeks following delivery and meet the criteria for major depressive episode as per DSM-5. Subjects had a HAM-D (Hamilton Rating Scale for Depression) total score of more than or equal to 26 at screening and first visit. The exclusion criteria also included history of seizures, bipolar disorder, and schizophrenia; administration of psychotropic medications initiated within 14 days prior to screening; attempted suicide associated with current episode of PPD, or a positive urine drug test at the screening visit.

Recruitment methods

For MDD study, recruitment methods used included sponsor provided flyers and brochures, physician referral, and social media as on-site recruitment strategies. For PPD study, recruitment methods used included the same as above except referrals from physician. For both the studies the off-site recruitment method used was clinical trial recruitment agency portal 'StudyKik'. All advertisements and recruitment materials were IRB approved.

Flyers and brochures

Sponsor-provided brightly colored flyers and brochures were posted at local general practitioner offices, the mental health institute, and community centers. These recruitment materials explained the purpose and procedures of the study and informed individuals on how to contact the research team.

Physician referral

The Principal Investigator informed her patients about the MDD study and referred several of them to the study site. When potential subjects were referred to the study site by a physician, site staff followed up the subjects by contacting them by phone. Subjects who meet the inclusion criteria and do not meet exclusion criteria were then brought to the site to complete informed consent requirements and enrolled into the study if they passed the screening.

Social media

The research team at the site used Facebook advertising platform for posting IRB approved study advertisements with study information, contact details, and a link to a pre-screening survey on the site website. Study coordinators followed up with all the interested candidates. Subjects who consented to participate in the study were considered enrolled in the study. Subjects who pass the baseline screening after enrollment were randomized in the study.

Off-site recruitment method

StudyKik was the paid recruitment agency website/ recruitment portal used by the site for both MDD and PPD studies. Recruitment agency used different types of marketing strategies to reach the target population. The most common strategies used were recruitment websites, social media, recruitment webinars, videos, books, and brochures. Studykik posted the list of trials given by the trial site so the patients could view the study information. They had communities across various platforms such as Instagram, Facebook, Twitter, Snapchat and others so that the maximum people could find information about the trial. After reviewing information on StudyKik.com, subjects signed up for the trials that they were interested in and received information about the trial site.

When potential subjects signed up for a particular study, the study staff received notifications via email with the subject's primary contact information. The study coordinators with access to the portal reviewed the information entered by these patients and contacted them to determine their eligibility for the study.

Data collection

For monitoring a source of recruitment for all the subjects enrolled in these trials, a recruitment dataset was documented on a Microsoft Excel spreadsheet. The dataset was taken from two sources: StudyKik and Intake Q. The recruitment agency portal, StudyKik, had the list of subjects who showed interest in the respective trials. The second source, Intake Q, is an online database which enables health professionals to optimize and streamline the patient intake process. It has subject demographics data such as race, gender, age, brief medical history, and other information. Average cost spent on off-site recruitment was derived from the monthly payment receipts from the StudyKik account. For on-site recruitment method, social media advertisement expenses were considered for the total cost.

Analytical Strategy

Efficiency of each recruitment method was evaluated based on the number of subjects enrolled and the number of eligible candidates who subsequently were randomized into the trial. For the MDD study, comparison of available subject demographics of participants was done to check if demographics varied with the source of recruitment for all the subjects enrolled as well as randomized. For the purpose of evaluating cost-effectiveness, the recruitment cost of on-site recruitment methods was compared with the cost of off-site recruitment method.

Statistical Analysis

For the MDD study, a contingency analysis was done to compare on-site recruitment methods to the off-site method in terms of enrollment and number of randomized subjects. For comparing demographics of subjects recruited by different recruitment methods, an unpaired t-test was used for age and Fisher exact test for gender and race. Differences between two groups were considered to be significant at a p value of <0.05. Statistical analyses were performed with GraphPad Prism 8.0.2 (GraphPad Software, Inc., San Diego, CA). Because of small sample size for PPD study descriptive statistics was used for comparison of the recruitment methods.

Results

Recruitment

Major depressive disorder study

For the MDD study, a total of 50 potential subjects were recruited either via on-site or off-site (StudyKik) recruitment methods. The eligibility of subjects was assessed as per the inclusion and exclusion criteria of the studies as stated in the protocol. Subjects who signed the informed consent and met the inclusion criteria and did not meet exclusion criteria were enrolled into the study. However, only subjects who passed the baseline screening assessments were eligible to continue the study and were randomized.

Of the 50 potential subjects, 27 (54%) were recruited via on-site recruitment strategies while 23 (46%) were recruited using StudyKik. A total of 784 referrals were provided by StudyKik over a period of 14 months (Feb 2017-Apr 2018) and 63 from on-site recruitment methods. From 784 referrals from StudyKik, only 23 passed prescreening and scheduled for a screening visit. All 50 subjects signed the informed consent and were enrolled in the study. Out of 27 on-site recruited subjects, 15 (55.55%) passed the baseline screening and were randomized in the study. Out of 23 subjects recruited using StudyKik, 9 (39.13%) were able to pass baseline screening and randomized.

Because of a small sample size, Fisher's exact test with a contingency table was used to check for significant differences between the number of enrolled and randomized participants across the two recruitment sources. As indicated by the p-value of 0.6176, there was no significant difference in number of enrolled and randomized participants across the two recruitment sources.

Table 1 summarizes number of subjects enrolled and randomized across the two recruitment sources for MDD study.

Table 1: Number of enrolled and randomized subjects by recruitment source

Recruitment method	On-site	StudyKik
	p-value (0.6176)	
Enrolled	27	23
% Enrolled	54	46
Randomized	15	9
% Randomized	55.55	39.13

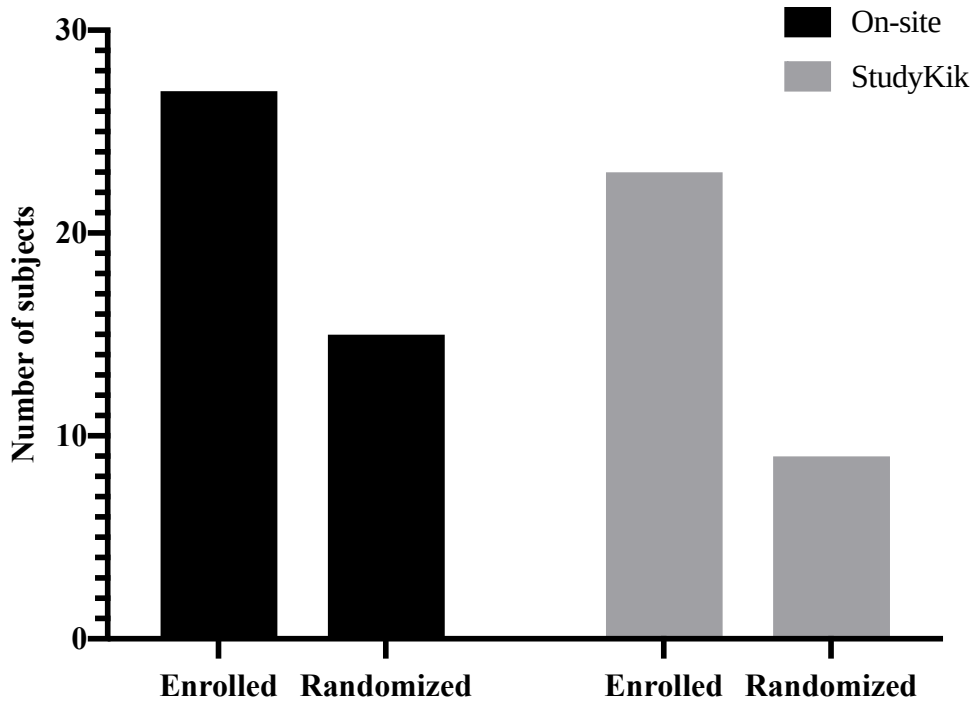

Figure 1: Number of Enrolled and randomized subjects by recruitment source

Out of 27 participants recruited from on-site recruitment methods, 12 subjects were enrolled via physician referral and 15 were enrolled from other methods such as social media, study flyers, craigslist, newspaper. Out of 12 subjects referred by physician 10 subjects (83.3%) were randomized. Out of 15 subjects enrolled using other on-site methods, 5 subjects (33.3%) were randomized.

The contingency table was analyzed using Fisher's exact test to check for significant differences between the number of enrolled and randomized participants across physician referral and other on-site recruitment sources (social media, study flyers). As indicated by the p-value of 0.2087, there was not a significant difference between the physician referral and other methods in terms of number of enrolled and randomized participants. Thus, out of 15 subjects randomized from on-site recruitment methods 10 were referred by a physician. Table 2 summarizes number of subjects enrolled and randomized across the on-site recruitment methods for MDD study.

Table 2: Number of enrolled and randomized subjects by on-site recruitment source

Recruitment method	**Physician referral**	**Other**
	p-value (0.2087)	
Enrolled	12	15
% Enrolled	44.44	55.55
Randomized	10	5
% Randomized	83.3	33.3

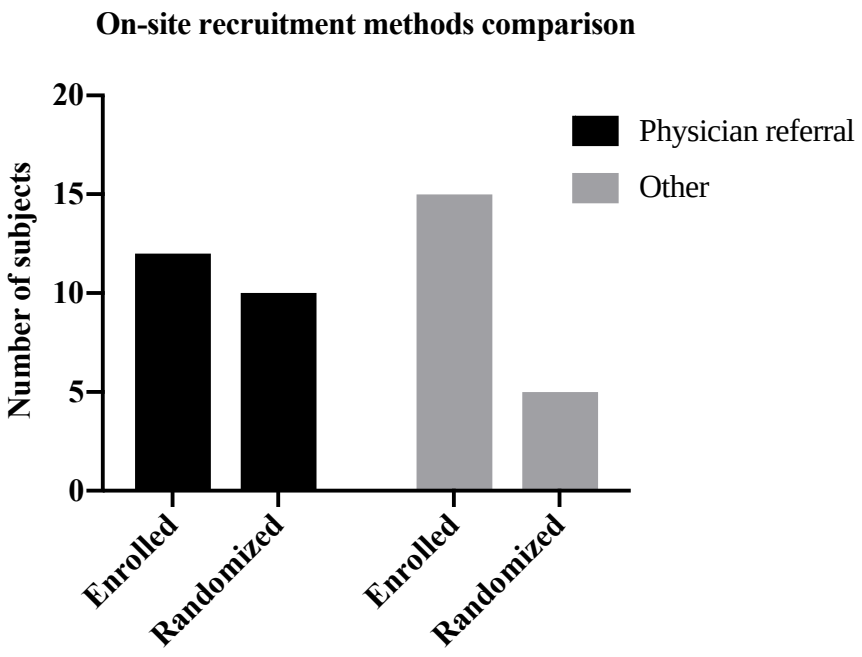

Figure 2: Comparison of on-site recruitment methods

Subject Demographics

A total of 50 potential subjects were recruited either via on-site or the off-site recruitment methods from February 2017 to June 2018 for the MDD study. Subject demographics were compared across two recruitment sources for enrolled as well as randomized participants. The mean age of the enrolled subjects using on-site recruitment was 41.44 $\pm$12.34 years, and 44.78 + 6.74 years for enrolled subjects from StudyKik. The mean age of the randomized participants using on-site recruitment was 40.33 + 12.07 years, and 44.44 $\pm$ 5.41 years for StudyKik recruited subjects. There were no significant differences in age in case of enrolled or randomized participants when recruited via different sources.

Of the 27 enrolled subjects via on-site methods, 18 (66.6%) were females and 9 (33.3%) were males and of 23 subjects recruited via StudyKik, 21 (91.3%) were females and 2 (8.7%) were

males. There was a significant difference (p-0.0458) in gender in enrolled subjects when recruited via on-site methods and StudyKik. Comparatively more number of men were recruited from on-site methods than StudyKik. Out of 15 randomized participants from on-site recruitment ten were females and five were males which was identical to enrolled subjects recruited from on-site recruitment methods. Of nine randomized participants recruited from StudyKik, eight were females and one was male. There was no significant difference (p-0.3509) in gender in the randomized participants across two recruitment strategies.

There was a significant difference (0.0053) in race in enrolled subjects when recruited from either on-site recruitment methods or the StudyKik. Among the enrolled subjects from on-site methods 24 were Caucasian and three were Non-Caucasian (1 Asian, 1 African American, 1 Hispanic). Out of 23 enrolled from StudyKik, 12 were Caucasian and 11 were Non-Caucasian (8 African American, 3 Hispanic). In case of randomized participants also, there was a significant difference (0.0119) in race among two recruitment sources. All 15 randomized subjects recruited from on-site methods were Caucasian and from nine randomized subjects recruited from Studykik five were Caucasian and four were Non-Caucasian. Table 3 summarizes subject demographics of enrolled and randomized participants for MDD study.

Table 3: Subject demographics of MDD study

	Enrolled		Randomized	
Recruitment method	**On-site**	**StudyKik**	**On-site**	**StudyKik**
Age	**p-value (0.253)**		**p-value (0.3479)**	
N	27	23	15	9
Minimum	25	30	25	36
Quantiles 25	29	38	29	39.5
Median	40	46	39	45
Quantiles 75	53	50	52	48.5
Maximum	65	54	65	53
Range	40	24	40	17
Mean	41.44	44.78	40.33	44.44
Std. Deviation	12.34	6.748	12.07	5.411
Std. Error of Mean	2.375	1.407	3.116	1.804
Gender	**p-value (0.0458)***		**p-value (0.3509)**	
Female	18	21	10	8
Male	9	2	5	1
Race	**p-value (0.0053)***		**p-value (0.0119)**	
Caucasian	24	12	15	5
Non-Caucasian	3	11	0	4

Postpartum depression study

For the Postpartum Depression Study, the target sample size was approximately 140 across 60 study centers in the United States. The target enrollment goal for the site was one. There were 45 referrals/initial contacts from StudyKik and 29 from on-site recruitment methods accounting for total 74. Out of total 74 subjects, only seven were eligible to be enrolled and five were randomized in the study. Out of 45 subjects referred by StudyKik, four subjects enrolled in the study, however,

only three subjects were randomized and completed the study. From the 29 subjects referred by on-site methods only three subjects were eligible to enroll into the study and randomized.

As the inclusion criteria for this study was females between ages 18-45 yrs., the mean age of the enrolled subjects was 27.57 $\pm$ 4.47 yrs. and 27.00 $\pm$ 5.36 yrs. for randomized subjects. Out of seven enrolled subjects, four were Caucasian and three were African-American. From five randomized subjects three were Caucasian and two were African-American. Table 4 summarizes subject enrollment and recruitment across the two recruitment sources for PPD study.

Table 4: Number of enrolled and randomized participants for PPD study

Recruitment method	On-Site	StudyKik
Referrals/Initial contacts	29	45
Enrolled	3	4
Randomized	2	3

Cost-Effectiveness of recruitment methods

For the purpose of evaluating cost-effectiveness, the amount spent on on-site recruitment methods was compared with the amount spent on the StudyKik. For on-site recruitment methods, study flyers and brochures were provided by sponsors so there was not any direct cost implemented for those methods. For the Major Depressive Disorder study, out of 27 participants recruited from onsite recruitment methods, 12 subjects were enrolled via physician referral, which was considered as an unpaid recruitment method. Only 11 subjects from on-site recruitment methods were recruited via a paid recruitment strategy, mainly social media advertisements.

StudyKik was used as recruitment strategy for 14 months (Feb 2017-Apr 2018) and the subscription cost during that period was $16725.80. Social media advertisements were used as a recruitment method for seven months (Apr 2018-Oct 2018) and the cost for that period was $379.11. The cost of recruitment methods per subject is summarized in Table 5.

Table 5: Cost per subject for different recruitment methods used for MDD study

Source of recruitment	On-Site		StudyKik	
	Number of Subjects	Cost per subject ($)	Number of Subjects	Cost per subject ($)
Enrolled	11	34.46	23	727.21
Randomized	4	94.77	9	1858.42

For the postpartum depression study, StudyKik was used as recruitment strategy for 2 months and cost during that period was $2594. Social media was used as a recruitment method for 7 months (Apr 2018- Oct 2018) and the cost for that period was $997.68. The cost of recruitment methods per subject is summarized in Table 6.

Table 6: Cost per subject for different recruitment methods used for PPD study

Source of recruitment	On-Site		StudyKik	
	Number of Subjects	Cost per subject ($)	Number of Subjects	Cost per subject ($)
Referrals/Initial Contacts	29	34.40	45	57.64
Enrolled	3	332.56	4	648.50
Randomized	2	498.84	3	864.67

Discussion

Subject recruitment strategies used in two randomized controlled trials, Major Depressive Disorder and Postpartum Depression studies were examined. All the recruitment strategies used by the site were effective and met the target enrollment goal for both studies. Target enrollment for the MDD study was 16, however, 24 subjects were effectively randomized out of 50 enrolled subjects. For the PPD study, five subjects were randomized and completed the study out of seven enrolled subjects.

For the MDD study, the number of initial referrals (784) from StudyKik was more than on-site initial referrals (63) however recruitment return in terms of randomized participants was not significantly different from on-site recruitment. As shown in Table 1, a comparatively large number of enrolled and randomized participants were recruited from on-site recruitment methods as compared to StudyKik, this may be due to the number of physician referrals, indicating that physicians play major role in subject recruitment as they have regular interactions with the patients. Out of 24 randomized participants, 15 were recruited from on-site methods and 9 were from StudyKik.

For the Postpartum Depression study, the number of referrals and enrolled subjects from StudyKik was higher than those of on-site methods. However, recruitment return in terms of randomized participants was almost identical between both StudyKik and on-site methods. Out of 29 subjects referred from on-site methods, primarily social media advertisements, three were eligible to be enrolled and two were further randomized in the study. Out of 45 subjects referred from StudyKik, four were eligible to be enrolled and three were further randomized into the study.

As shown in Table 3, for Major Depressive Disorder study, there was not a significant difference in age of subjects between those recruited via on-site recruitment method versus those recruited using StudyKik. Gender comparison showed significant differences in enrolled subjects, however there was not a significant difference in randomized participants. This may be due to smaller sample size of randomized subjects as compared to enrolled subjects. Among the total number of enrolled and randomized participants, comparatively more women were recruited through all the recruitment methods than men supporting the notion that women are more likely to seek help for mental health issues than men. There was a significant difference in race when subjects were recruited from on-site versus the StudyKik recruitment, greater number of Non-Caucasian subjects were recruited using the StudyKik as compared to on-site methods. StudyKik was more effective in recruiting diverse population sample including racial/ethnic minority groups.

Regarding cost effectiveness, on-site methods were found to be more effective in terms of recruitment return and less costly than StudyKik for both studies. In the case of on-site recruitment methods for the MDD study, physician referral played a major role in recruitment without implementing any referral cost while providing a higher percentage of eligible participants. StudyKik was found to be an expensive method of recruitment, costing $1858.42 per randomized participants in the MDD study and $864.67 per randomized participants in the PPD study. For on-site recruitment methods, primarily social media advertisements, average cost per randomized participant in the MDD study was $94.77 and it was $498.84 per randomized participant in PPD study. Although StudyKik was comparatively expensive, the database of initial referrals can be used in the future to check if those subjects would be eligible for other studies.

Study Limitations

One of the major limitations of this study was the small sample size. The total number of randomized participants in the Major Depressive Disorder study was 24, and for the Postpartum Depression study it was five. Unfortunately, with such a small sample size statistical analysis loses power to detect any significant differences between the groups. Conclusions drawn from such a small sample size may not apply to entire population for such studies.

Another significant limitation is the use of on-site and off-site (StudyKIk) recruitment strategies for different times. StudyKik was used for almost 14 months while the on-site social media advertisements were used for 7 months for these studies. These changes may yield differences in number of recruitments and in participants characteristics. Although the cost effectiveness of on-site and off-site recruitment methods was quantified in terms of direct cost, there were additional costs such as staffing resources which were not available to quantify.

Conclusion

All the recruitment strategies used, on-site and off-site (StudyKik), were effective in recruiting eligible subjects. In terms of recruitment return, on-site methods were more effective than StudyKik. From on-site recruitments, physician referral provided the most participants who successfully were randomized into the study. StudyKik was found to be more expensive than on-site social media advertisements, however, total referrals provided by StudyKik were higher than on-site referrals and might be useful for prescreening of potential subjects in future trials. StudyKik was more effective in recruiting diverse population sample including racial/ethnic minority groups.

Monitoring recruitment strategies implemented in the study and assessing their effectiveness would be helpful in employing strategies for future trials.

Future Research

For Major Depressive Disorder study, physician referral played a major role in recruitment without implementing any referral cost while providing a higher percentage of eligible participants. However, there was no any referral from physician for Postpartum depression study. Understanding the obstacles associated with subject recruitment to clinical trials by physician may help expedite subject recruitments. Engaging physicians/health care providers and encouraging them to refer patients in clinical trials may improve subject recruitment rate.

From the data analysis it was found that there were 52% screen failures in the Major Depressive Disorder study and 28.57% in the Postpartum Depression study. Identifying eligibility criteria that contributed to subject enrollment challenges may provide insight and guidance in future recruitments. Keeping a screen failures database including each subject's ineligibility reason may be useful to check if those subjects would be eligible for future clinical trials. Calculating screen failure rate and cost of resources spent in screen failures would help researchers planning budget for clinical trial recruitments.

CHAPTER III

INTERNSHIP EXPERIENCE

Description of Internship Site and Experience

I completed my clinical research internship at North Texas Clinical Trials, LLC, Fort Worth. The site was established by Dr. Brian Maynard in 2012 and has conducted pharmaceutical drug trials ranging from phase I-IV. The site focuses on conducting clinical trials associated with psychological and Central Nervous System disorders. In the past few years, site has conducted clinical trials for the treatment of Schizophrenia, Essential tremors, Bipolar disorder, Anxiety, and Migraine.

During the course of my internship, the site was conducting clinical trials for the treatment of Major Depressive Disorder, Tourette Syndrome, Postpartum Depression, and Parkinson's Disease Tremors. I was privileged to work on all aspects of a clinical trial under close supervision from site manager Jessica Anderson as well as Dr. Maynard. During my 7-month internship, I got a better understanding of all the aspects of clinical trials and the challenges of getting a drug to market. I learned valuable lessons while working at the clinical trial site and improved my ability to conduct and manage clinical research.

I was also able to learn about the different roles that fit into clinical trial process which helped me decide which specialty is right for me. I had the pleasure of working with a great staff who helped me develop my skills and broaden my knowledge that I can now implement in my future career. I will continue to work on improving my skills in order to attain my desired career objectives. I am very grateful for this opportunity.

Journal Summary

I started my internship at North Texas Clinical Trials, LLC, on 20th August, 2018. During the first few days, I became familiar with the site operating procedures. I studied protocols in order to learn inclusion and exclusion criteria and the visit schedule. I started shadowing research coordinators during study subject visits. Under supervision, I was responsible for taking vital signs such as blood pressure, temperature and pulse. I also assisted in doing ECGs on subjects of various ages. After patient visits, I was responsible for verifying that source documents are filled out and signed. I learned how to conduct a prescreen call to check eligibility of the candidate interested in the study as per the inclusion and exclusion criteria. I also assisted in entering data from source documents into sponsor provided EDC (Electronic data capture) and answering sponsor-initiated queries in EDC. I was also able to help with the patient lab processing.

In reference to regulatory affairs, I was responsible to maintain Investigator Site File/ Regulatory binders for each study. These binders contain all study-specific documentation such as study protocol, IRB correspondence, Informed consent forms, investigator statement, etc. which provides easy access to essential documents by trial monitor or auditor. I was also responsible for organizing study subject binders, filing updated informed consent forms, maintaining drug accountability, and drug dispensation records. I have learned that maintaining and organizing study or regulatory binders needs attention to detail. I also assisted in dropping off recruitment materials such as study flyers and booklets at physician offices and community centers.

During my internship, I had a chance to learn different aspects of clinical research from study start up to study close out such as submitting study feasibility criteria before starting new study,

planning and implementing subject recruitment, regulatory proceedings and IRB approvals. From my daily tasks, it became clear that subject recruitment is the most challenging part of clinical trials and hence it is important to plan and conduct thorough assessment of the recruitment phase of the study.

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APPENDIX A

DAILY JOURNAL

WEEK 20 AUG -24 AUG 2018

20 AUG 2018
On Aug 20th I started my internship at North Texas Clinical Trials, LLC. I had chance to get familiarized with the all operating procedures and clinical drug trials. One of the Clinical research coordinator on the site told me daily tasks such as keeping the temperature logs of drug room as the medicines are restricted by narrow temperature ranges and it is important to note any deviations.

21 AUG 2018
I had chance to listen a pre-screen call. There are leads that consist of names, contact numbers and emails of individuals who are interested in studies at the trial sites. It is the responsibility of study coordinators to get a hold of people and to check if they meet study criteria. I watched my site manager perform phlebotomy and learned how to check vitals (BP, pulse, temp) and ECG.

22 AUG 2018
It was patient visit day. We saw eight study subjects today. I assisted in doing vitals and ECG. These subjects were part of the Major Depressive Disorder (MDD) study which consist of infusion of XXXX drug. Patients vitals such as BP, pulse is checked before and after the infusion. Subjects also have to do scales (kind of questionnaire) to check their depression level.

23 AUG 2018
We spent the day doing office reorganization and clean up. I organized the study binders as per the study and patient numbers.

24 AUG 2018
I spent most of the day getting to know studies currently going on the site, reading study protocols. In addition, we had two patient visits. I assisted in measurement of vital signs.

WEEK 27 AUG -31 AUG 2018

27 AUG 2018
We had site meeting with the team regarding distribution of work and schedule of next week. We saw two MDD patients today. We also made patient visit source documents ready for this week.

28 AUG 2018
We saw six MDD patients today. I assisted in taking vitals and doing ECGs as per the visit requirement on them. After all the visits, I am responsible to check if source documents are filled out and ready for Principal Investigator's (PI) signatures.

29 AUG 2018
I had chance to learn how to make regulatory box of a study. I made regulatory binder for pediatric Tourette study. It consists of essential documents reviewed during audits and inspections. Documents can be those generated before study start up, during trial conduct and after study completion. In addition, we saw two patients today.

30 AUG 2018
We only had one patient today. I did some clerical duties and filing back source documents from visit binder to their respective study binders. As I have been delegated the task of organizing binders, I took the time to check for missing documents.

31 AUG 2018
We had meeting in the morning. I was responsible to check this week's patient visit documents and make them ready to enter into electronic data capture (EDC). EDC system is a software that stores patient data collected during each visit in clinical trial.

WEEK 4 SEP -7 SEP 2018

4 SEP 2018
After long weekend we made sure all the patient visits binders are ready for today's visits. I made source documents ready. Five MDD patients came in for their regular visits. I assisted in doing their vitals and ECG.

5 SEP 2018
We had 4 major depression patients today. I completed all visit related procedures in timely manner. We also had one study close out visit. I made regulatory binder for MDD open label after care study which is the continuation of depression study. It consists of essential documents reviewed during audits and inspections.

6 SEP 2018
Today was a monitoring visit day for one of the study at the site and we saw two major depressive patients. I assisted with doing their vitals and ECG.

7 SEP 2018
Besides working with patients today I worked on my research proposal for my upcoming research proposal meeting.

WEEK 10 SEP -14 SEP 2018

10 SEP 2018
We made sure everything is set, all the source documents are ready for this week's visits. We also had our weekly meeting where we discussed plans for this week.11 SEP 2018. I had my first committee meeting for my research proposal in the morning. It was a patient visit day. WE saw 6 depression patients. I did vitals and ECG on them.

12 SEP 2018
Today I did Inventory of the Covance shippers. These are shippers used for sending labs specimens or biological samples for testing by testing services. They come in different temperature-controlled conditions. Also, one patient came in for depression study visit. I assisted in doing patient related procedures.

13 SEP 2018
I did some regulatory filing today. My responsibility was to match up all the drug kit lot numbers with requisition forms and their corresponding sections in the accountability binder. We also had one patient visit today.

14 SEP 2018
I made sure all the source documents are filled out and ready for entering into EDC. Also filled back source documents from each patient visit binder to their individual study binder.

WEEK 17 SEP -21 SEP 2018

17 SEP 2018
We had our weekly meeting today. I did some regulatory filling and worked on my research proposal.

18 SEP 2018
Today was a patient visit day. We had four MDD study patients for their regular visits. I assisted in doing all patient related procedures. We also had one screening visit for depression study. A screening visit is one of the longest visits lasting up to 3 hours. During that time, we take vitals and ECG's, draw blood, assess mental stability by administering various scales, collect urine for a pregnancy test, urinalysis, and drug screen.

19 SEP 2018
I did some filing of regulatory documents. We had two patients came in today for depression study who had their vitals, scales, and infusions done.

20 SEP 2018
I started my day with filing bracket reports in respective binders. Later in the day we had two patient visits. I made a new binder for patient in MDD study. Each binder has different sections like demographics, adverse events log, Concurrent medications log, labs, ECGs, visit source documents.

21 SEP 2018
I started my day with filing bracket reports which are depression scales in respective binders. Also, we saw two major depressive patients who had their vitals, scales, and infusions done.

WEEK 24 SEP -28 SEP 2018

24 SEP 2018
We had our weekly meeting discussing about this week work plans. I went to some places to drop off study flyers for recruitment of subjects for different studies at our site.

25 SEP 2018
I started my day by making source documents ready for this week's visits. We had three MDD patients today. I assisted in doing all patient related procedures. We also had one screening visit for post-partum depression study.

26 SEP 2018
Today I spent most of the day in filing back of documents and qc of binders. We only had one patient visit today.

27 SEP 2018
We had one prescreening visit for depression study in the morning and three patients later in the day. I assisted in all patient related procedures. I went over the informed consent and made sure that everything was filled out on the patients' part and part of the staff and not missing any signatures.

28 SEP 2018
We had one major depression study and one post-partum depression study prescreens today. Later in the day we had two depression study patient visits. I assisted in doing their vitals and ECGs.

WEEK 1 OCT -5 OCT 2018

1 Oct 2018
Weekly team meeting. Uploaded the sources from Friday visits on meister task. Decided in meeting to check quality control (QC) of a binder each day. I worked on doing QC of MDD binders.

2 Oct 2018
We had 3 patients visit for depression study. I assisted in doing their vitals and ECGs. I spent rest of the day doing QC of MDD binders.

3 Oct 2018
Filed back the ECGs, lab reports and bracket reports in the respective binders. Worked on my research proposal edits. Filed some inform consents in the respective binders.

4 Oct 2018
We had 4 patients visits today. 3 depression study and 1 Tourette's study. I did pre and post vitals. I worked on my proposal. I worked on QC of a binder.

5 Oct 2018
I started my day with filing the drug kit assignment documents in respective binders. And kit number labels (IP labels) in the accountability binders.

WEEK 8 OCT -12 OCT 2018

8 Oct 2018
We had our general meeting with site staff. I filed back source from patient visit binders to their respective study binders. Made the copies of ECG ready for sign of PI. I went through the patient binders making sure recent labs, ECGs, and concomitant medications were filled out dated and signed.

9 Oct 2018
Patient visit day. Made the visit binders ready with the source for this week. I did qc for one Rap03 study binder. We had one PPD (Post-partum depression study) patient. two MDD study patients came in today. I assisted in collecting vitals and doing ECG.

10 Oct 2018
We had 2 patients came in for visits, one in the afternoon and one late in the evening. I assisted with vital checks before and after infusion. Also, worked on QC of two subject binders and made action lists for what missing.

11 Oct 2018
We had two post-partum depression patients in the morning and three MDD patients later. I assisted in all patient related procedures and made sure all the source documents are filled out and signed.

12 Oct 2018
I started my day with doing QC of binders. We had 2 patients came in the morning and two later in the day. I assisted with doing vitals and ECGs. I am responsible for completing and making sure that all the patient charts in the office are up to date and have all of the necessary signatures as well as paperwork in appropriate sections of the binders.

WEEK 15 OCT -19 OCT 2018

15 Oct 2018
Filed back IWRS (Integrated web response system) dispensation records in the respective binders. IWRS is the technology used by for randomizing study subjects or keeping track of subject data. We had staff meeting where Jessica, our site manager discussed how to QC a subject binder. We had Pediatric Tourette study patient visit today. I assisted in performing ECG.

16 Oct 2018
We had weekly group meeting. We discussed plans for upcoming monitor visits. I did pre and post infusion vitals on one MDD patient.

17 Oct 2018
In the anticipation of upcoming monitor visit our goal is to QC each patient binder, old and current patients so I spend most of the day doing QC.

18 Oct 2018
Thursday was very busy day. We had interim monitor visit for postpartum depression study. In addition, we had our regular MDD patients and one Tourette study and one post-partum depression study patients. I was responsible for helping with vitals, data capture, data quality control, and completion. I helped my coworker with the process of patient admission and check out, as well as ECG.

19 Oct 2018
I spent most of the day doing QC of study binders, noting all of the missing documents, signatures, IWRS sheets, lab results, and bracket prints outs. In addition, we had two patient visits. I assisted in doing vitals and ECG.

WEEK 22 OCT -26 OCT 2018

22 Oct 2018
Because of the upcoming monitor visits, we spent most of day doing QC of the MDD study binders. I worked with site staff to get missing things from the binders such as bracket print outs, IWRS.

23 Oct 2018
I spent all day doing QC of MDD study binders. Also filled back all visit source documents from patient visit binder to the respective study binders.

24 Oct 2018
I spent all day doing QC of binders. Also made the source documents ready for next two days visits.

25 Oct 2018
We had 3 depression study patients visit today. I assisted with doing vitals before and after their IP infusion. Also, I continued doing QC of study binders.

26 Oct 2018
We had 1 post-partum depression study patient, one pediatric Tourette study patient and one MDD patient visits in the morning. I was responsible for helping with vitals and ECG.

WEEK 29 OCT-2 NOV2018

29 Oct 2018
We had our weekly meeting discussing about this week's patient visits and plans. I spent most of the day doing QC of binders and making this week's source documents ready for visits. We had only one patient visit late in the evening.

30 Oct 2018
Today was a busy day. We had two post-partum depression study patients in the morning and four MDD study patients visit today. I was responsible for helping with vitals, data quality control, and completion. I helped my coworker with the process of patient admission and check out, as well as ECG and scales.

31 Oct 2018
We had this day off.

1 Nov 2018
I spent most of the day doing QC of MDD study binders noting and completing some missing things. I also made an informed consent binder for MDD study which is the compassionate care study extension of major depression study.

2 Nov 2018
I started my day with filing back some regulatory documents and QC of patient binders. Late afternoon we had three MDD patient visits. I assisted with checking their vitals and ECG. I also assisted in processing blood labs.

WEEK 5 NOV-9 NOV 2018

5 Nov 2018
As usual, we had our weekly meeting today discussing about week's plan. I filed back some regulatory documents and cleaned the office for next week's monitor visit. Also worked on Qc of MDD binders which are on priority list for next week's monitor visit.

6 Nov 2018
I spent most of the day doing QC of binders. Also made source documents ready for this week's patient visits. I assisted in filing back regulatory for some of the earlier studies done at the trial site.

7 Nov 2018
I had this day off.

8 Nov 2018
We only had one patient visit today. Because of upcoming monitor visits, we spent some time in rearranging and organizing the office. I spent some time in reading the MDD study protocol.

9 Nov 2018
I spent most of the day in filing back the drug kit assignment documents in respective binders. And kit number labels (IP labels) in the accountability binders

WEEK 12 NOV -16 NOV 2018

12 Nov 2018
I spent most of the day in filing back bracket reports (subject visit summary reports) and labs signed by PI in respective patient binders. Then I spent time in reading and understanding study protocol.

13 Nov 2018
I started my day with printing and filing some regulatory documents in regulatory binder of Tourette's study. Made a new patient binder for MDD study which is extensive compassionate care study treatment for the MDD patients. Also made the patient source documents ready for this week's visit. We had tremor study monitoring visit today.

14 Nov 2018
We had MDD study interim monitor visit today, so we spent time in checking the binders and making sure all the documents are filed appropriately. I filed back some documents in their respective binders.

15 Nov 2018
Today was a busy day. We had Parkinson's tremor study screening visit in the morning. This is a phase 2 study of XXXX in adults with tremor associated with Parkinson's disease. I had chance to listen how informed consent is explained to subjects. I did vitals and ECG on subject. We also had 3 regular MDD patient visits today. I did vitals and ECG for them too.

16 Nov 2018
Today was third day of MDD study monitor visit and second day of PPD study interim monitor visit. In addition, we had one Tourette's study screening visit and 3 MDD study visits. I got chance to process labs for one of the patient and make it ready for shipping.

WEEK 19 NOV- 21 NOV 2018

19 Nov 2018
We had this day off.

20 Nov 2018
In the morning I called the labs who work for the site about some changes in the lab reports. I spent most of the day comparing data from the source documents to the data entered in the EDC (Electronic data capture).

21 Nov 2018
We had half day off today. I spent most of the time comparing data from the source documents to the data entered in the EDC (Electronic data capture).

22-25 Nov 2018
Thanksgiving weekend.

WEEK 26 NOV-30 NOV 2018

26 Nov 2018
I spent most of the day in filing back the drug dispensation documents in respective binders. And kit number labels (IP labels) in the drug accountability binders. I spent some time in reading and understanding one of the study protocol.

27 Nov 2018
I spent most of day in printing and filing some of the regulatory documents in regulatory binders of the respective studies. I went through the subject binders of MDD study making sure all the source documents are filled out and signed by PI.

28 Nov 2018
I had sick day off.

29 Nov 2018
I worked on making source documents ready for Friday patient visits. Filed back completed and signed source documents into respective patient binders.

30 Nov 2018
We had four patient visits today. One of them had ECG and labs for this visit and others had their infusion and vitals done.

WEEK 3 DEC -7 DEC 2018

3 Dec 2018
I started my day with filing back the drug kit assignment documents in respective binders. And kit number labels (IP labels) in the accountability binders. Also printed the lab reports and made ready for sign of PI.

4 Dec 2018
I started my day with printing and filing regulatory documents into respective investigator site file. We had one pediatric Tourette's study patient visit and two MDD study patients visit. I did ECG on them and checked vitals.

5 Dec 2018
I worked on making lists of subjects interested in trials as per their intake forms. We had interim monitor visit on site for Post-partum depression study.

6 Dec 2018
We had one Tourette's patient visit today. I assisted in doing vitals. I spent most of the day in entering one of the study data into EDC.

7 Dec 2018
We had 4 patient visits today. I was responsible for assisting with all visit related procedures.

WEEK 10 DEC -14 DEC 2018

10 Dec 2018
We had this day off.

11 Dec 2018
We had one Tourette's patient visit in the morning. I assisted in doing vitals and ECG.
We had our weekly meeting discussing about this week's schedule and work. I assisted in answering EDC queries for MDD study.

12 Dec 2018
We had one MDD study patient visit today. I spent most of the day answering EDC queries. We also had interim monitor visit for pediatric Tourette's study.

13 Dec 2018
I spent all day in organizing study binders, filing back source documents from patient visit binders to respective binders. Also, filed back the drug kit assignment documents in respective binders and kit number labels (IP labels) in the accountability binders.

14 Dec 2018
We had one MDD study and one Tourette's study patient visit in the morning. I worked on making the list of invoices for the pharmacokinetics and pharmacodynamics labs of recent visits and sending out to our accounts manager. I filed back some drug dispensation reports.

17 Dec 2018 – 4 JAN 2018
Christmas break

WEEK 7 JAN -11 JAN 2019

7 Jan 2019
We had weekly staff meeting. Since our site is relocating we made inventory of all lab supplies, drugs of each study and office supplies. In the anticipation of our upcoming monitor visit we started doing qc of MDD study binders and filed back required source documents.

8J Jan 2019
I spent most of the day in filing back the drug dispensation records in respective binders. And kit number labels (IP labels) in the accountability binders. Also printed the lab reports and made ready for sign of PI. We had Parkinson's tremor study screening patient visit. I was responsible for collecting vitals and ECG.

9 Jan 2019
Today and next two days we have Study monitor visit for MDD study. We had one Tourette's study patient in the morning. I spend some time collecting data for my internship practicum report.

10 Jan 2019
As our site is relocating we continued doing inventory of supplies, study binders and lab kits. Today was second day of monitor visit. We started on working on action items he made during his visit.

11 Jan 2019
We had 4 patient visits today for different studies. I collected vitals and made sure all the source documents are filled out and complete. I filed back some of the drug accountability documents. Since our site was relocating we spent time to update our regulatory documents such as FDFs (Financial disclosures) and FDA 1572 (Investigator statement) with the new address and filed back appropriately.

WEEK 14 JAN-18 JAN 2019

14 Jan 2019
Today we relocated to a new place. We all worked together in packing and moving things to new location. It was nice to learn how the drugs are shipped according to standard operating procedures without causing any temperature excursion while transportation.

15 Jan 2019
We all site staff worked together unpacking binders and study documents. Most of the day was spent in organizing the study binders and filing back of documents.

16 Jan 2019
We spent all day in organizing the office and making patient rooms ready for the visits. We did the inventory of all the drugs we have on hand for all the studies.

17 Jan 2019
Since we were in the process of relocating and unpacking the things we didn't see patients on these days. We worked together in filing back regulatory documents in respective study regulatory binder. I spent time in checking and making sure we had all regulatory documents ready for tomorrow's monitor visit.

18 Jan 2019
We had monitor visit for post-partum depression study. I spent some time in making sure all the regulatory documents for that study are filed in respective binders. All the FDFs (Financial disclosure forms) and FDA 1572 with new address were filed back in the regulatory binder.

WEEK 21 JAN- 25 JAN 2018

21 Jan 2019
Our site manager trained us how to read and implement Inclusion and exclusion criteria while enrolling patients. We spent time in reading protocol and learned how to be ready for screening visit. We also did phlebotomy practice.

22 Jan 2019
I went over some of the informed consent forms to check if they are signed properly and filed back in the respective informed consent binder. I spent time in reading protocol and collecting data for my internship practicum project.

23 Jan 2019
I worked on entering data into the EDC and resolving some of the queries of MDD study.

24 Jan 2019
I spent time in printing some of the lab reports and bracket visit summaries and made ready for the signature of PI. I filed back some of the drug dispensation records and IP labels in the accountability binder.

25 Jan 2019
We had patient visits today. I helped in collecting vitals. Later in the day I spent time in entering data and resolving queries from EDC.

WEEK 28 JAN- 1 FEB 2019

28 Jan 2019
I started my day with reading and understanding one of the pediatric Tourette's study protocol. I spent time entering data and answering some of the queries of MDD study into EDC.

29 Jan 2019
We had Interim Monitor visit for pediatric Tourette's study. I spent time in organizing and updating site staff box which contains curriculum vitae and trainings of all the staff at the site. As we have relocated we had to make new CV for all the site staff with the updated address.

30 Jan 2019
I started my day with printing lab reports and making ready for PI signature. Worked on resolving EDC queries for MDD study. Printed and filed some of the regulatory documents. I got chance to talk to our study monitor about the work he does at a monitoring visits at different sites. Since I was responsible for maintaining regulatory binders for that particular study he asked me to work on couple of things and to file back some of the documents in the respective binder.

31 Jan 2019
I started my day with resolving some of the EDC queries form MDD study. I had half day off today.

1 Feb 2019
I started my day with printing some of the subject visit summary reports and made ready for the signature of PI. Also made sure all the subject charts are completed and ready for signature of PI. We had MDD patients visit today, I collected vitals for them.

WEEK 4 FEB – 8 FEB 2019

4 Feb 2019
I started my day with filing back some of the drug dispensation records and visit summary reports of the patients in the respective binders. We had pre-study site qualification visit for new study. This study is phase 2 study for treatment resistant depression. This visit is conducted by a study monitor in order to determine site's ability to conduct the clinical trial. Monitor briefly explained study protocol including inclusion exclusion criteria, schedule of visits, etc.

5 Feb 2019
We did some office reorganization in the morning. I spent most of the day collecting and compiling data for my project from the patient database intake forms.

6 Feb 2019
I filed some of the drug dispensation records in respective binders and kit labels in drug accountability binders. Later in the afternoon I assisted in collecting and scanning some of the regulatory documents we required as per initial regulatory packet for one of the new study. To ensure that site is ready to conduct research sponsors require CDA (confidentiality disclosure agreement), signed FDFs (Financial disclosure forms), CVs and medical license of PI. The purpose of CDA is to ensure that confidential information is protected.

7 Feb 2019
I made source documents ready for upcoming patient visits. Also made sure all lab reports and bracket reports (Visit summary reports) are printed and ready for sign of PI. We had one of the

pediatric Tourette's patient visit today. He completed one part of study and rolled into the second part, so we had to take his informed assent and his parents informed consents today. Then we completed all procedures such as taking vitals, drawing labs and ECG.

8 Feb 2019
We had two MDD study visits today. One had her infusion done and the other patient had her last visit of one part of study requiring a lot more time than usual visit. I assisted in doing vitals, ECG. We also had screening visit of pediatric Tourette's study. We completed all visit related procedures such as informed consents, blood draw, ECG, vitals and scales.

WEEK 11 FEB - 15 FEB 2019

11 Feb 2019
I worked on collecting some of the documents requested by one of the sponsors after closing out of the study. Printed out some of the subject visit summaries and made ready for the signature of PI.

12 Feb 2019
I spent all day in printing and filing regulatory documents in the respective study binder. I worked on updating Site staff box containing CVs and trainings of all the staff.

13 Feb 2019
I spent most of the day answering emails from ECG vendor regarding ECG queries along with completing ECG query forms and resending them to vendor.

14 Feb 2019
I started my day with printing some of the lab reports and making ready for signature of PI. Printed some of the regulatory documents. I called Clinical Laboratory Improvement Amendments (CLIA) office to follow up regarding our certification update. It is the certificate required for quality control of laboratory.

15 Feb 2019
In the morning, I kept all the current subject binders, lab reports visit summary reports ready for PI signature. We had one pediatric Tourette's patient visit today. I assisted in taking his vitals, ECG and labs. I worked on answering some of the ECG queries of one of the study.

WEEK 18 FEB -22 FEB 2019

18 Feb 2019
I had this day off.

19 Feb 2019
We spend some time in reorganizing office. I worked on some of the ECG queries, where we have to confirm subject number, timepoint, collection date and time of ECG. If the vendor does not

receive transmitted ECG we have to mail them a copy of ECG with one paper ECG submission form.

20 Feb 2019
I started filing away some drug dispensation records of MDD study into respective subject binders. I also worked on resolving some of the ECG queries in MDD EDC.

21 Feb 2019
I worked on collecting data for my internship practicum. I printed out some of the labs and subject visit summaries and kept ready for signature of PI. We had pediatric Tourette's study patient today and one MDD study patient. I collected vitals and assisted in other visit related procedures.

22 Feb 2019
Today was a patient visit day. We had one MDD study patient and one Parkinson's tremor study patient. She is our first eligible Parkinson's tremor study patient. This study is designed to explore the ability of digital tools to quantify motor function changes in Parkinson's disease and to monitor subject compliance with study medication.

WEEK 25 FEB -1 March 2019

25 Feb 2019
We had this day off.

26 Feb 2019
I spent most of the day in printing regulatory documents, drug dispensation emails and filing back into respective binders. I worked on getting ECG confirmations from ECG vendor portal.

27 Feb 2019
I started my day with printing some of the documents and filing in regulatory binder. I spent some time in collecting and compiling data for my project.

28 Feb 2019
Today I worked on making the informed consent binder for Parkinson's essential tremor study. I had meeting with my committee member regarding some statistical questions about the data. Later in the day I kept all the lab reports, ECGs and subject charts ready for our sub investigator's signature and filed back in respective subject binders. We had team meeting discussing about next week's plan and recruitment plan for our new studies.

1 March 2019
I started my day with making source documents ready for today's patient visits. We had one Parkinson's tremor patient visit today morning and two MDD study patients later in the day. I assisted in doing vitals and ECG. For Parkinson's patients we have to do all the vitals and ECGs in triplicate. We also do video recording of tremors levels in these patients.

WEEK 4 MAR – 8 MAR 2019

4 Mar 2019
I spent some time in reading and learning new depression study protocol for which the site will soon start recruiting subjects. I worked on checking subject binders and comparing the data in EDC.

5 Mar 2019
We had one new pediatric Tourette's screening visit for which we checked subject's vitals, an ECG and scales. But because of low tic score she could not pass the screening and was a screen failure. We also had another Tourette's patient for his baseline visit. I assisted in doing all visit related procedures such as vitals, ECG.

6 Mar 2019
I worked on downloading ECG confirmation reports from ECG vendor. I also updated informed consent log with new subject informed consents. Later in the day, I worked on my internship project.

7 March 2019
I started my day with printing some subject visit summary reports. We had a site staff meeting. I worked on answering MDD study queries in EDC. Later in the day, I made a binder for one of pediatric patients who went into extension phase of the study. We had one pediatric Tourette's study patient visit. I assisted in doing vitals, ECG and scales.

8 March 2019
I started my day with printing some visit summary reports for Tourette's study and filed back in respective binders. I worked on ECG vendor portal to get some ECG overreads/confirmed ECG, printed and made ready for sign of PI. Then I spend rest of the day working on EDC queries.

WEEK 12 MAR – 15 MAR 2019

12 March 2019
We had one pediatric Tourette's patient early morning and one later in the afternoon. As our other site coordinator was off today I had to conduct today's visits. One of the patients was on last visit of one part of study so he had his labs and ECG done along with vitals and tics scales. The other patient had to be reconsented today. I conducted all visit related procedures and processed labs for shipping to the labs vendor.

13 March 2019
We spent all day preparing for tomorrows monitor visit for MDD study. Along with other intern I spent some time in doing quality control check of subject binders and printed some subject visit summary reports. I worked on informed consent binder to check everything is filed properly as per the table of contents. I spent rest of the day resolving some of the queries in the EDC.

14 March 2019
We had monitor visit for one part of MDD study. We made subject binders ready for him. As the study is closed he asked to hand all on-site drug and shipped it to sponsor site. I worked on collecting some ECG confirmations from ECG vendor portal.

15 March 2019
It was second day of monitor visit today. As study is closed we have to send back ECG machine provided by ECG vendor so I worked on getting packing slip and packing materials from the vendor as we did not save our original packing for the machine. We also had one patient visit. I assisted in doing vitals and making drug ready for dispensation.

WEEK 18 MAR – 22 MAR 2019

18 March 2019
I worked on printing some bracket subject visit summary reports and making ready for PI signature. I also worked on some action items send by the sponsor of one of the old studies. I scanned some temperature logs that we keep for monitoring temperature of investigational product that was on the monitor action items as well.

19 March 2019
We had site staff meeting with Dr. Maynard today. We discussed about current studies status and recruitment plan for the upcoming studies. We had one MDD study patient and one pediatric Tourette's patient in the afternoon. I assisted in doing their vitals, ECG. I continued to work on monitors action items and filed back some drug dispensation reports.

20 March 2019
I worked on filing some documents in respective patient binders and making source documents ready for Friday patient visits. I spent most of the day in making a regulatory binder for new study and working on action items of the monitor.

21March 2019
I had a chance to attend a site initiation visit for new depression study. The study monitor/ CRA discussed the protocol of the study and explained inclusion and exclusion criteria of the study. It would be interesting to work on this study. Later in the day I completed and scanned some documents for providing to one of the study monitors.

22March 2019
Today was a patient visit day. We had two pediatric Tourette's patients and one Parkinson's study patient. I was responsible for doing vitals and ECGs on them. For pediatric Tourette's study, patient has to do some tics scales and questionnaires on a Tablet. We also had one MDD study patient. After patient visits we made sure all the source documents are completed and ready to enter in EDC.

WEEK 25 MAR – 29MAR 2019

25 March 2019
Today I worked on making source documents ready for this week's visits. I spent some time in answering email from ECG vendor. I also worked on making the informed consent log for one study. We took some time to do inventory of some lab supplies.

26 March 2019
I worked on action items of PPD study sent by monitor after his study close out visits. We had meeting discussing about current studies and recruitment for new depression study. The site is aiming for 10 subject screens by the end of next week. Later in the day we had pediatric Tourette's patient. I assisted in all visit related procedures.

27 March 2019
I spent some time in reading a protocol of new depression study. I worked on my thesis draft corrections and presentation.

28 March 2019
I worked on my thesis corrections and presentation.

29 March 2019
We had one Parkinson's study patient and one MDD study subject. I assisted in measurement of vital signs and ECG.

WEEK 1Apr – 5Apr 2019

1 Apr 2019
I spent most of the day working on my internship practicum report presentation.

2 Apr 2019
I had my internship practicum presentation today morning. Later in the afternoon we had screening visits for two subjects for new depression study and a pediatric Tourette study subject visit. I assisted in measurement of vitals and ECG.

3 April 2019
I worked on making Informed consent log list for two studies. I printed regulatory documents for a new study. Later in the day we had one pediatric Tourette study subject visit today. I assisted in doing all visit related procedures.

4 April 2019
I spent some time in printing subject visit summary reports of MDD study and drug dispensation emails then transmitted ECGs. We had one pediatric Tourette subject visit today. I assisted in visit related procedures.

5 April 2019

I started my day with making source documents ready for today's visits. We had one pediatric Tourette subject visit and one new depression study screening visit. I spent time in filing lab reports and visit summary reports in respective subject binders.