Patel, Eva K. Analysis of Factors that affect Recruitment Process and Effectiveness of Recruitment Methods in Treatment Resistant Depression Study
Master of Science (Clinical Research Management), November 2019

Introduction:

The following Research Project is a Process Improvement Study to identify the factors affecting the recruitment process and identify best recruitment method in Treatment Resistant Depression Study. Adequate recruitment is essential to any study's success. Most studies report only the effectiveness of recruitment method, but very few report the cost of randomizations. This research project will analyze the effect of different recruitment methods in the Treatment Resistant Depression Study. The study will work on cost analysis which can be critical when deciding which recruitment methods to implement in Randomized Controlled Clinical Trials.

Methods:

For this research project, a study will be conducted to analyze the factors that affect the recruitment process and compare the effectiveness of different recruitment methods. Factors include demographical data such as age, gender, ethnicity, race and distance from site. Data for this study will be collected from a randomized double blind, active controlled "Treatment Resistant Depression Study" conducted at North Texas Clinical Trials, Fort Worth, TX. Data will include how many subjects were consented, how many of them were enrolled and how many of them failed the screening process.

Results:

All four recruitment methods were compared, based on the number of subjects referred, enrolled and randomized for the study. Statistical analysis showed that there was no significant difference between subjects referred, enrolled and randomized using all four methods (p-value: 0.1920). Analysis was performed on data which showed a statistically significant difference between the number of subjects referred and randomized through subject database and clinical connection (p-value: 0.0184). Total pooled data revealed race and distance from site being the only predicting factors on the outcome of being screened into the study.

Conclusion:

Patient recruitment is a vital component in assuring the success of a clinical trial and can be time consuming. One method of recruitment alone is not sufficient to meet the target enrollment. It was difficult to prove significant effect of all the factors on the recruitment process due to small sample size, but future studies with larger sample size could potentially reveal more significant impact of factors associated with the recruitment process.

ANALYSIS OF FACTORS THAT AFFECT RECRUITMENT

PROCESS AND EFFECTIVENESS OF RECRUITMENT

METHODS IN TREATMENT RESISTANT

DEPRESSION STUDY

Eva Patel, B.S., M.S.

APPROVED:

_____
Stephen Mathew, Ph.D, Major Professor

_____
Keisa Mathis, Ph.D., Committee Member

_____
Brian Maynard, Ph.D., Committee Member

_____
Jessica Anderson, CCRP, Committee Member

_____
Patricia Gwirtz, Ph.D., Department Chair

_____
J. Michael Mathis, Ph.D., Ed.D., Dean
Graduate School of Biomedical Sciences

Analysis of Factors that affect Recruitment Process and Effectiveness of Recruitment Methods in Treatment Resistant Depression Study

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the
Graduate School of Biomedical Sciences
University of North Texas Health Science Center
At Fort Worth, Texas

In Partial Fulfilment of the Requirements
for the Degree of
MASTER OF SCIENCE IN CLINICAL RESEARCH MANAGEMENT

By:
Eva Patel
Fort Worth, Texas
October 2019

ACKNOWLWDGEMENTS

I would like to express my sincere appreciation to my major professor, Dr. Stephen Mathew, for his constant guidance and encouragement. He has served as an unwavering source of motivation along each step of the way to the completion of this project. A special thanks to Dr. Keisa Mathis for her timely support and suggestions.

A great deal of appreciation goes out to Jessica Anderson and Dr. Brian Maynard. The overall internship experience was incredible because of the guidance and assistance of these people. Thanks to Jessica Anderson for her incredible mentorship and investing countless hours in helping me throughout the internship, you are a true inspiration for me. Thank you to Dr. Maynard for your advice throughout the internship.

Last but not least, I am highly indebted and thoroughly grateful to my loving husband and my parents whose continued support has given me strength in pursuing my dreams. This accomplishment would not have been possible without them.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER I

INTRODUCTION

Background

Clinical studies, also called clinical trials, are essential to disease research. No matter how promising a new intervention looks when tested in the laboratory (nonclinical studies) or in animals (preclinical studies), it cannot be approved for use in humans until it has been carefully evaluated through several phases of clinical trial—research involving a group of people who volunteer to participate in the intervention under close experimental conditions [1].

Clinical trials are research studies performed in humans to assess a pharmaceutical, surgical or behavioral intervention. It is a primary method by which researchers evaluate a new treatment and determine safety and efficacy in humans. Often a clinical trial is used to learn if a new treatment is more effective and/or has less harmful side effects than the standard treatment [2]. This type of research study prospectively assigns human participants to one or more health-related intervention(s) in order to evaluate health outcomes [3].

Clinical trials are extremely costly, they consume up to 33% of research and development budget provided by any pharmaceutical company. Low recruitment rates and failure have been reported to cause 45% of clinical trial delays [4]. The length of the trial may need to be extended, leading to increased use of resources and costs. Extended trials delay the availability of potentially beneficial therapies for the public [5]. The integrity and validity of the results also rely on adequate sample size. If the sample size is not achieved, there is an increased chance of Type 2 error, that is finding no difference between treatments when one actually exists [6].

Clinical studies greatly depend on successful patient recruitment in order to produce valid and reliable results. However, despite heavy spending on recruitment, many studies fail to meet their enrollment goals. A study conducted in 2011 by the Tufts Center for the Study of Drug Development (CSDD) reported that two thirds of clinical trial sites do not meet their enrollment

requirements [7]. A 2015 analysis of registered trials revealed that nineteen percent of clinical trials were closed or terminated early because they could not accrue enough patients [8].

In an attempt to address recruitment issues, the National Institute of Mental Health (NIMH) released a series of "points to consider" for research staff [9]. The suggestion calls for establishing a relationship with potential subjects. This includes engaging the subject's network of support to prevent communication and trust barriers [9]. The suggestions created by the NIMH emphasize the pivotal role of the research staff in a clinical trial. It is up to the researcher to appropriately communicate the study aims and improve a subject's understanding and expectations. They are also responsible for speaking with family members in answering any concerns regarding the study procedures. Spending time with the subject and their family to provide culturally and linguistically relevant educational materials can be an effective way to foster the research relationship [10].

The suggestions from the NIMH provide a framework to improve the success of recruitment in clinical research trials. More importantly these strategies create a path for future research studies. Building a positive relationship with the community of research subjects can facilitate the success of future studies. Identifying and preventing the barriers to recruitment is an ongoing process that has to be consistently addressed. While clinical research trials require people to expose themselves to a certain amount of risk, the evidence gained can potentially provide new treatments, improving the lives of thousands of patients [11].

In order to more effectively combat the issue of insufficient recruitment, factors regulating this crucial step in clinical research have been stringently examined. The first step required in conducting clinical trials effectively is recruitment. A study cannot be completed without adequate number of subjects, recruited subjects are pivotal in the development of a new drug or device that will eventually serve to improve healthcare of the broader population. It is through recruitment that the process of developing a potential drug can begin to take shape. Identifying factors that promote recruitment will help researchers to develop a feasible strategy to improve the enrollment of subjects in a clinical trial [11].

Since under-recruitment is one of the most common causes of trial failures, identification of the causes of poor recruitment in a clinical trial will allow for the development of appropriate strategies to overcome these problems and facilitate successful trial completion. Therefore, it is very important to analyze the predictors of poor recruitment using data obtained from a clinical trial. This research project will compare different factors that affect subject recruitment.

The recruitment method and tactics may vary depending on the type of the study, disease or subject demographics. Because recruitment is an important factor in the conduct of clinical trials, it is important to evaluate the different methods of recruitment and investigate possible barriers. Enrollment inadequacies significantly impact both scientific and financial aspects of the study [12]. Recruitment techniques have remained stable over the last 20 years [13]. Some of the more common recruitment methods include media advertising via television, newspaper, radio advertisements [13], physician referrals [14], press releases/public service announcements [15], posting flyers [16], mailings [Messer], and "cold" calls [17]. Researchers are now turning more to internet recruitment techniques however to fully utilize this medium, substantial planning and resources must be invested [18].

Most studies report the efficacy of each recruitment method in terms of number of interested potential participants who contact the study and the number ultimately enrolled [19]. A few trials also report the cost per call and per randomization [14]. Such a cost analysis is critical in deciding which recruitment methods to implement with limited resources [20]. It is important for researchers to understand the recruitment process, identify associated barriers, and execute strategies to overcome these challenges. Further research must be performed to determine the recruitment method that has the highest impact in recruiting subjects. Additionally, more studies are needed to determine factors that can be controlled to obtain adequate recruitment to optimize results.

The strategies implemented through suggestions from the NIMH will certainly increase the success of recruitment in clinical research trials at the present time. More importantly these strategies will create a path for future research studies. Building a positive relationship with the community of research subjects can facilitate the success of future studies. Identifying and

preventing the barriers to recruitment is an ongoing process that has to be consistently researched. While clinical research trials require people to put themselves at risk, the evidence gained can provide a greater degree of certainty in medical decision making [11].

Depression is a highly controversial topic in psychiatry as there are long-standing disputes between the biologically and the analytically oriented psychiatrists. A major depressive disorder (MDD) is indicated by the presence of at least five of the following symptoms occurring independent of physical illness, normal bereavement, alcohol or drugs: Abnormal depressed mood, abnormal loss of interest and pleasure, appetite or weight disturbance, sleep disturbance, disturbance in activity, abnormal fatigue or loss of energy, abnormal self-reproach or inappropriate guilt, poor concentration or indecisiveness, morbid thoughts of death or suicide (American Psychiatry Association 2013).

There is not a standard definition of treatment resistance in depression. It may be defined as an unsatisfactory response to two adequate trials of two different classes of anti-depressants at optimum dosage for sufficient duration [23], but there is no strict criteria to measure clinically meaningful improvements and the number and type of treatment trials that a patient should experience before being labelled as refractory depression [24]. Several factors like long duration of depressive episodes, moderate high suicidal thoughts, anxious comorbidity, higher number of hospitalizations, age factors, may account for non-response to recruitment efforts and even non-compliance after recruitment.

CHAPTER II

SIGNIFICANCE

Over the last few years, the complexity, size, length and globalization of clinical trials have continued to expand - in parallel with soaring trial costs. We know that there is an estimated 2.6 billion dollars average cost of bringing a drug to market [21], and the largest portion of drug development cost is for human clinical trials. As drug development costs and complexity spiral, sponsors continue to face mounting pressures from regulatory agencies, the medical community, insurers and the public to reduce these costs while improving the time to develop a drug, expand pipelines, improve drug quality and safety, and meet more stringent regulatory expectations [22].

Increasing bureaucratic hurdles, accruing expenditures and difficulty in patient recruitment are important factors that directly contribute to increase in costs associated with a clinical trial [17]. Optimization of patient recruitment can help find eligible subjects that are likely to complete the trial. This will lead to collection of accurate data without delaying or increasing the cost of the trial. Identification of factors that cause poor recruitment of subjects will allow for controlling such factors in future trials.

Recruitment comparison and analysis will allow for more efficient recruitment methods to be used in future studies, promoting successful clinical trial participation. Focused and controlled factors can help the research sites achieve targeted enrollment in a timely manner.

CHAPTER III

HYPOTHESIS/ PROBLEM & SPECIFIC AIMS

PROBLEM

A 2015 analysis of registered trials revealed that 19% of clinical trials conducted were closed or terminated because they were unable to accrue ample subjects [1]. Recruitment issues cause delays in up to 86% of clinical trials that do not reach recruitment targets within their specified timeline [2-4]. In addition, recruitment challenges are reported to be the cause of 45% of study delays which often exceeds 6 months [4].

Failure to achieve recruitment goals jeopardizes the quality of the study, compromises the study power, consumes resources allotted to other parts of the study, and causes broadening of inclusion criteria, therefore potentially reducing the validity of the study [14].

SPECIFIC AIMS

Primary Aim: To analyze the efficacy and cost effectiveness of various recruitment methods utilized in Treatment Resistant Depression Study.

In this aim, we will evaluate different recruitment methods for enrolling subjects using data from the treatment resistant depression trial, which can provide the research staff with insight on what methods are most efficacious for future study recruitment.

Secondary Aim: To analyze factors affecting recruitment process in Treatment Resistant Depression Study.

In this aim, we will evaluate the factors that have the most impact on subject recruitment using data from the treatment resistance depression research study. In order to achieve successful enrollment, the barriers must be acknowledged and corrected.

CHAPTER IV

DESIGN AND METHODOLOGY

Data for this project was collected from a randomized, double-blind, active controlled Treatment Resistant Depression Study conducted at North Texas Clinical Trials in Fort Worth, TX during 2019. This study was selected from a pool of clinical trials at this site because it had more than one recruitment method and large population size in comparison to other studies which can bolster statistical analysis. In this project, we analyzed different factors that affect recruitment in clinical trials like subject age, race, time taken to contact potential subjects, geographical distance from the site, and the ability to meet inclusion/exclusion criteria. Using data from this trial, various methods have been compared on the basis of enrollment efficiency and cost effectiveness.

STUDY

The Treatment Resistant Depression Study is a randomized, double-blind, active-controlled, 12 week, two-period, Phase 2/3 study, consisting of a six-week open-label lead-in (Period 1), and a six-week, double-blind period with randomized treatment of variable duration (period 2). The trial is being conducted in subjects with treatment resistant depression. Subjects are considered to have treatment resistant depression if they have had a historically inadequate response to 2 or more antidepressant treatments (ADTs) and a prospective inadequate response to treatment with bupropion SR during Period 1.

RECRUITMENT METHODS

Subject recruitment for the Treatment Resistant Depression study included recruitment methods used by the site as well as provided by the sponsor. The recruitment method provided by the sponsor is an online clinical trial portal. Recruitment methods used by the site include physician referral, obtaining data from the site's patient database, and online recruitment using Clinical Connection, a clinical trial recruitment portal. When potential subjects are referred from any of

these methods, site staff followed up with the subjects by contacting them on the phone. Online methods include post recruitment advertisements on Google and social media sites such as Facebook, Twitter, Pinterest, Instagram and Snapchat for subject recruitment. Clinical Connection is a leading web-based service for clinical trial notification and information. Clinical Connection works with research organizations worldwide and delivers clinical trial alerts to its members.

DATA COLLECTION

The data used for analysis in this study have be compiled from two internal sources: a recruitment tracking program and internal subject database. The program used for recruitment tracking captures the progression of the recruitment process of each individual. This program contains the contact information, date of receipt of information and the date of all attempted/completed contacts made by site staff. The online database contains detailed personal information on each potential subject including age, gender, race, geographical location, diagnosis and prescribed medications. Data from these two sources has been collected, documented and combined over a six-month period for analysis.

STATISTICAL ANALYSIS

Two-way Analysis of Variance (ANOVA) and Fisher Exact test has been used to assess significant differences in recruitment results using different methods. Two-way ANOVA is an extension of One-way ANOVA and examines the influence of two different categorical independent variables on one continuous dependent variable. Fisher Exact test is used to determine if there are non-random associations between two categorical variables. Chi-square test is also used for the same purpose, but as we have a small sample size, Fisher Exact test was used.

Regression analysis has been performed to compare the factors that affect recruitment process. Factors considered are age, gender, race, ethnicity and distance from site. Regression analysis is a powerful statistical method that allow to examine the influence of one or more independent variables on a dependent variable. Logistic regression has been performed as the dependent variable is dichotomous (binary).

CHAPTER V

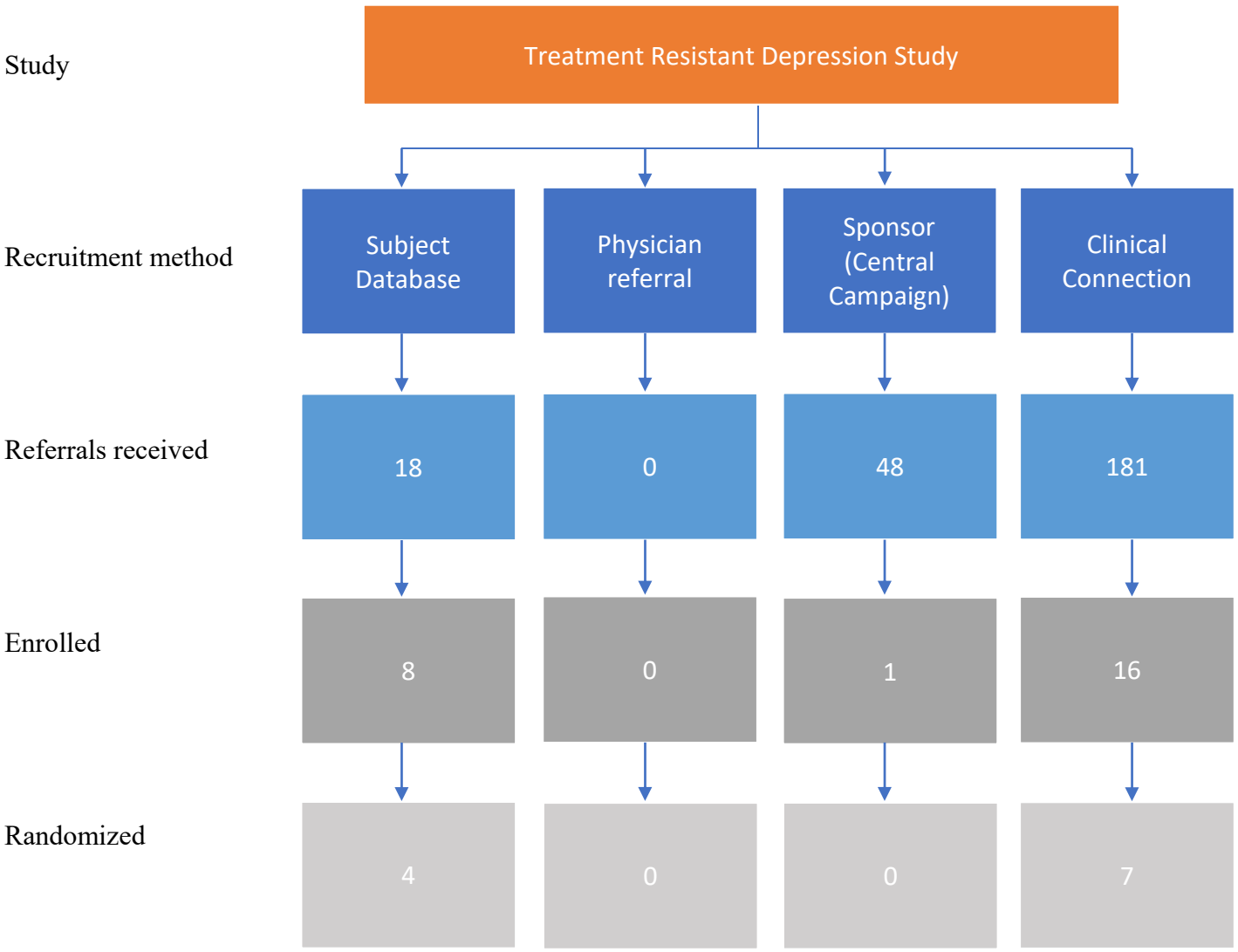
RESULTS

RECRUITMENT METHOD ANALYSIS

A total of 247 potential subjects were either referred from database or signed up on the clinical trial portal for the Treatment Resistant Depression Study between March 2019 and August 2019. The eligibility of subjects was assessed based on the inclusion and exclusion criteria as stated in the study protocol. Potential subjects who expressed interest in the trial were prescreened by phone. Those who passed the prescreening by verbally meeting all the inclusion criteria and not meeting exclusion criteria were brought in for a screening visit and were enrolled in the screening process. Subjects who passed the screening assessments were randomized in the study.

Out of 247 potential subjects, 18 subjects were referred form subject database, 48 subjects were referred by sponsor and 181 subjects were referred by Clinical Connection. Out of the 18 subjects from subject database, 8 subjects were enrolled and 4 out of the 8 enrolled subjects were randomized into the study. Of the 48 referrals received from sponsor through central campaign, only 1 subject was screened which ultimately screen failed. Clinical Connection provided 181 referrals out of which 16 subjects were enrolled and 7 out of the 16 enrolled subjects were randomized in the study. As shown in Figure 1, no referrals were obtained by physician referral.

Figure 1: Summary of Recruitment method and Enrollment Diagram



Recruitment methods were analyzed using 2-way ANOVA test to check for significant differences between the number of referred, enrolled and randomized subjects across the different recruitment methods. As indicated by the p-value of 0.1920, no statistically significant difference is observed between the methods of enrollment. Table 1 summarizes number of subjects referred, enrolled and randomized across the different recruitment methods for the Treatment Resistant Depression study. Table 2 presents the statistical results obtained by performing two-way ANOVA.

There is still significant difference between the number of subjects referred and randomized through database and clinical connection which is lost due to overlapping of enrolled and randomized subjects. Table 3 summarizes number of subjects referred and randomized through Subject Database and Clinical Connection methods and the data was analyzed using Fisher Exact test. p-value of 0.0184 shows significant difference between number of subjects referred and randomized using the two methods.

Table 1: Number of subjects referred, enrolled and randomized by different recruitment methods

Recruitment methods	Subject Database	Central Campaign	Clinical Connection
Number of subjects referred	18	48	181
Percentage of subjects referred	7.28 %	19.43 %	73.27 %
Number of subjects enrolled	8	1	16
Percentage of subjects enrolled	32 %	4 %	64 %
Number of subjects randomized	4	0	7
Percentage of subjects randomized	36.36 %	0 %	63.63 %

Table 2: Two-way ANOVA test

	Recruitment methods	Recruitment process
Percentage of variation	43.48 %	22.60 %
Degree of freedom	2	2
F-value	2.564	1.332
p-value	0.1920	0.3602
p-value summary	Not statistically significant	Not statistically significant

Table 3: Number of subjects referred & enrolled through Subject Database & Clinical Connection

Recruitment methods	Subject Database	Clinical Connection
Number of subjects referred	18	181
Number of subjects randomized	4	7

Table 4: Fisher Exact Test

Test	Fisher Exact test
One- or two-sided	Two-sided
p-value	0.0184
p-value summary	Statistically significant

COST EFFECTIVENESS OF RECRUITMENT METHODS

For the purpose of evaluating the cost-effectiveness among the methods used for subject recruitment, cost of enrollment per subject as well as the cost of recruitment per subject was compared. No direct cost is associated with database and physician referral as subject leads are identified either by the physician or obtained from the site's subject database, but the cost of keeping the database in an internal subject database was $50/month, which totals to $250 for five months. Clinical Connection is an online recruitment method that was used by the site for 5 months (March 2019 to August 2019). Depending on the advertisement package selected, subscription cost for the first three months was $297 ($99 per month) and for the remaining two months was $1095 ($399 per month), which totals to $1392 for five months. The cost of recruitment methods per subject is summarized in the table 3.

For the Treatment Resistant Depression study, 8 subjects were enrolled out of which 4 subjects were randomized from site database, 17 subjects were enrolled from which 7 subjects were randomized from the subject referrals obtained from Clinical Connection and Central Campaign, which were recruited via paid recruitment strategy, mainly social media advertisements.

Table 5: Cost analysis of different recruitment methods

Recruitment method	Clinical Connection	Database
Number of subjects enrolled	16	8
Number of subjects randomized	7	4
Cost per Enrollment	$87	$31.2
Cost per Randomization	$198.85	$62.5

FACTORS AFFECTING RECRUITMENT PROCESS

SUBJECT DEMOGRAPHICS

Out of 247 subjects that were referred to the site, only 50 were included in the data analysis due to information completion and rate of subject responsiveness. The subject response rate was therefore estimated to be 20.24%. Though 72 subjects were willing to go through the prescreening process for the study, only 50 subjects agreed to disclose their demographics. 50 of the 72 subjects disclosed their demographical data. Of the 50 subjects that disclosed their gender 62% were females and 38% were males. Of those who provided information, 66% of subjects were Caucasians, compared to 26% African Americans, and 4% Asians. Of those who disclosed ethnicity, 18% were Hispanic or Latino, 72% were not Hispanic or Latino and 10% were unknown.

Table 6: Demographics

		N	Marginal Percentage
Status	Referred	25	50.0%
	Enrolled	14	28.0%
	Randomized	11	22.0%
Race	White	33	66.0%
	Black African/American	13	26.0%
	Asian	2	4.0%
	Others	2	4.0%
Ethnicity	Hispanic or Latino	9	18.0%
	Not Hispanic or Latino	36	72.0%
	Unknown	5	10.0%
Gender	Male	19	38.0%
	Female	31	62.0%

The preliminary analysis of subject demographics demonstrated that subjects that showed greatest interest in answering the prescreen calls and emails were mostly White Non-Hispanic women.

Table 7: Demographics: Continuous variables

	N	Minimum	Maximum	Mean	Std. Deviation
Age (years)	50	18	65	44.26	12.28
Distance from site (miles)	50	0.5	101	24.48	19.45

50 subjects provided their age, with a low being 18 years of age and a high of 65. The average age was 44.26 years with a standard deviation of 12.28 years. Average distance from the site was 24.48 miles with the standard deviation of 19.45 miles, maximum being 101 miles and minimum being 0.5 miles.

Table 8: Demographics of randomized subjects

Race	White	8
	Black African/American	2
	Asian	1
	Others	0
Ethnicity	Hispanic or Latino	4
	Not Hispanic or Latino	7
	Unknown	0
Gender	Male	6
	Female	5

LOGISTIC REGRESSION

Primary analysis on the pre-screened population was performed by including all six of the factors in the model building. Logistic Regression was performed to analyze the effects of different factors on subject recruitment. Different factors including age, gender, race, ethnicity and distance from site were compared for subjects referred and subjects randomized in the study. Binary logistic regression was performed as the dependent variable was dichotomous – subjects referred for the study and subjects randomized in the study.

Pooled imputed dataset presented a significant finding for only ethnicity and distance from site with p-values of .030 for ethnicity and .042 for distance from site.

Table 9: Logistic Regression Model

Effect	Chi-square	Degree of freedom	pseudo R-square	p-value
Age	.656	1	.017	.427
Gender	.207	1	.006	.648
Race	10.136	6	.227	.119
Ethnicity	10.736	4	.239	.030
Distance from site	4.123	1	.107	.042

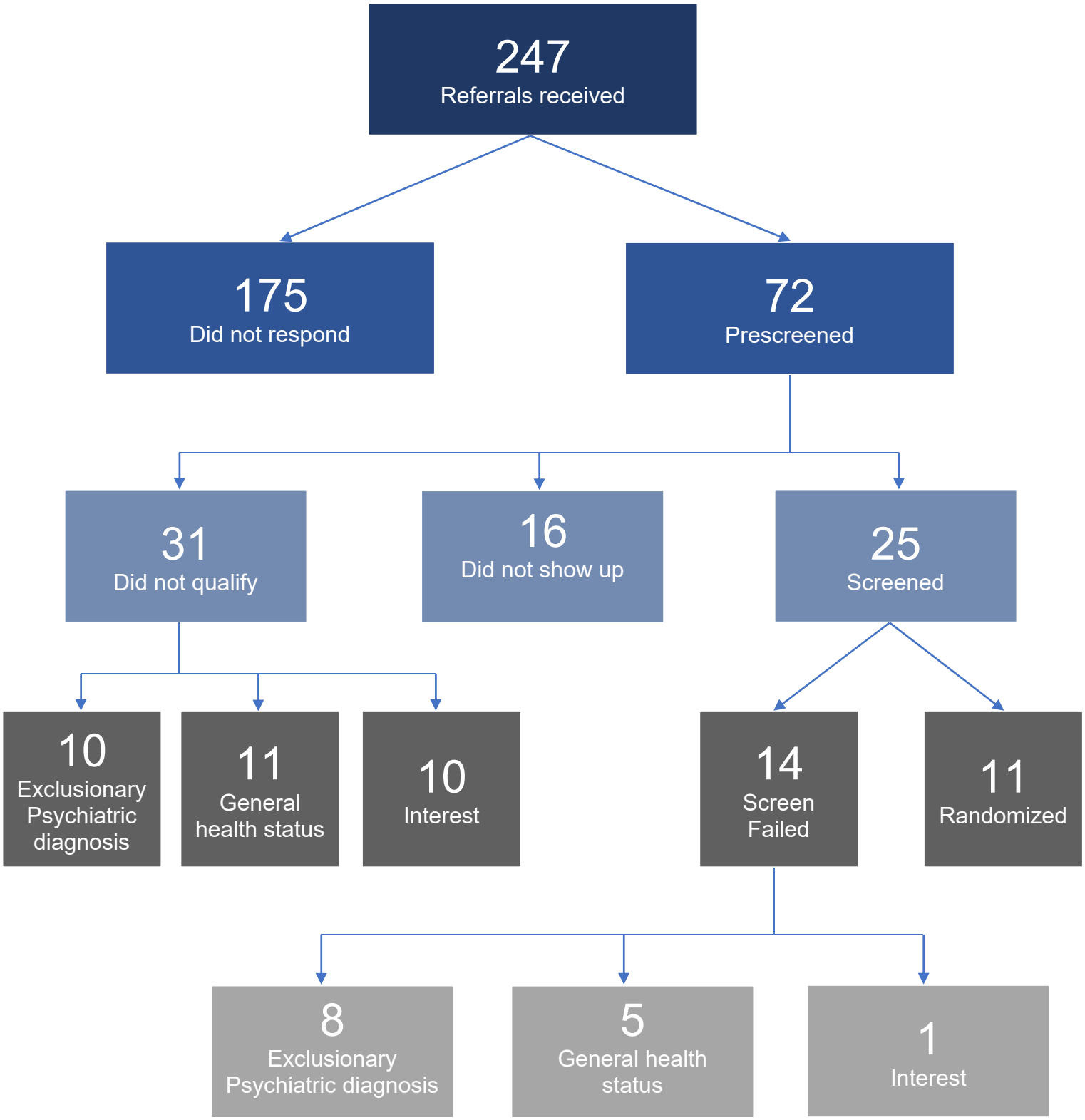
RECRUITMENT PROCESS

For the Treatment Resistant Depression study, 247 subject referrals were collectively obtained from all four recruitment strategies in a time period of five months. As the subjects were referred to the site, the research coordinators contacted the subjects first by text, then by phone call, followed by email. Three attempts were made to contact the subjects for recruitment. 72 subjects responded to the contact made by the site and were prescreened on phone at their time of convenience. An intake form was sent to all the 72 subjects which helped to determine whether the subject was a good fit for the study.

Out of the 72 prescreened subjects, 31 did not qualify for the study due to exclusionary psychiatric diagnosis, mental health status and interest. 3 subjects did not qualify due to distance, 7 subjects lost interest with time, one had no prior antidepressants, six had bipolar depression, five were on exclusionary medications, two had active PTSD, one was not diagnosed with Major depressive disorder, one was pregnant, two did not fall in the age range, one had higher BMI and two had HIV.

Out of the 41 subjects that passed the prescreen, 16 subjects did not show up for the screening visit. 25 subjects were screened at the site after signing the Informed Consent form. Out of the 25 screened subjects, 14 subjects screen failed due to one of the three reasons – exclusionary psychiatric diagnosis, mental health status and interest. Five subjects did not qualify as per PI's view of non-compliance, one was not ready to release medical records, two were Hepatitis C positive, one had high BMI, three failed the SAFER call which is a part of screening process for the Treatment Resistant Depression study and one was found to have seizures during childhood. 11 subjects that passed the screening process including the laboratory findings, ECG reports and physical and mental examination were enrolled for the study.

Figure 2: Recruitment Process Flow-chart



CHAPTER VI

DISCUSSION AND CONCLUSION

DISCUSSION

Recruitment of clinical research subjects is said to be effective if more eligible subjects are enrolled in a short period of time by the study team at minimal cost to site. This project compares different recruitment methods, analyzes different factors that can act as a barrier for recruitment and tracks the complete process of recruitment from obtaining subject referrals through randomization. Out of the 247 referrals obtained through various recruitment methods, 72 subjects were prescreened with the intention of enrolling the subjects for the Treatment Resistant Depression study.

All four recruitment methods were compared, based on the number of subjects referred, enrolled and randomized for the study. Statistical analysis showed that there was no significant difference between subjects referred, enrolled and randomized using all four methods (p-value: 0.1920). Significance was not achieved because of the overlapping data between the subjects enrolled and randomized. Analysis was performed on data which showed a statistically significant difference between the number of subjects referred and randomized through subject database and clinical connection (p-value: 0.0184). Number of initial referrals obtained from clinical connection were more than that from subject database, however in terms of randomized subjects, database provided the site with higher percentage of suitable subjects.

Patients trust their physicians and will be more likely to participate in a study if their physician tells them about it, but they rarely have time to communicate clinical trials to patients and sometimes even forget to mention the trial to the patient, therefore an initiation can be made to provide brochures and pamphlets to the physicians which they can have at their clinic and send reminder emails about subject recruitment. Including major inclusion/exclusion criteria can enable physicians refer eligible subjects to the site.

On-site methods were found to be more cost effective in terms of subject randomization compared to the online methods. Online methods were found to be an expensive method for recruitment, but comparing the two online methods, Clinical Connection was found to be more beneficial as it provided a higher percentage of eligible subjects than any other method. Subject database played a major role in recruitment without implementing any referral cost while providing a good number of randomized subjects. Although the online methods were comparatively expensive, the database of initial referrals can be used in future studies.

Using regression analysis, the effect of factors on the recruitment process was analyzed. Total pooled data revealed race and distance from site being the only predicting factors on the outcome of being screened into the study. Furthermore, individuals closer to the site were nearly four times more likely to become enrolled compared to individuals that were further (more than 32 miles) from the site. With respect to the data analysis, certain statistics cannot be ignored. According to the prescreened data, 72% subjects were not Hispanic or Latino, 66% were Caucasians and 62% were females. Further analysis with a larger sample could shed light on this in future studies.

STUDY LIMITATIONS

Due to the short length of the internship, time was a major hindrance to the data collection process. The data for this project has been collected from the Treatment Resistant Depression study which is an active study at the site and so the recruitment for the study is still ongoing. Due to this the subject sample size was small. With small sample size, the statistical power is lost where smaller effects are harder to detect and may go unnoticed. Unfortunately, the analysis loses power and introduces error by failing to show statistical significance where one might exist.

Another significant limitation may be incomplete database. Although all the information originated from phone calls and intake forms, some portions were left incomplete or some subjects denied disclosing their personal information.

CONCLUSION:

This study highlights the importance of different recruitment processes in the successful completion of a clinical trial. Patient recruitment is a vital component in assuring the success of a clinical trial and can be time consuming. One method of recruitment alone is not sufficient to meet the target enrollment. It was difficult to prove significant effect of all the factors on the recruitment process due to small sample size, but future studies with larger sample size could potentially reveal more significant impact of factors associated with the recruitment process.

BIBLIOGRAPHY

1. Seattle Cancer Care Alliance. *Guide to Clinical Trials- Importance of Clinical Studies*. Retrieved from https://www.seattlecca.org/patient-guide-clinical-trials/importance-clinical-studies

2. https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies

3. http://www.who.int/topics/clinical_trials/en/

4. Anderson, DL; "*A Guide to Patient Recruitment*". Center Watch / Thomson Healthcare, Boston, Massachusetts, USA:2001

5. Watson, JM; Torgerson, DJ; *"Increasing recruitment to randomized trials: a review of randomized controlled trials"*. BMC Med Res Methodol 2006; 6:34

6. Thoma, A; Farrokhyar, F; McKnight, L; Bhandari, M; *"How to optimize patient recruitment"*. Can J Surg, Vol. 53, No. 3, June 2010, 205

7. http://csdd.tufts.edu/news/complete_story/rd_pr_apr_2011

8. Carlisle, B; Kimmelman, J; Ramsay, T; MacKinnon, N; *"Unsuccessful trial accrual and human subjects protections: an empirical analysis of recently closed trials"*. Clinical Trials 12 (2015) 77-83

9. *"Points to consider about recruitment and retention while preparing a clinical research study"*. (2005). National Institute of Mental Health, June 2005, 1-9

10. *"Recruitment challenges in clinical trials for different diseases and conditions"*. Institute of Medicine (2012), 3rd edition, Washington D.C., National Academies Press

11. Duong, P; *"Factors that Impact Patient Enrollment in Clinical Trials"*. Fort Worth, Tx: University of North Texas Health Science Center; (2014)

12. Sido, O.V; *"Analysis of Patient Recruitment Methods for Clinical Trials of Different Heart and Lung Diseases"*. Fort Worth, TX: University of North Texas Health Science Center; (2018)

13. Bielski, RY; Lydiard, RB; *"Therapeutic trail participants: where do we find them and what does it cost?"*. Psychopharmacology Bulletin 1997; 33: 75-78

14. Adams, J; Silverman, M; Musa, D; Peele, P; *"Recruiting older adults for clinical trials"*. Controlled Clinical Trials 1997; 18: 14-26

15. Flicker, L; Wark, JD; *"Recruitment strategies for randomized clinical trials in elderly Australians"*. Medical Journal of Australia 1997; 167: 438-439

16. Bjornson-Benson, WM; Stibolt, TB; Manske, BA; Zavela, KJ; Youtsey, DJ; Buist, AS; *"Monitoring recruitment effectiveness and cost in a clinical trial"*. Controlled Clinical Trials 1993; 14: 52-67

17. Spilker, B; *"Guide to clinical trials"*. New York: Raven Press; 1992

18. Harris, PA; Lane, L; Biaggioni, I; *"Clinical research subject recruitment: The Volunteer for Vanderbilt Research Program"*. The Journal of the American Medical Informatics Association. 2005 Nov-Dec. 608-613

19. Connett, JE; Bjornson-Benson, WM; Daniels, K; *"Recruitment of participants in the lung health study, II- assessment of recruiting strategies"*. Controlled Clinical Trials 1993; 14: 38-51

20. Feman, SP; Nguyen, LT; Quilty, MT; Kerr, CE; Nam, BH; Conboy, LA; Singer, JP; Park, M; Lembo, A; Kaptchuk, TJ; Davis, RB; *"Effectiveness of Recruitment in Clinical Trials: AN analysis of Methods used in a Trial for Irritable Bowel Syndrome patients"*. Contemp Clin Trials. 2008 March; 29(2): 241-251

21. Tufts Center for the Study of Drug Development, 2014. Retrieved form http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study

22. American Pharmaceutical Review. *Ways to Lower Costs of Clinical Trials and How CROs Help*. Retrieved from https://www.americanpharmaceuticalreview.com/Featured-Articles/185929-Ways-to-Lower-Costs-of-Clinical-Trials-and-How-CROs-Help

23. Thase, ME; Rush, AJ; "*When at first you don't succeed: sequential strategies for antidepressant non-responders"*. J. Clin Psychiatry 1997; 58(Suppl 13):23-29

24. Pandarakalam, JP; "*Challenges of Treatment-Resistant Depression"*. Psychatria Danibina, 2018; Vol. 30, No. 3, 273-274

25. American psychiatric association. "*Diagnostic and Statistical Manual of Mental Disorder"*. 5th edition, DSM-5 APA. 2013

INTERNSHIP EXPERIENCE

Alongside this project, I completed my internship at North Texas Clinical Trials in Fort Worth, TX for the partial fulfillment of the requirements for the degree of Master of Sciences in Clinical Research Management. It was a privilege for me to work under the direct guidance of site director Dr. Brian Maynard, site manager Jessica Anderson and site coordinator Rachel Sevener. I got the opportunity to learn the different aspects of Clinical Research from starting a study, subject recruitment, regulatory proceedings, source development, IRB approvals till the completion of study.

North Texas Clinical Trials was established by Dr. Brian Maynard in 2012 and focuses on conducting clinical trials on psychological disorders. In the past, site has conducted clinical trials for treatment of Migraine, Anxiety, Bipolar Depression, Schizophrenia, Postpartum Disorder, Parkinson's disease tremors and Essential tremors. During my course of internship, the site was conducting clinical trials for the treatment of Tourette's Syndrome, Treatment Resistant Depression and Major Depressive Disorder.

During the course of internship, I was very fortunate to work under the close supervision of Jessica Anderson, she brings an array of clinical knowledge from her experience in clinical research. The important tasks required getting an in-depth review of study protocols, inclusion/exclusion criteria, and electronic databases. The day-to day tasks included screening and enrollment for active studies, subject visit completion, data capture on electronic database, source preparation and preparing for monitor visits.

My experience at the site gave me a better understanding about the clinical research industry and exposed me to the acquisition of new skills that will be vital for a successful career in clinical research.

CHAPTER VII: APPENDIX

Appendix A: Journal Summary

May 16, 2019 **Thursday**	It was my first day of internship in North Texas Clinical Trials. I was received by Aiden Smith, who is the Clinical Research Coordinator. He gave me a tour on the facility. I referred all the charts and files to know the studies going on. I worked with Aiden and learned the procedure of recruiting patients through phone calls.
May 17, 2019 **Friday**	I was introduced to my mentors, Mrs. Jessica Anderson, who is the Site Manager as well as Senior Clinical Research Coordinator and Dr. Brian Maynard, who is the PI and the Site Director at North Texas Clinical Trials. Later that day, I shadowed Nancy Tuomey, who is also a coordinator at the site while she was taking vitals.
May 20, 2019 **Monday**	Along with another intern at the site, Karli Silar, I arranged the Lab inventory and learned about all the inventory items and their storage conditions.
May 21, 2019 **Tuesday**	I was assigned to go through the protocol to learn the details of the study that was performed at the site. I also learned how to prepare patient's Screening File.
May 22, 2019 **Wednesday**	We had a meeting where I interacted with everyone working at the site, learned what they expect from me and I also told them about my interests in the field. I was explained the important details in the inclusion and exclusion criteria and what all should be included in the source document
May 23, 2019 **Thursday**	I was trained to perform vitals, like measuring blood pressure, performing ECGs, blood draw. I

	also got to practice taking vitals on subjects that visited on the day.
May 24, 2019 Friday	I performed vitals and ECG on subjects coming to the site for their screening or weekly visits. I was assigned to approach potential subjects for prescreening by calling them on phone and giving them information about the study and sending them intake forms to determine if they are a potential fit for the study.
May 27, 2019 Monday	Memorial Day holiday.
May 28, 2019 Tuesday	I reviewed all the folders of the study currently performed at the site and made sure all the lab reports and ECG reports were in place. I also reviewed documentation of the subjects who failed the screening to make sure that the reason of screen fail was mentioned.
May 29, 2019 Wednesday	I had a chat with Dr. Maynard and Ms. Jessica Anderson who are my committee members regarding my research topic, got really helpful views on it. Went through all the study data on which my research project is to be based and tried to figure out things. I also continued with performing vitals on study subjects.
May 30, 2019 Thursday	I called potential subjects to approach them for prescreening. I worked on literature review for my research project. I also took vitals of the subjects that came for their visits.
May 31, 2019 Friday	I took vitals for the subjects that came in for their visits and for the remaining time I worked on preparing presentation for the committee meeting of my research project.

June 3, 2019 **Monday**	There were no subject visits on this day, so I was given an off on this day. I stayed home and prepared for my committee meeting, tried to figure out how to analyze the data that I am going to collect for my research project.
June 4, 2019 **Tuesday**	I took vitals for the subject that came for her visit. Even on this day I spent some time working on my research project. We also had a meeting, which was very important to know the things that can be improved.
June 5, 2019 **Wednesday**	Received access to various portal used by the site to enter and review subject information. Even worked on preparing power-point presentation for the committee meeting.
June 6, 2019 **Thursday**	Performed ECG and vitals on subjects that came in for their weekly visits. Also worked on the recruitment list prioritizing possible subjects to be called as early as possible.
June 7, 2019 **Friday**	Worked on updating the recruitment list. It really helps me in understanding the recruitment process, which is important for me as I am planning to compare the effectiveness of recruitment methods as a part of my research project. I also performed vitals and ECG on subjects that came for their visits.

June 10, 2019 **Monday**	I took vitals for subjects that showed up in the morning for their weekly visits. I had my committee meeting at 1:00 PM at the university. We had discussion on my research topic. I got some really great suggestions from the committee members on what could make the project even better.
June 11, 2019 **Tuesday**	As usual I took vitals and ECG for the subjects that came in. I was also engaged in listing the Investigational Product and organizing it.
June 12, 2019 **Wednesday**	I continued working on the investigational product, scanned the used blister packs, took pictures of the used drug bottles and listed them in order for drug accountability.
June 13, 2019 **Thursday**	I started my day with some training on GCP. I observed the monitor who was at the site for inspection. I attended the close-out meeting in the evening, it helped me a lot to understand what a sponsor expects from the site and what are the key considerations that should be highlighted while working on the site.
June 14, 2019 **Friday**	In the morning, I continued with the GCP training. Later in the day, I had a meeting with Gita Pathak who is a PhD student at UNTHSC. She helped me with the statistical analysis of my research project and gave me ideas regarding how to write a research proposal.

June 17, 2019 **Monday**	It was Monday and usually there are no subject visits on Mondays but there was a new subject that came for screening visit. I performed vitals and because I had some time, I shadowed the Research Coordinator, Aiden Smith and Site Manager, Jessica Anderson perform the screening process.
June 18, 2019 **Tuesday**	I started the day with completing training for the handling/offering for transportation of Dangerous goods from Mayo Clinic. It was very informative regarding how lab samples and infectious materials should be packaged and labelled for transportation. Later in the day, I reviewed some documentation and other routine stuff.
June 19, 2019 **Wednesday**	I worked on preparing my research proposal today after having discussion related to the project with Ms. Jessica Anderson. She gave me the vision for my project that helped me prepare the proposal. I worked on arranging the ECGs, making copies and overreads and documenting them for review by the physician who is the sub-investigator in the study.
June 20, 2019 **Thursday**	It was a busy day. There were many subjects coming in for their regular visits and some for their screening. I performed vitals, took scales and helped Aiden in drug accountability.
June 21, 2019 **Friday**	Reviewed all the study binders to make sure that all the information required is filled in and all the documents have been signed by the person responsible. I also worked with the physician, getting her review all the medication charts, lab reports, ECGs, etc.

June 24, 2019 **Monday**	As it was Monday, there were no subject visits at the site. I invested my day in learning some new things. I emailed the CTNI forms for SAFRER calls. I researched for the fax numbers of subject's primary physician to send their Medical Record Release Forms.
June 25, 2019 **Tuesday**	I started my day by printing source documents for the subjects coming in the week for their regular visits. I reviewed all the study binders to look for places that needed to be filled and any missing signatures. Later in the day, I also completed Good Clinical Practice training by Nida Clinical Trials.
June 26, 2019 **Wednesday**	I made improvements in my research proposal as per suggestions from Dr. Mathew. I also worked on preparing a summary of my research proposal to obtain exempt from IRB. I also called current subjects to obtain details regarding their medical history and current medications.
June 27, 2019 **Thursday**	I went through the documents for the monitor review and printed and filed the required documents in the folders. I also learned accounting the drugs received from the sponsor through shipment. I matched the medication numbers and entered them in the site portal and got them reviewed by the research coordinator.
June 28, 2019 **Friday**	I started my day early today as we had 4 subjects coming in today as well as the physician and monitor were going to be there. I performed vitals and captured ECG for the subjects that came in for their regular visits.

July 1, 2019 **Monday**	Its Monday and so we didn't have many subjects coming in for their visits. I received access to various portals and to the calendar where the scheduled subject visits were entered. I also worked on improvising my research proposal.
July 2, 2019 **Tuesday**	I started my day with calling subjects to confirm their upcoming visits. I also printed out source documents from Dropbox, for the subjects that had their visits scheduled for July 3, 2019 and filed them in their respective folders.
July 3, 2019 **Wednesday**	As it is a holiday tomorrow, i.e., 4th of July, we had many subjects scheduled for today. I spent my day taking vitals and filling the source documents for the subjects. I got the subjects complete their self-scales. Also, I helped the coordinator with drug dispensation and spent some time in organizing other stuff.
July 4, 2019 Thursday **and** **July 5, 2019 Friday**	Thursday and Friday, I had day off due to Independence Day.

July 8, 2019 **Monday**	I started the week by preparing the source documents for the subject visits that were confirmed for the week. I prepared the screening folders for the new subjects that are expected to be at the site for their screening. I reviewed all the folders of a study to prepare them for the monitor visit this week.
July 9, 2019 **Tuesday**	The study from which I am going to collect the data for my research project is going to stop recruiting subjects on 16 August so currently recruiting patients is the high priority job on the list. We had a new subject screen today along with the regular visits. Throughout the day, I helped the site coordinator in completing the visits.
July 10, 2019 **Wednesday**	Today was a quiet busy day, we had a new subject screen as well as we had monitors coming in for inspection of two different studies. I completed vitals and scales for the subjects that came in today as well as helped the coordinator in preparing documentation for the monitors to review.
July 11, 2019 **Thursday**	Today we had no visits scheduled but there was pretty much everything going on. I made sure that all the ECGs and labs completed throughout the week have over-reads and are ready to be reviewed by the physician.
July 12, 2019 **Friday**	Today we had the physician coming so I arranged all the folders and documents that needed to be reviewed by her. I also completed taking vitals and scales for the subjects that came in for their regular visits.

July 15, 2019 **Monday**	As the deadline for recruiting subjects for the treatment resistant depression study is coming close, recruitment is on the top of the priority list. I called the new leads that we received through Clinical Connection and tried to get the eligible subjects scheduled for screening. I reviewed the data entered in the EDC against the source documentation to check everything has been entered.
July 16, 2019 **Tuesday**	I started my day by calling the new leads on Clinical Connection for treatment resistant depression study recruitment. I started getting familiarized with the new portal that we started using for the current studies.
July 17, 2019 **Wednesday**	Today we had a couple of weekly subject visits, so I helped the coordinator by performing vitals, ECGs and scales. I also spent time rearranging some stationary stuff and arranging the study folders.
July 18, 2019 **Thursday**	It was not a busy day with subjects and so I started with requesting access for EDC for a new study, as soon as the request was accepted, I completed the required training for data entry to EDC.
July 19, 2019 **Friday**	I started my day by preparing the documents to be signed by the physician that was going to be at the site today. I printed and collected all the ECGs, copies and over-reads to arrange them in the subject folders. Later I performed vitals, ECG and scales for the subjects that came for their weekly visits.

July 22, 2019 **Monday**	Like other Mondays, we did not have any subject visit today. I called the subjects to confirm their visits throughout this week. I printed the source for the subject visits. I the free time, I organized the stationary supply.
July 23, 2019 **Tuesday**	I performed vitals, scales and ECG for the subjects that came in for their regular visits and filled in their source. I entered all the data captured throughout the visits on EDC.
July 24, 2019 **Wednesday**	As there were not many subject visits today, I spent time reviewing the subject binders. Site manager Ms. Jessica Anderson showed me how to QC the subject binders, it was one of the best learning lessons for me over here.
July 25, 2019 **Thursday**	I continued reviewing the study binders today. I went through the protocols for the new studies that were going to start at the site. I also went to UNTHSC to file the Intent to Graduate Form where I met Dr. Mathew and discussed with him regarding the final defense and my research project.
July 26, 2019 **Friday**	It was one of the busiest days at the site. We had subject visits scheduled from 9:30 AM in the morning till 4:30 PM in the evening. I along with the site staff performed vitals, scales and ECG for the subjects that came in as well as filled the source documents.

July 29, 2019 **Monday**	I spent my day completing the charts from last Friday and reviewed them for signatures. I entered the data on EDC for all the visits last Friday. I also made copies of the ECGs captured and arranged the lab requisitions at its place.
July 30, 2019 **Tuesday**	I called subjects to confirm their visits for this week, printed the source for the visits and arranged them in the respective binders. I made copies of the informed consent, got them reviewed by everyone and filed them in the informed consent binder. I arranged the lab reports that we received with their requisition forms.
July 31, 2019 **Wednesday**	I started my day by printing informed consents and screening documents for the studies running at the site and made screening binders ready for new subjects. I helped the Ms. Jessica Anderson in arranging the regulatory documents of the completed studies.
August 1, 2019 **Thursday**	It was a busy day as we had subject visits throughout the day. I performed vitals, ECG and scales for the subjects. I made sure we have enough study binders ready for the upcoming days and printed scales for tomorrow's subject visits.
August 2, 2019 **Friday**	As usual it was a busy Friday. There were few screenings as well as regular subject visits. I helped the coordinator complete vitals, scales and ECG. We had the physician coming in at the site so I made sure all the ECGs and e-CSSRS performed throughout the week are reviewed by her.

August 5, 2019 **Monday**	Today I spent the whole day reviewing the study binders of the active studies making sure there are no blank spaces to be filled. Later in the day I entered data on the EDC for subjects that were seen at the clinic last week.
August 6, 2019 **Tuesday**	I started with printing and arranging the regulatory documents. I called ERT to resolve a mistake accidentally made last Friday. I called subjects to confirm their visits for the week. I arranged all the study binders to have easy access to active study binders.
August 7, 2019 **Wednesday**	I started my day preparing for the close-out visit taking place on Thursday and Friday. I printed source documents for subject visits this week. I sent CTNI SAFER forms to schedule SAFER calls for the newly screened subjects.
August 8, 2019 **Thursday**	I called the subjects whose SAFER calls have been scheduled for this week to prepare them for the SAFER interview. I entered data for the newly screened subjects on EDC.
August 9, 2019 **Friday**	I performed vitals and scales for subjects that came in for their regular visits at the site. I entered collected data on EDC. Physician was at the site today, so I made sure she reviews and signs all the ECGs and labs collected this week.

August 12, 2019 **Monday**	I spent my day completing the charts from last Friday and reviewed them for signatures. I entered the data on EDC for all the visits last Friday. I also made copies of the ECGs captured and arranged the lab requisitions at its place.
August 13, 2019 **Tuesday**	I called subjects to confirm their visits for this week, printed the source for the visits and arranged them in the respective binders. I arranged the lab reports that we received with their requisition forms.
August 14, 2019 **Wednesday**	We had monitor visits this week, so I helped the site staff in arranging documents for the monitor. I worked on finding the regulatory documents and completing the forms that required to be filled.
August 15, 2019 **Thursday**	It was a busy day as we had subject visits throughout the day. I performed vitals, ECG and scales for the subjects. I made sure we have enough study binders ready for the upcoming days and printed scales for tomorrow's subject visits.
August 16, 2019 **Friday**	As usual it was a busy Friday. There were few screenings as well as regular subject visits. I helped the coordinator complete vitals, scales and ECG. We had the physician coming at the site so I made sure all the ECGs and e-CSSRS performed throughout the week are reviewed by her.

August 19, 2019 **Monday**	Like other Mondays, we did not have any subject visit today. I called the subjects to confirm their visits throughout this week. I printed the source for the subject visits. After confirming all the visits for the day, I entered data from source to the EDC.
August 20, 2019 **Tuesday**	I called ERT and collected information for data correction for previously collected ECGs. I reviewed the study binders for the active studies and tried to solve the queries that we had on EDC.
August 21, 2019 **Wednesday**	I worked on IP accountability today. I printed the list of currently available IP and dispensed IP and matched them with the IP kits that we have in the drug room. In the free time, I just arranged all the subject charts and some regulatory documents.
August 22, 2019 **Thursday**	Today we did not have many visits scheduled but there was pretty much everything going on. I made sure that all the ECGs and labs completed throughout the week have over-reads and are ready to be reviewed by the physician.
August 23, 2019 **Friday**	It was a busy Friday as usual, we had 5 visits scheduled for today. I worked with the coordinator to complete the subject visits and reviewed the binders for the Treatment Resistant Depression Study as we were expecting Sponsor visit on Monday and Tuesday next week.

August 26, 2019 **Monday**	Monitor for the Treatment Resistant Depression study was at the site today. I started with giving her the binders and regulatory documents for the study. I also worked with the study team in solving all the queries that the monitor came up with for the study.
August 27, 2019 **Tuesday**	The monitor continued the inspection today. I helped the study team in completing the subject drug accountability sheets. We also had a protocol training with the monitor.
August 28, 2019 **Wednesday**	After finishing the monitor visit, today I called the subjects to confirm their visits for the week. I also made sure their source was ready for the week ahead.
August 29, 2019 **Thursday**	We had a couple of visits today, after which I worked on solving the queries for the active studies on EDC.
August 30, 2019 **Friday**	It was a busy Friday as usual, so helped the coordinator complete subject visits for the active studies. In the free time, entered the data from the source on EDC and tried working on systematically arranging all the study documentation.

September 2, 2019 **Monday**	Labor Day holiday.
September 3, 2019 **Tuesday**	I was not well today so I took a day off.
September 4, 2019 **Wednesday**	We had monitors at the site from today till Friday for 2 different studies. I helped with arranging all the documents for the monitors. I called subjects to confirm their visits for the week.
September 5, 2019 **Thursday**	I started my day with getting the source ready for subject visits and getting documents ready for the monitor. I performed vitals, ECG and scales for subjects that came in today for their regular visit. I collected the ECGs and labs that needed physician review.
September 6, 2019 **Friday**	It was a busy day, we had couple of visits and screening for a new study. I worked on completing the subject visits and getting all the source documents completed, transmission of ECG and arranging all the lab requisitions at its place.

September 9, 2019 **Monday**	As it is a Monday morning, we did not have any subject visits scheduled for the day. I spent my time calling subjects to confirm their visits for the week and printing the source documentation. Later I worked on arranging some regulatory documents.
September 10, 2019 **Tuesday**	I reviewed binders for the active studies for places missing data or signatures. I entered data for the visits performed last week on EDC. Later, I worked on thesis writing, completed background review and methodology.
September 11, 2019 **Wednesday**	I started my day with completing subject visits, capturing their vitals, completing scales and completing the source documentation. Then in free time at the site, I discussed with the data manager regarding the data collection for my research project.
September 12, 2019 **Thursday**	I entered the data from source documents on EDC and checked for any previous data that needs to be entered on EDC for any of the active studies at the site. I worked with the coordinator in solving data queries on EDC.
September 13, 2019 **Friday**	As expected, it was a busy Friday. We had our physician coming at the site to complete physical examination for subjects. I arranged all the ECGs and labs that needed to be reviewed by her. Helped the coordinator in completing the subject visits and recording the data.

September 16, 2019 **Monday**	As it is a Monday morning, we did not have any subject visits scheduled for the day. I spent my time calling subjects to confirm their visits for the week and printing the source documentation. I also worked on my thesis writing.
September 17, 2019 **Tuesday**	I reviewed the study binders for the active studies and tried to solve the queries that we had on EDC. I also worked on completing the Subject IP accountability sheets.
September 18, 2019 **Wednesday**	Today we did not have many visits scheduled but there was pretty much everything going on. I made sure that all the ECGs and labs completed throughout the week have over-reads and are ready to be reviewed by the physician.
September 19, 2019 **Thursday**	I started the day by making recruitment calls for the new studies. I also worked on patient database to find eligible subjects for the new study.
September 20, 2019 **Friday**	It was a busy day, had several subject visits including the new screening visits. Worked on completing the visits the entire day. Made sure all the ECGs collected throughout the day were transmitted to ERT.

September23, 2019 **Monday**	Monitor for a Tourette study was at the site today. I started with giving her the binders and regulatory documents for the study. I also worked with the study team in solving all the queries that the monitor came up with for the study.
September 24, 2019 **Tuesday**	The monitor continued the inspection today. I helped the study team in completing the subject drug accountability sheets. We also had a SIV training for the extension study.
September 25, 2019 **Wednesday**	After finishing the monitor visit, today I called the subjects to confirm their visits for the week. I also made sure their source was ready for the week ahead.
September 26, 2019 **Thursday**	We had a couple of visits today, after which I worked on solving the queries for the active studies on EDC. Worked on solving queries on EDC in the remaining time.
September 27, 2019 **Friday**	It was a busy Friday as usual, so helped the coordinator complete subject visits for the active studies. In the free time, entered the data from the source on EDC and tried working on systematically arranging all the study documentation.

September 30, 2019 **Monday**	I spent my day completing the charts from last Friday and reviewed them for signatures. I entered the data on EDC for all the visits last Friday. I also made copies of the ECGs captured and arranged the lab requisitions at its place.
October 1, 2019 **Tuesday**	I called subjects to confirm their visits for this week, printed the source for the visits and arranged them in the respective binders. I transferred all the ECGs to the ERT portal and printed the e C-SSRS reposts for the physician to review.
October 2, 2019 **Wednesday**	I started my day by printing informed consents and screening documents for the studies running at the site and made screening binders ready for new subjects. In the remaining time I worked on getting my Thesis completed and worked on the discussion part.
October 3, 2019 **Thursday**	I performed vitals, ECG and scales for the subjects. I made sure we have enough study binders ready for the upcoming days and printed scales for tomorrow's subject visits. I also flagged the documents for the physician to review as she is at the site every Friday.
October 4, 2019 **Friday**	As usual it was a busy Friday. There were few screenings as well as regular subject visits. I helped the coordinator complete vitals, scales and ECG. We had the physician coming in so I made sure all the ECGs and e-CSSRS performed throughout the week are reviewed by her.

October 7, 2019 **Monday**	Like other Mondays, we did not have any subject visit today. I called the subjects to confirm their visits throughout this week. I printed the source for the subject visits. After confirming all the visits for the day, I entered data from source to the EDC.
October 8, 2019 **Tuesday**	I spent time with the site manager discussing about my research project and making corrections. She was really helpful in analyzing the statistics and helping me decide what to put and what not to put in the results and how to describe it.
October 9, 2019 **Wednesday**	I worked on IP accountability today. I made sure the IP dispensed is entered in the accountability sheets and accountability has been completed at the end of each visits. I made sure all the medication kits are there in the inventory.
October 10, 2019 **Thursday**	Today we did not have many visits scheduled but there was pretty much everything going on. I made sure that all the ECGs and labs completed throughout the week have over-reads and are ready to be reviewed by the physician.
October 11, 2019 **Friday**	It was a busy Friday as usual, we had 5 visits scheduled for today. I worked on entering all the data on EDC and made sure we have no outstanding queries for the active study. After completing all the tasks for today, I worked on making corrections on my thesis.

October 14, 2019 **Monday**	I spent my day completing the charts from last Friday and reviewed them for signatures. I entered the data on EDC for all the visits last Friday. I also made copies of the ECGs captured and arranged the lab requisitions at its place.
October 15, 2019 **Tuesday**	I called subjects to confirm their visits for this week, printed the source for the visits and arranged them in the respective binders. I arranged the lab reports that we received with their requisition forms.
October 16, 2019 **Wednesday**	I started working on IP compliance for an active study. I made sure all the medication kits are at the correct place and inquired to patients regarding the missing kits. I also counted the pills in the IP kits and reviewed them with the subject charts.
October 17, 2019 **Thursday**	It was a busy day as we had subject visits throughout the day. I performed vitals, and scales for the subjects. I made sure we have enough study binders ready for the upcoming days and printed scales for tomorrow's subject visits.
October 18, 2019 **Friday**	I worked on reviewing the screen fail binders for an active study and made sure all the documents have been completed and signed by the PI. I also worked on reviewing the Informed Consent forms for the same study for subject signatures.

October 21, 2019 **Monday**	I started the week by preparing the source documents for the subject visits that were confirmed for the week. Later in the day, I worked on making final corrections on my thesis before sending it to the committee members.
October 22, 2019 **Tuesday**	I focused on making sure all the data has been entered on EDC for all the subjects in the active studies. I also worked on solving the queries on EDC. I left early to complete my thesis.
October 23, 2019 **Wednesday**	I called subjects scheduled for the week to confirm their visits for the week and printed the source and prepared scales for the upcoming visits. I also worked on preparing the visit forecast that is helpful for the site to be prepared for the upcoming visits.
October 24, 2019 **Thursday**	Today we had no visits scheduled but there was pretty much everything going on. I made sure that all the ECGs and labs completed throughout the week have over-reads and are ready to be reviewed by the physician.
October 25, 2019 **Friday**	I completed solving all the queries for the active studies and later in the day, I worked on preparing presentation for defense.