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Recruitment continues to be one of the largest barriers to clinical trial success. Based on review of clinical trial marketing literature, there are no marketing industry standards established for recruitment of HIV/AIDS clinical trials. The purpose of this study was to begin finding optimal marketing recruitment strategies in HIV/AIDS clinical trials research. A literature review yielded 20 articles detailing recruitment marketing practices. A ClinicalTrials.gov search found 57 trials meeting inclusion criteria. Data extracted included recruitment strategies, original enrollment goals, estimated enrollment goals and actual enrollment goals. Regression analysis found no significant relationship between marketing strategies and recruitment rate. Added financial and managerial considerations should be incorporated with a robust site level marketing campaign to optimize recruitment potential.

QUALITATIVE ANALYSIS ON HIV/AIDS CLINICAL TRIAL

RECRUITMENT MARKETING PRACTICES

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QUALITATIVE ANALYSIS ON HIV/AIDS CLINICAL TRIAL RECRUITMENT MARKETING PRACTICES

INTERNSHIP PRACTICUM REPORT

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In Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE

IN CLINICAL RESEARCH MANAGEMENT

By

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I. INTRODUCTION

The following practicum report was conducted during an internship at the UNT System College of Pharmacy (UNT-SCP) at the UNT Health Science Center (UNTHSC). UNTHSC Reagents Professor of Pharmaceutical Sciences and Executive Director of Preclinical Sciences Dr. Simecka was serving as the major professor for the project. Assistant Professor of Pharmacotherapy Dr. Gibson, Assistant Professor of Pharmacotherapy Dr. Gaviola, Associate Professor of Biostatistics and Epidemiology Dr. Nandy, Adjunct Professor of the Department of Physiology and Anatomy Dr. Gwirtz and Dr. Clay have served as key mentors in the internship and practicum report. UNT-SCP student Ryan Chishimba served as a co-investigator on the development and research that this practicum report provides.

The initial focus of this practicum report was the examination and comparison of recruitment marketing strategies employed for clinical trials in the Dallas-Fort Worth Metropolitan Statistical Area (DFW-MSA) over the past ten years (since 2008). After a preliminary assessment, for feasibility reasons (n=2,007 clinical trials identified by clinicaltrials.gov), the analysis was limited to clinical trials involving HIV/AIDS and their affiliated conditions (opportunistic infections, comorbidities, etc.) as this was the key population of interest for the intern's site. However, upon DFW-MSA clinical trial searches, none met inclusion criteria. This shifted the purpose of the study to focus more on qualitatively describing currently used marketing techniques in the HIV/AIDS clinical trials nationally. Marketing was a key point of interest given how such techniques are used to reach the desired population and play a critical role in clinical trials given the voluntary nature of recruitment.[1]

The purpose of this study was to describe the identifiable, deployed clinical trial marketing recruitment strategies used in HIV/AIDS human clinical trials. Step 1 involved the

identification of “suggested recruitment practices” through a literature review. After conducting a literature review, step 2 consisted of searching for HIV/AIDS clinical trials across the United States (conducted between 01/01/2008-12/31/2018). Clinical trials were selected as per inclusion criteria, which included study protocols and statistical analysis plans (SAPs) that contained the necessary information to determine recruitment marketing strategies. “Suggested recruitment practices” from the literature were used for initial categorization of marketing procedures and organically changed depending on the marketing strategies discussed in United States (U.S.) wide clinical trials. Following the collection of clinical trial recruitment marketing strategies across the U.S., these “compiled recruitment practices” were the finished dataset that underwent qualitative statistical analysis.

The last step used statistical analysis to determine if the deployed practices could be reasonably considered to be ‘best.’ A regression analysis was done that looked to determine if there was a relationship between the change in recruitment (i.e., enrollment goal initially sought versus actual enrollment/estimated enrollment), and the number (types) of marketing recruitment strategies employed or a particular marketing strategy. Analysis of recruitment data will help understand marketing techniques effectiveness in HIV/AIDS clinical trials in the U.S.

Following the analysis of collected marketing strategies, there was no statistically significant relationship between the total number of recruitment categories used per trial and the recruitment rate. Furthermore, there was no statistically significant relationship between any one recruitment strategy category and recruitment rate. Overall, this study demonstrates a need to divest into alternative modes of thinking about what contributes to successful clinical trial recruitment.

II. PROBLEM & HYPOTHESIS

Patient recruitment is recognized as a key determinant of success for clinical trials.[2] Participant size is a critical value for any clinical trial, and various practices are utilized to ensure such goals are reached. The importance of participant size cannot be overstated as "selection criteria for recruitment of patients into Randomized Control Trials (RCTs) will influence the length of the recruitment period, the statistical power, and the external validity of the results."[3]

A major issue that arises when a clinical trial cannot meet the preferred sample size is the possibility of type 2 error.[4] A type 2 error is a special condition where the investigator fails to reject the null hypothesis, i.e., false negative, and in this case, due to insufficient numbers of participants. In addition, failure to meet preferred sample size is a reason many trials are delayed until the specified participant count has been met. As many as 53% of trials are delayed, and another 14% are canceled due to not meeting the desired sample size.[2]

Recruitment of participants for clinical trials is important when one considers the time and money involved in conducting a clinical trial. Most clinical trials cost upwards of thousands of dollars and involve many work hours in planning, recruitment, and execution.[5] However, despite the efforts of many in the research community, the goal of having the right participant count can often be difficult to obtain. This can be attributed to various reasons, including cultural, demographic, and messaging to different people groups.[6]

One of the main challenges that still remains is how to appropriately communicate the importance of a clinical trial to the desired population.[5] Historically, minority racial and ethnic groups have been difficult to enroll in human clinical trials. In some cases, this is because there is a misconception that minority communities are not interested in research. Due to this frame of reference, it hinders different researchers from marketing in those communities and results in

less awareness.[7] It has been widely reported that certain minorities, such as African American's, distrust human clinical research due to the vast and wide-ranging history of abuse they have endured.[8] However, this is not to say that recruitment among these populations is impossible nor impractical. Recommendations have involved conducting pilot studies to test the robustness of the recruitment strategies implemented as well as employing multiple recruitment strategies aiming to screen at least double the desired sample size.[11] However, while there are recommended strategies that can work to increase recruitment, there is a need to identify currently utilized strategies. Due to human experimentation events such as the Tuskegee syphilis study, research institutions now have an investigational review board (IRB).

Even though the main function of the IRB is to make sure that clinical trials are carried out in a safe and ethical manner, the extensive IRB approval process may further complicate marketing for clinical trials. Subsequently, this can slow down the recruitment process and in some cases hinder it.[8] Considering previous clinical trials such as Tuskegee, having an IRB is invaluable in ensuring that human clinical trials consider participant safety first. However, it could also present a challenge in the recruitment process as every change has to be reviewed, further lengthening the already cumbersome procedure.[9]

The major question that is often asked is "how research organizations can design an effective recruitment marketing strategy?". Marketing is the process or technique of promoting, selling, and distributing a product or service. However, it must be noted that for clinical trial recruitment to be successful, investigators must use the most innovative, population-specific, and up to date marketing strategies. This may include social media, print, door-to-door, phone calls, bus ads, flyers, billboards, and direct to practitioner communications.

PROBLEM: Based on the review of clinical trial marketing literature, there are no marketing industry standards or minimal infrastructure that have been established for achieving recruitment for clinical trials (in conducting HIV/AIDS trials specifically).

HYPOTHESIS: Clinical trials that we determine to use a greater number of marketing practice categories will have a better chance of meeting recruitment goals.

***Aim 1*:** Provide a descriptive analysis on the marketing landscape of HIV/AIDS clinical trials in the U.S. as it pertains to employed recruitment strategies and infrastructure.

Aim 2: From the gathered marketing practices and recruitment strategies employed, inform on successful methodologies by which HIV/AIDS clinical trials can increase recruitment by way of marketing.

III. BACKGROUND

Randomized clinical trials (RCTs) are widely recognized as the gold standard when evaluating healthcare in terms of safety and effectiveness.[10] Notably, it is the reduction of a host of biases such as systematic selection and ascertainment biases, as well as the high degree of power by which RCTs operate which affords them this title.[10,11] However, it was not always the case in which RCTs were so obviously the right choice in observing the relationship between intervention and outcome nor even known in their current form. Clinical trials have a long and sometimes fraught history with many innovations in methodology and thought, to bring them to the forefront of pioneering science as they are today.

The first clinical trial of the modern era is often cited to have been performed by James Lind, whereby in 1747 he compared the health outcomes of 12 selected patients with scurvy presenting symptoms based on method of treatment.[12] Treatments selected were quite the menagerie including cyder, vinegar, drops of vitriol elixir and of course ingestion of oranges and lemons, which contained the necessary Vitamin C.[13] This comparative form of clinical trial was to be the norm for the 1800s, mainly looking at the effects of vaccines on diseases such as cholera, smallpox and diphtheria.[12] It was during the early 1800s when another pillar of modern clinical trials came into discussion, the term "placebo."[13] "Placebo" was defined as "an epithet given to any medicine more to please than to benefit the patient" in *Hooper's Medical Dictionary* of 1811.[13] Although the term "placebo" had been used, it wasn't until 1863 that Austin Flint, a U.S. physician, performed a rudimentary placebo clinical trial using a "dummy" treatment compared to an established treatment for rheumatism.[16] In a span slightly greater than 100 years the first clinical trial had been performed and the use of a placebo controlled clinical trial was completed. Both these achievements would be but the beginning of the evolution of

clinical trials, with the next pillar of thought not coming until the United Kingdom proposed a trial for the treatment of the common cold.

The next advancement in clinical trials came in 1943 with the advent of the double-blind controlled trial, performed by the Medical Research Council (MRC) in the UK, on the usage of patulin for the common cold.[12] Although the experiment resulted in no perceived protective benefits from patulin, the trial would make history as being one of the last to use non-randomized allocation of subjects.[12,13] In 1946, MRC conducted the first placebo-controlled randomized clinical trial; being the first to randomly assign participants to either an experimental or control arm. The trial evaluated the effects of streptomycin on tuberculous and became the model for prospective randomization clinical trials, which would become the gold standard after WWII.[12,13] The landmark methods employed were "allocation concealment" at the time of patient enrollment and the use of objective standards of measurement.[16] The "allocation concealment" was the randomization method developed by Sir Bradford Hill, the statistician of the MRC streptomycin study, that relied on distributing participants via referencing a statistical series based on random sampling numbers drawn up for each sex.[16] While the objective standards refer to the fact that x-rays were evaluated by experts blinded to the participants treatment.[16] Not only was the methodology used innovated over the development of the placebo-controlled randomized clinical trial but so too were the ethical considerations.

Ethical considerations in clinical trials or Good Clinical Practices (GCP) developed as clinical trials developed and at times in response to ethical shortcomings. Roots to the protections of participants trace back to the Hippocratic Oath around 500 B.C. whereby physicians swear to practice medicine justly and ethically.[13,14] Although these protections were assumed to transfer to participants in clinical trials, they were not respected in human

experimentation.[13] It was not until the first International Guidance on ethics involving human experimentation that informed consent was defined in a way that highlighted the aspect of voluntariness.[13,14] This International Guidance would be titled the Nuremburg Code, a response to the atrocities of human experimentation conducted under the Third Reich.[14] Following the thalidomide tragedy where severe fetal limb deformities were linked to maternal use of thalidomide for morning sickness, the U.S. adopted the Kefauver-Harris Amendments in 1962 to the Federal Food, Drug, and Cosmetics Act of 1938, requiring the FDA to evaluate drugs for efficacy and safety.[13,14] In 1964 the Declaration of Helsinki was developed by the World Medical Association (WMA) to further outline the protection of participant rights in human clinical trials.[14] Institutional Review Boards (IRBs) were established in 1974 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which itself was established through the 1974 National Research Act.[14] Following the Tuskegee experimentation events being reported by the *New York Times* in 1972 this same agency created the Belmont Report in 1979 whereby three fundamental ethical principles were established: (1) respect for persons, (2) beneficence, and (3) justice which informed on the principles of informed consent, assessment of risk, and selection of participants.[14] These ethical considerations and sanctioned laws set the foundations for conducting clinical trials in the modern era. The success and failure of clinical trials can depend on several factors that must be appropriately and methodically accounted for in the clinical trial.

The success of a clinical trial can depend upon concrete objectives such as obtaining needed legislative approval to more transitive forms like maintaining the willingness of the individual participant to continue to take part in the study.[15] The barriers to successful clinical trials can be the inability to implement successful strategies as well as additional concerns, which

tend to form barriers specifically for participant recruitment. Patient concerns such as procedural time, preferences to treatment group, knowledge and trust of the trial, and concerns over patient health information and consent have shown to be key points.[15,16] However, recruitment remains one of the most glaring and challenging issues facing RCTs.[17] A UK study investigating what influences recruitment to RCTs found that of the 114 trials that fulfilled their inclusion criteria, only 38 (31%) achieved their original recruitment target at the original specified time point and 65 (53%) were extended.[2] In addition, a study on discontinued trials due to recruitment failure found that 89% (25/28) of the reported reasons were preventable, with recruitment failure due to overestimation of prevalence of participant eligibility being the most frequent reason.[18] While the previous examples looked at more broadly applicable reasons affecting the success of clinical trials, further clarification should be given to clinical trials aiming not only for a more diverse set of participants, but also those trials particularly recruiting from minority populations.

The issue of minority population recruitment adds additional complications to clinical trial recruitment techniques due to cultural barriers within these communities.[11] When examining the African American population, lack of participation can include a lack of trust and cultural and linguistic barriers as reasons.[7] Additional complicating factors revolve around financial gains for participants, financial gains of recruiters, attitudes of health providers and lack of study awareness.[7,19] The Tuskegee Syphilis experimentation caused considerable damage to the trust in minority populations and especially so in the African American population.[19] It has been argued that the Tuskegee study was not the singular event it has been portrayed as but rather a culmination of mistrust and history of abuse and exploitation.[20] This was then portrayed by experiments like Tuskegee that led to distrust in the African American community.[20] The ramifications of this distrust is self-evident in recruitment of minority populations.[21] One of the

major ways to circumvent these recruitment issues is through marketing focused methods.[21] Establishing open dialogue and communication with minority health and community leaders, in addition to advocating for the importance of minority participation in clinical trials through health education programs are some recommended actions.[21] Recruitment concerns are not just an issue with regard to minority populations, but underscore a more pervasive point regarding clinical trial recruitment strategies as a whole.

One must then perceive an added constraint that arises due to pushing back recruitment dates; cost. Several strategies to address these recruitment shortcomings have focused on a business minded approach, resulting in new business models by which to conduct clinical research. In fact, the National Health Service (NHS) R&D Health Technology Assessment (HTS) reported recommendations upon which future studies should consider when planning for human clinical trials in terms of cost.[11] An example of such recommendations was that treatment costs should be included as an end-point and that a health economist be consulted.[11] Although, these recommendations do address in some capacity recruitment costs associated with unmet sample size goals, they do not give targeted solutions. Furthermore, one study focused on translating marketing strategies , which are known collectively as "The Marketing Black Box," into the activities performed in an RCT.[21] Five new distinct stages of RCT recruitment were proposed and tested culminating in the Marketing and Information Technology (MARKIT) model.[21] This model was used as a framework or roadmap to guide a clinical trial of weight loss for college students.[21] They reported that not only did this study meet recruitment goals on-time but also reported 86% retention at 24 months and a minimum of 57% engagement with the intervention over the 2-year study.[21] Another marketing strategy model focused on the recruitment issue from another angle, namely that recruitment needs were not being met due to

poor management.[22] They developed a four-step conceptual approach to improving recruitment in clinical trials to be used along with marketing constructs (such as the 7 P's).[22] The 7 P's of marketing refer to product, prices, promotion, place, packaging, positioning and people. The 7 P's marketing scheme is a construct that one should continually refer to once a marketing strategy has been agreed upon. By using this construct one can keep ahead of an everchanging market landscape and support efficiency of the marketing directive. This optimization model was applied to a case study termed txt2stop, which looked at the effects of trying to change behavior via supportive text messages concerning smoking cessation.[22] This optimization model is dynamic in nature, due to the focus on learning, and is based on the Kolbian learning cycle. The Kolbe cycle is a learning style model whereby learning is represented in the form of a spiral. Concrete experiences (doing/having an experience) leads to reflective observation on the experience which leads to abstract conceptualization of the experience (what you conclude or learn from the experience) and lastly active experimentation (planning/trying out what you have learned).[22] The framework was assessed to be best used as a reference source rather than a diagnostic tool by which to assess a trial. Business marketing approaches to solving recruitment concerns have shown to improve recruitment efficiency in limited circumstances, but more information is needed to optimize efforts to plan and execute successful clinical trials, especially in the area of subject recruitment and retention strategies.

To make further advancements in recruitment of subjects into clinical trials, there is a need to understand the types of recruitment strategies currently used and which contribute to a successful recruitment. Identification of successful marketing strategies may reduce costs by providing a starting point for planning of studies that include optimal recruitment methods tailored to the study's goals. Thus, the identification of principles that lead to success in

recruitment through utilization of proven ways to market and advertise for clinical trials will likely increase the performance and reduce the cost of clinical trials. This study attempts to begin identifying optimal marketing recruitment strategies in HIV/AIDS clinical trials research.

SIGNIFICANCE

According to the research findings of McDonald and colleagues, many institutions that conduct research studies are in need of assistance when it comes to recruiting for clinical trials.[2] What makes this a matter of great significance is the fact academic institutions, private research recruiters, as well as government agencies all face challenges in recruiting. Study participant recruitment is perhaps the major barrier of any clinical trial[23], it not only helps in validating the study findings, but it is also used as a barometer to justify the application and adoption of a particular set of findings.[11]

A question that is often asked is how do investigators recruit the right people for a particular study?[11] This is a glaring question that has its origins in marketing. Traditional marketing methodology can be applied and used successfully in a clinical trial environment, particularly in the area of recruitment.[23]

The CDC reported at the end of 2016 that there are 1.1 million persons living with HIV.[24] Although overall rates of infection have decreased in the U.S., there are notable racial discrepancies with African Americans showing the largest increase in rate of diagnosis of HIV of 49.6 per 100,000 persons with the rate for Hispanics/Latino being 23.9 per 100,000 at the end of 2016.[25] As the need for clinical trials to determine optimal ways to manage and treat HIV remain necessary, recruiting from minority populations to participate is critical. At year-end 2016, the largest percentage of those living with HIV was African Americans at 41% and the reported

deaths due to HIV infection were also the highest in the African American population with 16.9 per 100,000.[24] Historically, minority participation and recruitment into clinical trials has been underrepresented, however a new trend sees an increase in articles regarding minority participation.[26] To improve the health outcomes and mitigate these racial discrepancies more effort must be done to include minorities into HIV research, and marketing to HIV positive minorities is conceivably the first step. Future methodologies to improve recruitment could be enhanced by understanding marketing techniques in HIV clinical trials.

IV. RESEARCH DESIGN AND METHODOLOGY

DATA COLLECTION

Identification of clinical trials meeting inclusion criteria as well as recruitment methodology extracted from identified clinical trials was carried out via the government database, ClinicalTrials.gov. Created by the National Library of Medicine, ClinicalTrials.gov is a public database where all United States-based clinical trials of FDA regulated drugs, biologics, and devices have been mandated to be registered. Clinical trials meeting the criteria of an applicable clinical trial (ACT) must register the clinical trial and submit results per the requirements described in Section 801 of the Food and Drug Administration Amendment Act (FDAAA 801) of 2007.[27] Additionally, it is the policy of organizations such as the International Committee of Medical Journal Editors (ICMJE) that all medical journal editors require registration of clinical trials in a public trials registry at or before the time of first patient enrollment as a precondition to publication.[28] As such, the website affords a large inclusion of clinical trial listings and therefore the capture window should be adequate.

METHODS

Determining the HIV/AIDS recruitment marketing compiled practices

As there were no standard best practices for HIV/AIDS recruitment by which to base the search in the U.S. Step 1 was a literature review of recruitment marketing practices that determined "suggested recruitment practices." The PubMed database was used, and the search criteria was documented in Appendix B. Step 2 involved the use of ClinicalTrials.gov, whereby U.S. wide clinical trials involving HIV/AIDS and their affiliated conditions were searched and

clinical trials meeting inclusion criteria were included in the study. U.S. recruitment practices were collected from included clinical trials and combined with "suggested recruitment practices" as categories for representative marketing strategies were identified. Both sets of recruitment practices were combined to give "compiled recruitment practices."

To identify clinical trials across the United States, ClinicalTrials.gov was used. The search **criteria/inclusion** are as follows (*Please see Appendix A*):

- On ClinicalTrials.gov
- U.S. clinical trial
- Condition or disease is HIV/AIDS
- Recruitment (Not yet recruiting, Recruiting, Enrollment by invitation, Active, not recruiting, Suspended, Terminated, Completed, Withdrawn, Unknown)
- Patient population (no age restriction)
- Both Male or Female sex
- Interventional study type
- Protocol and statistical analysis plans (SAPs) are provided
- Results (no restriction given concerning provision)
- Discusses recruitment methodology
- Clinical trial was initiated (doesn't need to be completed) between 01/01/2008 to 12/31/2018

Collection of data consisted of extracting marketing strategies used per clinical trial from the provided protocols and SAPs. These specific methods of recruitment were used to create a table which was classified as "our data collection tool". Analysis was, in part, based on the number of times each method was utilized which was used to inform the number of categories

used per clinical trial. As such, use of a marketing technique was assigned only once as documented by the clinical trial protocol per individual clinical trial (n=1). This was delineated by a "**1**" or "**0**" which will show that the organization had either used or was lacking the specified marketing strategy. As new methods of recruitment were discovered retrospective documentation was completed concerning a clinical trials list of utilized recruitment marketing methodologies.

Statistical Analysis

Once data collection completed the "complied recruitment practices," it was condensed into new categories based on either the marketing medium or the intended subject of the marketing strategy, as to provide a more effective analysis of the data. This noted a change in the data collection whereby the possibility of marketing strategy per clinical trial can exceed $\mathbf{n \geq 1}$. Analysis was performed comparing the total number of clinical trials per study and specific marketing strategies used to the clinical trials change in expected vs actual enrolled recruitment numbers. Regression analysis was run in the statistical software "R."

V. RESULTS

RAW DATA COLLECTION

Literature Review

Due to a lack of standard best practices on HIV/AIDS clinical trial recruitment, a literature review was conducted to inform on creating "suggested recruitment strategies." The "suggested recruitment strategies" served as a guide during initial recruitment method categorization collected from the ClinicalTrials.gov review. A PubMed search was conducted using the created search function from MeSH (Medical Subject Headings) terms such as "clinical trials" and "patient selection" and restricting these search terms to major topics (Full listing of search terms/search function in Appendix B). These papers were read, and recruitment methodology was noted, if mentioned, and a summary of recruitment methods was made.

The PubMed search resulted in 92 papers, only 20 (22%) noted any form of recruitment method best practice. The recruitment strategies found via literature review could be summarized into eight main categories, which were as follows: Recruitment Website, Social Networking, Online Data Registries, Clinical Research Organizations (CROs), Print Media, In-House Sources, Referrals, and Health Care Volunteering.

Clinical Trial Recruitment Strategies

Based on the PubMed search results above a list of "suggested recruitment strategies" was compiled. These strategies were used to help determine recruitment practices during the initial ClinicalTrials.gov search. U.S. clinical trials involving HIV/AIDS and their affiliated

conditions meeting inclusion criteria were reviewed and recruitment strategies were collected from listed SAPs and protocols.

Clinical Trials listed on ClinicalTrials.gov that met inclusion criteria and were listed by Aug 12, 2019, were 113 trials. Of those 113 clinical trials that met inclusion criteria, only 57 (57/113, ~50%) clinical trials had readily accessible recruitment strategies listed in their SAPs or protocols. These 57 trials produced 22 recruitment strategies as shown in Table 1. Of the collected strategies Local EMR (Local Participant Repository from earlier studies), Flyers, Provider Referrals, Online Advertisement, and Community Outreach were the highest reported recruitment strategies.

Table 1: Clinical trial recruitment strategies prior to consolidation

STRATEGY	No. Trials
Local EMR (Local Participant Repository)	31
Provider Referrals	31
Flyers	26
Online Ads (i.e., google.com, craigslist, etc.)	19
Community Outreach (i.e., workshops)	18
Social Media	12
News Paper/Magazines	9
Recruiter	9
Unspecified Print Media	7
Participant Referral	7
Newsletter	4
Case Managers	4
Online HIV Research Bulletin Board	4
Direct Mail to Physician	3
Mass Emailing	3
National EMR	3
Local EMR (Out-House)	3
Metro	2
Direct to Patient Mailing	2
Radio	2
Email to Physician	1
Study Coordinator Recruitment	1

Consolidation of Data

The above recruitment categories, due to statistical analysis limitations and the low sampling categories, required consolidation. Of the 22 recruitment strategies originally collected, 16 strategies were merged into 6 strategy categories based on similar marketing media or the intended subject of the marketing, resulting in a total of 12 strategies, as described in Table 2.

Table 2: Clinical trial recruitment strategies post-consolidation

STRATEGY	No. Trials
Print Media (Flyers, Newspaper/Magazine, Metro, Newsletter, Unspecified Print Media)*	48
Local EMR (In/Out House)*	34
Provider Referrals	32
Online Media (Online Ads, Social Media)*	31
Community Outreach (i.e., workshops)	18
Recruiter	9
Mass Recruitment (Radio, Mass Emailing, National EMR)*	8
Participant Referral	7
On-Site Recruiters (Study Coordinator Recruitment, Case Managers)*	5
Direct to Physician Mail (Email to Physician, Direct Mail to Physician)*	4
Online HIV Research Bulletin Board	4
Direct to Patient Mailing	2

* – Consolidated recruitment strategies

Enrollment

During the collection of clinical trial recruitment strategies listed above, the recorded enrollment numbers were also collected as part of the clinical trials' characteristics. These were collected for all 113 clinical trials, if available, and were included in all 57 trials that met inclusion criteria, as stated above. A sample table (Table 3) using 5 of the 57 clinical trials shows the data that was utilized in the regression analysis performed. Notably the introduction of the terms "Original Estimated Enrollment," "Actual Enrollment," and "Estimated Enrollment."

These terms originate from ClinicalTrials.gov and reflect how recruitment numbers are categorized based on when in the life cycle of the clinical these recruitment numbers are reported. Original Estimated Enrollment is the original recruitment number reported on ClinicalTrials.gov at the start of the clinical trial's life cycle. Actual vs Estimated Enrollment depends on the clinical trial's recruitment status, with Actual Enrollment being reported for either completed studies or closed recruitment status studies. While Estimated Enrollment is the up-to-date enrollment target for actively recruiting studies that may or may not be different from the Original Estimated Enrollment. However, the term Estimated Enrollment has been known to show up for "active, not recruiting studies," whereby the study is not actively recruiting but those enrolled are receiving treatment. It should be noted that for the regression analysis the Actual Enrollment and Estimated Enrollment were combined to represent the end point by which to compare to original recruitment goals stated.

Table 3: Sample Analysis Table

Ref No.***	Recruitment Strategies (x12)*	Total per Trial	Actual/Estimated Combined	Original Estimated Enrollment
1	1	1	63	78
2	4	4	210	320
3	10	10	350	350
4	1	1	197	254
5	10	10	180	180

Total per Recruitment Strategy**	X	X	X	X

* – Note for simplicity the strategies were listed in a compact manner

** – Not available for sample table due to missing trials

*** – Reference to supplementary data (not shown)

Original Estimated Recruitment collected from the 57 trials that met inclusion criteria were compared with the Actual/Estimated Enrollment to give a generalized idea of what percentage of trials that met inclusion criteria and met their original recruitment goals. Data are summarized in Table 4.

As described in Table 4, 29 (51%) successfully met or exceeded the original recruitment with 28 (49%) not meeting the original recruitment target. Of the 57 trials that met inclusion criteria, 9 (15.8%) trials only managed to recruit less than or equal to 50% of the original estimated enrollment.

Table 4: Trial Recruitment

	N	n (%)
Successful Recruitment	57	
Yes		29 (50.9)
No		28 (49.1)
Original Enrollment Target	57	
≥ 100%		29 (50.9)
≥ 80% but < 100%		7 (12.3)
< 80%		21 (36.8)
≤ 50%		9 (15.8)

STATISTICAL ANALYSIS

Regression analysis was performed in the statistical software “R” comparing the number and specific marketing strategies used to the clinical trials’ change in expected vs actual enrolled recruitment numbers. Following analysis of collected marketing strategies no statistically significant relationship between the total number of recruitment categories used per trial and the recruitment rate. Furthermore, there was no statistically significant relationship between any one recruitment strategy category and recruitment rate.

VI. DISCUSSION

The purpose of this study was to examine the types of recruitment strategies currently being used in clinical trials concerned with HIV/AIDS in the U.S. and determine whether recruitment strategies found made a significant difference in the enrollment outcomes of the clinical trials. To accomplish this, a PubMed literature review was carried out to determine recruitment categories used in HIV/AIDS clinical trials, and were then used in a search of ClinicalTrials.gov to identify past HIV/AIDS clinical trials in the U.S. The U.S. HIV/AIDS clinical trials meeting inclusion criteria were reviewed for their recruitment strategies and enrollment figures. These categories of strategies were condensed to increase statistical power necessary to perform regression analysis to compare the relationship between the recruitment strategies and enrollment outcomes.

Based on data collection in U.S., HIV/AIDS clinical trials recruitment continues to present a challenge. As described previously in Table 4, close to half of the 57 clinical trials, that were reviewed, did not meet their initial recruitment goals. Furthermore, 9 (15.8%) trials only managed to recruit 50% or less of the original estimated enrollment. This clearly demonstrates that initial recruitment goals were not being met by a large number of HIV/AIDS clinical trials in the U.S. Unfortunately, the data obtained from ClinicalTrials.gov does not differentiate between actual enrollment and estimated enrollment or provide insights on why they were changed. Thus, we were unable to determine whether the completed studies lowered their target enrollment due to problems in recruitment and as a result were then able to meet these lower recruitment numbers. Future studies that examine the reasons for adjustment of enrollment goals would provide insights into the types of unforeseen issues that impact the performance of a clinical trial.

There was no clear relationship between the types or numbers of recruitment strategies used and recruitment into a clinical trial. In our study, the 12 categories of recruitment strategies were shown to have no statistically significant relationship between the total number of recruitment categories used per trial and the recruitment rate. Furthermore, there was no statistically significant relationship between any one recruitment strategy category and recruitment rate. This is in contrast to the original hypothesis that more recruitment strategies used result in better recruitment outcomes. A possible explanation as to why no significant relationship was found may be linked to the need for individual tailoring of recruitment for each site, rather than a generalize approach for recruitment at all sites. Individual tailoring may mean the site team tasked with recruiting in these different geographical locations are utilizing recruitment strategies most useful for the surrounding target populations and relevant customs. In this way, it would not be the recruitment strategies in and of themselves that are playing a significant role but rather the tailoring methods and decisions being made at the site level. This indicates that recruitment success is dependent on the practices at each site. Not only would this include the types of recruitment strategies but also decisions made about financing and management that impact successful recruitment outcomes.

Financial considerations are often an overlooked subject area in the grand scheme of clinical trial optimization.[29] Often empirical considerations revolve around specific costs associated with conducting a clinical trial. Factors such as the lack of availability of clinician hours and supporting staff have a direct negative impact on recruitment rates.[29] However, more interestingly a U.K. based study looked at the hard to qualify concept of how trialists' navigation through funding structures impacted recruitment rate.[29] The research team selected four "exemplar trials" that met the criteria of being of diverse research settings, methods, and clinical

specialties; additionally, they were on schedule to meet sponsor's expectations.[29] Snowdon and colleagues conducted 45 interviews amongst the four trials and drew upon a diverse set of professions involved in clinical trials. Two major takeaways from their research focused on the extent to which industry influences clinical trials and the skills necessary to successfully navigate funding structures.[29] A clear conclusion drawn from the trialists' interviews was the difficulty in not compromising the clinical trials main goals with the often competing interests of industry.[29] The difficulty facing trialists regarding clinical trial integrity varied based on funding vulnerability, i.e., how dependent the trial was on funding from industry.[29] Those trials with less diversified funding, relying more heavily on industry, were less flexible and thus vulnerable to funding disturbances.[29] A more nuanced conclusion dealt with the skills and experience needed to successfully negotiate with sponsors (public or industry) for proper funding. Not only were these skills applicable to initial funding requests but also in dealing with sudden funding cuts (i.e., industry pulls funding 2 years into the clinical trial), which requires flexibility.[29] Development of a training program aimed at educating trialists on these skills and gaining insight into handling complex funding structure situations should be prioritized. A UK variant of such a program exists as a support network it provided by the UK Clinical Research Network.[29] Financial considerations represent one area whereby improvement can be made, however, management on the trialists part offers another route by which clinical trials can be understood.[1]

Managerial concerns are an additional component linked as a possible variable in improving recruitment rates.[1] A unique trial conducted by Francis and colleagues focused on developing a marketing strategy for the Corticosteroid Randomization after Significant Head injury (CRASH) trial, during the recruitment phase, in the aim of providing a business minded framework for future trials to reference.[1] A successful framework was created based on

methodology ranging from in-depth interviews with trial management to business minded techniques from adaptive theory.[1] Notably, the trialists involved with advising CRASH and creating this framework were from the academic business field grounded in marketing and strategy specialty. The background of Francis and colleagues highlighted one of the core reasons for undertaking this study which was realizing the dual nature clinical trials represent. Clinical trials are an amalgamation of both clinical and managerial process, that are independent of each other, yet rely on the other for successful recruitment.[1] As such, continued improvement of clinical trials may need to focus on aspects outside of clinical research, like business strategy, to solve recruitment issues.

VII. SUMMARY & CONCLUSION

Overall, recruitment of subjects for HIV/AIDS clinical trials is still a significant problem, and it does not appear that marketing strategies are linked to the recruitment rate. The strength of this study is the use of the comprehensive collection of U.S. HIV/AIDS clinical trials found in ClinicalTrials.gov. Roughly 50% of HIV/AIDS clinical trials in the U.S. did not meet their original recruitment goals. In contrast to the original hypothesis, marketing was not a significant factor in recruitment rate, and tailoring of recruitment at a more local level of the trial site is likely having an impact on recruitment rate. Although the influences of marketing may be more complex than expected, these results suggest that other factors may also play a role in a successful recruitment of subjects for clinical trials. There are likely managerial and financial factors, in addition to marketing, that need to be addressed to optimize recruitment efforts. As mentioned by Francis and colleagues and supported by our results, perhaps the future innovations of clinical research will be sourced from the interplay between differing disciplines.

Limitations

Part of the issue that exists and presents a hindrance to the development of a more detailed analysis of marketing recruitment techniques is the limited information currently available. Information concerning the successful marketing strategies utilized are often kept hidden as part of a specialized CRO's unique databases. The practice of hiding recruitment strategies by a CRO is not unfounded, due to the competitive advantage drawn from keeping such practices confidential. Although concealing such information affords the organization advantage, such action is detrimental to the analysis of recruitment techniques in the clinical trial

space. In addition, many authors of clinical trials do not include the reasons for failures and success in their clinical trials.

This makes collecting data about recruitment marketing strategies more challenging. One reason that makes data collection challenging is that it is difficult to know how to classify the success of any research program solely based on the recruitment data. The method of clinical trial data collection, ClinicalTrials.gov, while having a great deal of information, lacks considerably when marketing and recruitment strategies are the target of analysis. Beyond denoting the phase of recruitment and the number of enrolled participants at varying points of the recruitment phases, additional recruitment information must be extracted from SAPs and protocols, if they contain such information at all. Additionally, only a small minority of clinical trials post protocols and SAPs to ClinicalTrials.gov, further limiting data collection.

Future Directions

Prioritizing creation of a central repository of information about clinical trials conducted in the U.S. will be an important step for the future. This all-in-one source of information could be a proxy to ClinicalTrials.gov which mandates institutions to share data about their trials in a public format. Increasing the amount of information collected in the ClinicalTrials.gov database or proxy database as stated previously, such as recruitment information and mechanisms of recruitment performed, could provide a more comprehensive view on current recruitment methods and ways by which to improve poor recruiting. Additionally, future research modeling the trialist focused funding navigation done in the UK funding structure with “exemplar” trials would be insightful for U.S. based trials.

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IX. INTERNSHIP EXPERIENCE

My internship experience was completed at the University of North Texas System College of Pharmacy. I performed my research under the guidance of Dr. Patrick Clay as the Principal Investigator and Karen Ndagui as the Clinical Research Coordinator. The study I participated in was as follows: Medical Record Based Versus Non-Medical Record Based Community Pharmacy Provided Medical Therapy Management.

During my internship, I performed the following duties:

1. Protocol development
    a. Literature Review
    b. Search Function Creation using MeSH Terms
    c. Data Entry
    d. Statistical Analysis
2. Clinical Trial Recruitment
    a. Marketing Resources
    b. Face-to-Face Recruitment
    c. Consenting
    d. Community Engagement
3. Point-of-Care Techniques
    a. Blood Pressure
    b. A1C
    c. Cholestech LDX System

Journal Summary

The first couple of months focused on preparing for recruitment to be re-started for the MTM clinical trial Dr. Clay was heading. Recruitment initially focused on data collection for potential area zip codes to target the best population (HIV individuals, self-identifying as Black or African American) and specific organizations (churches, barbershops, CVS, Walgreens) in the DFW Metropolitan Statistical Area (DFW-MSA). This research gave us a map distribution of areas and/or locations we needed to visit to distribute our IRB approved flyers and clinical trial summaries for the pharmacists at CVS or Walgreens. Once enrollment started, I spent most of the remaining months attending to various visits all around the DFW-MSA. I spent a lot of time in Dallas at or around the Cedar Springs Walgreens, Prism Health North Texas Oak Cliff, and South Dallas locations. Interspersed with these visits Karen and I attended various community events and awareness campaigns. Following COVID-19 we switched mostly to data entry of the CRFs into the created data collection tool in LabArchives. This continued until Dr. Clay departed UNTHSC unexpectedly.

APPENDIX A

CLINICALTRIALS.GOV SEARCH METHOD

APPENDIX A

ClinicalTrials.gov Search Method – U.S.

The government website ClinicalTrials.gov was accessed. From the homepage select “Advanced Search” option.

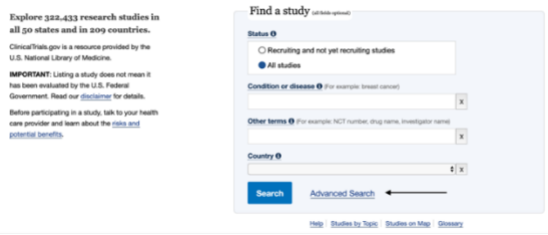

Figure A1. Advanced Search Option.

Once the advanced search option was selected, the “Condition or Disease” was selected based on the available options generated concerning HIV/AIDS. The available search options concerning HIV were documented (Figure A2), along with “HIV/AIDS” search options (Figure A3); HIV/AIDS was selected from the displayed selection (Figure A4).

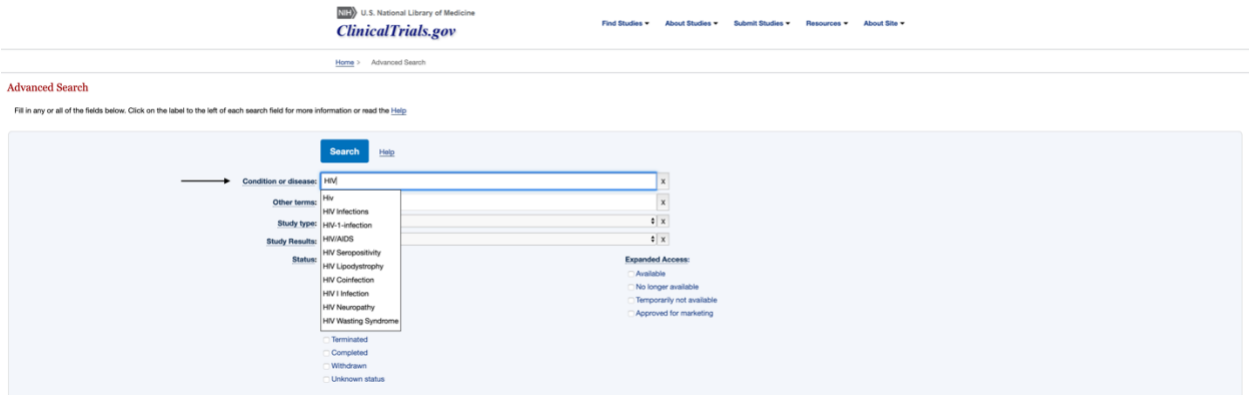

Figure A2. HIV Selection Options.

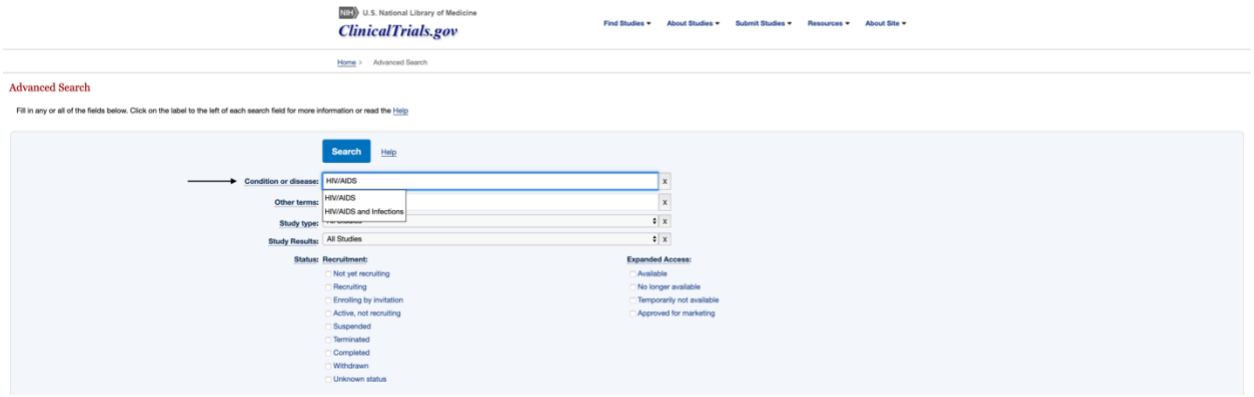

Figure A3. HIV/AIDS Selection Criteria

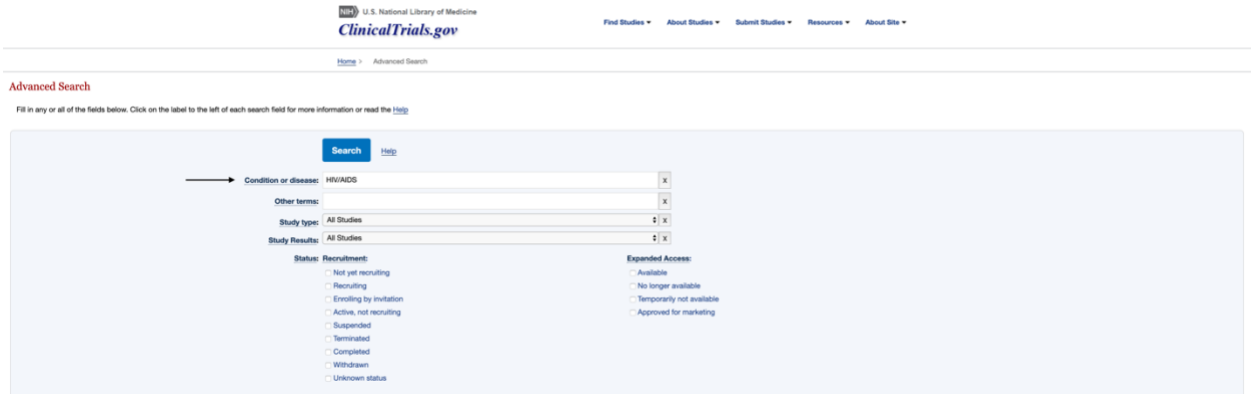

Figure A4. HIV/AIDS Condition or Disease Selection.

Following Condition/Disease selection study type was selected from the available drop-down menu to be “Interventional Studies (Clinical Trials).”

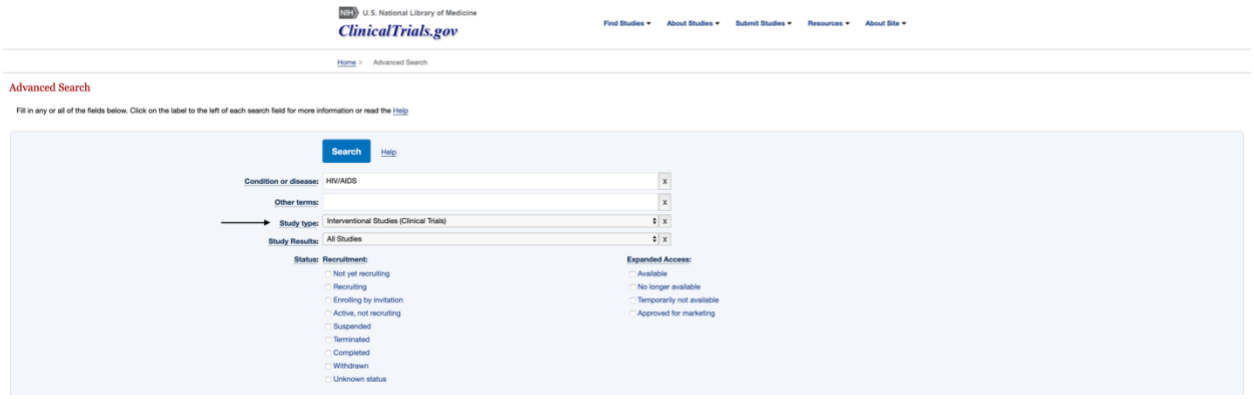

Figure A5. Study Type Selection.

Following the selection of study type, the study results search criteria was left at the default selection of "All Studies."

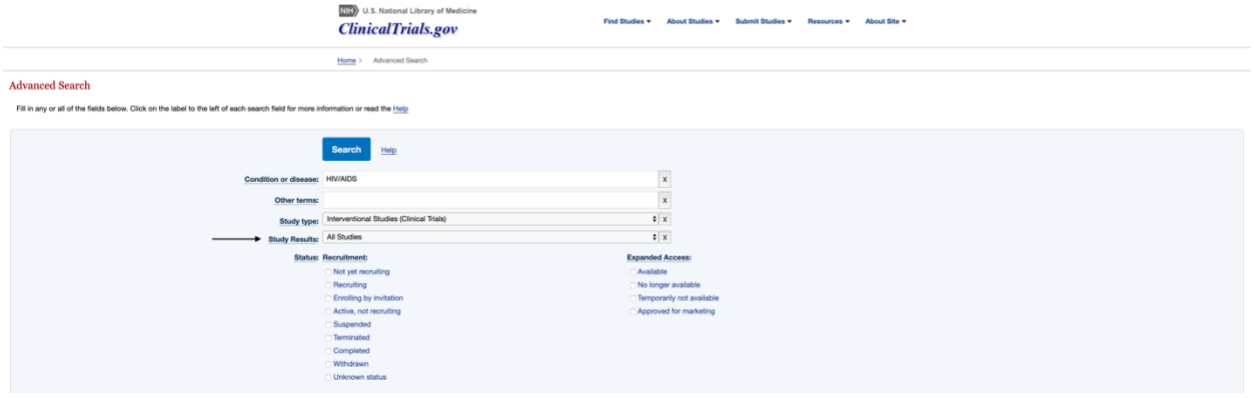

Figure A6. Study Results Selection.

No exclusion was made concerning recruitment status.

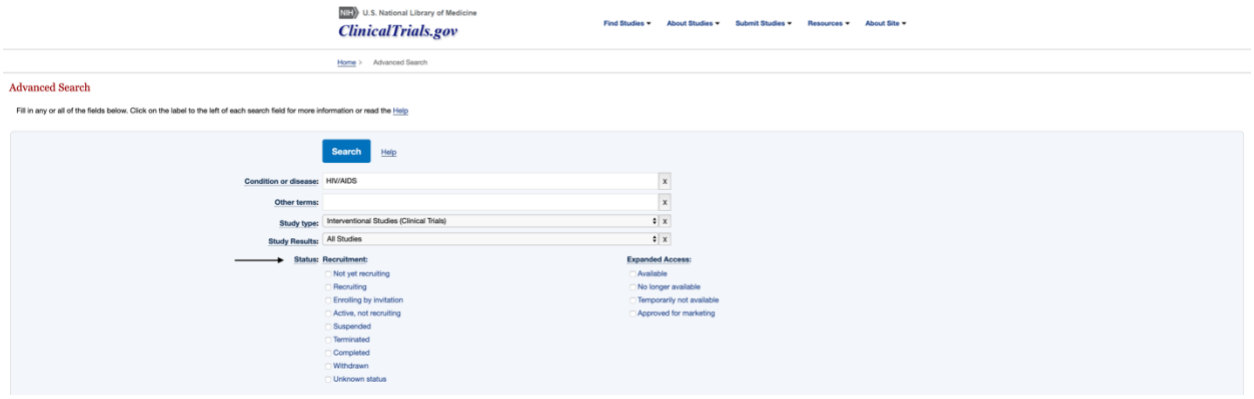

Figure A7. Recruitment Status Selection.

No additional search restrictions were selected under “Eligibility Criteria” nor under “Targeted Search” sections.

Figure A8. Eligibility & Targeted Search Sections.

Under the “Locations” section for “Country” search the United States was chosen.

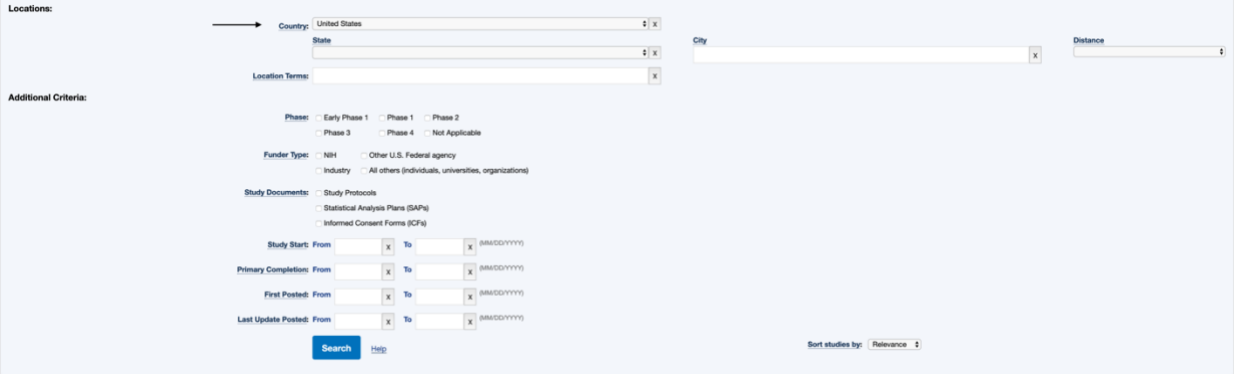

Figure A9. Location Selection – U.S.

In the section additional criteria, under "Study Documents" both "study protocol" and "statistical analysis plans (SAPs)" were selected.

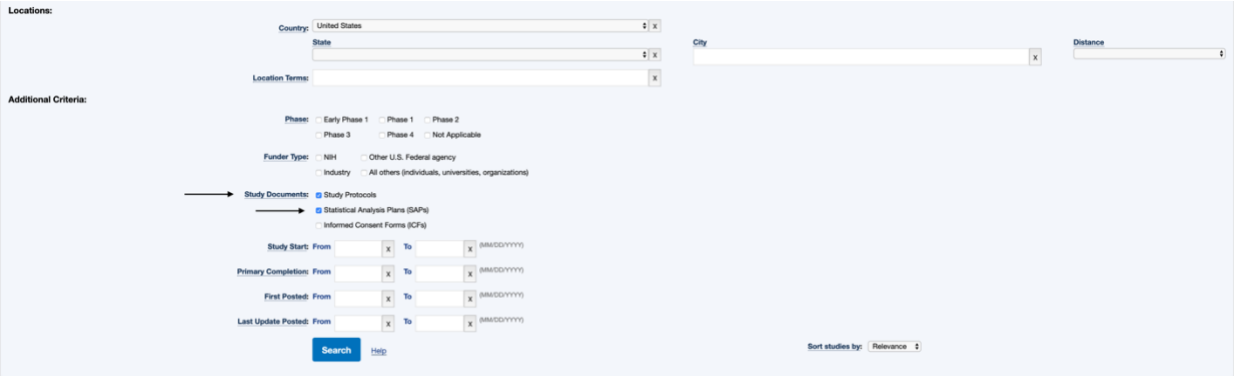

Figure A10. Study Document Selection.

Lastly, the study time frame was selected under "Study Start" and was chosen from 01/01/2008 – 12/31/2018.

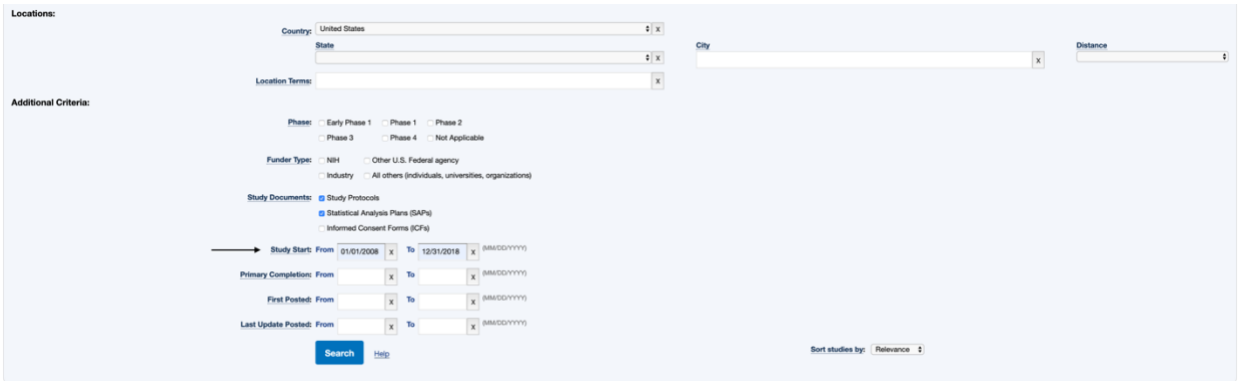

Figure A11. Date Selection.

APPENDIX B

NCBI PUBMED SEARCH FUNCTION

APPENDIX B

NCBI PubMed Search Function

((“Clinical Trials as Topic”[Majr]) AND “Patient Selection”[Majr] AND full text[sb] AND “last 5 years”[Pdat] AND Humans[Mesh] AND English[lang])) NOT china*) AND full text[sb] AND “last 5 years”[Pdat] AND Humans[Mesh] AND English[lang])) NOT ((“43anada” OR “43anada/a” OR “43anada/43anada” OR “43anada/43anada/india” OR “43anada/43anada/middle”))) AND full text[sb] AND “last 5 years”[Pdat] AND Humans[Mesh] AND English[lang])) NOT 43anada*) AND full text[sb] AND “last 5 years”[Pdat] AND Humans[Mesh] AND English[lang])) NOT asia*) AND full text[sb] AND “last 5 years”[Pdat] AND Humans[Mesh] AND English[lang])) NOT 43anada4343a*) NOT 43anada*) NOT south 43anada43*) NOT 43anada) AND full text[sb] AND “last 5 years”[Pdat] AND Humans[Mesh] AND English[lang])) AND United States*) AND full text[sb] AND “last 5 years”[Pdat] AND Humans[Mesh] AND English[lang])) NOT cancer*) AND full text[sb] AND “last 5 years”[Pdat] AND Humans[Mesh] AND English[lang])) NOT transplant*) AND full text[sb] AND “last 5 years”[Pdat] AND Humans[Mesh] AND English[lang])) NOT neurological*) NOT psychiatric*) NOT prisoner*) NOT pregnancy*) AND full text[sb] AND “last 5 years”[Pdat] AND Humans[Mesh] AND English[lang])) NOT surgery*

APPENDIX C

INTERNSHIP JOURNAL

APPENDIX C

INTERNSHIP JOURNAL

05/28/2019 – Showed up to the office early – around 7:30 – to start preparing for the HIV MTM investigator meeting to be held at IREB. The meeting went well. Lots of information discussed about pharmacy MTM and the main study Dr. Clay will be working on.

05/29/2019 – Studying Medical Record Based Versus Non-Medical Record Based Community Pharmacy Provided Medical Therapy Management protocol. Will be quizzed about the contents. Need to be able to give consents.

05/30/2019 – Onboarding training … yay!

05/31/2019 – Onboarding training

06/03/2019 – Went to PDRT Orientation meeting with Ryan Chishimba, will be my co-investigator for project.

06/04/2019 – 06/07/2019 – Beginning literature review necessary for proposal meeting in about a week with committee. Difficult to find articles about marketing literature. May need to ask for assistance on how to go about procuring business marketing materials. A need for research regarding marketing but how to structure this is up for debate. Need to read more.

06/11/2019 – 06/13/2019 – Found some good articles detailing some in-depth recruitment marketing research done in the UK. Question is can I use this research since it is from a different country? Do we have the same laws and regulations? YES! Found articles detailing similarity enough for UK research to be useful in developing a type of proposal.

06/14/2019 – CRM Research Advisory Committee meeting today. Went well … need to expound on statistical analysis and/or determine how to analysis any data.

06/18/2019 – 06/21/2019 – Research is proving to be difficult in formulating a proposal. Background is being worked on and revising summary as ideas continue. A literature review may be worthwhile as a starting point before additional analysis? Are there any standards…

06/22/2019 – Research update meeting with Dr. Clay. Stressed need to create a concrete plan first.

06/26/2019 – Blog presentation at Ryan White. Continued document writing afterwards at office.

06/27/2019 – 06/28/2019 – Created background information and beginning of aims

07/02/2019 – Proposal Review. Good progress. Will be making a concerted effort next two weeks to create finished proposal.

07/10/2019 – 07/12/2019 – Additional proposal meetings and finalizing. Finished limitations. Still need to make mock tables. Tables have been made.

07/15/2019 – Met with library staff regarding creating a MeSH search function. Going to do some further research on previously found articles to help determine which terms would be most appropriate.

07/16/2019 – Had weekly meeting with Dr. Clay, Karen and Ryan regarding the MTM study. Going to begin recruiting soon. Need to approve consenting ability of pharmacy students and clear Karen and Ryan.

07/18/2019 – Going to be going to Prism Health North Texas to meet with staff as they will be helping us recruit for our study via physician referrals and their own EMR database.

07/19/2019 – Presenting today at JPS Healing regarding MTM study and their role as potential recruitment populations in JPS. Attended Texas HIV Medication Advisory Committee.

07/23/2019 – Went to sites around Fort Worth that could be useful for recruitment for the MTM study. Primarily Black churches and barbershops.

07/24/2019 – Helped Karen prepare for AOC presentation tomorrow. Writing source documentation for upcoming consenting restart. Read some literature this evening.

07/25/2019 – Met with librarian again to create a search MeSH function for PubMed. Search function done!

07/26/2019 – So I spent the day downloading the PubMed 92 resulting articles! Figuring out a plan of attack to read and determine recruitment methods.

07/31/2019 – Had consenting visit at Walgreens on Rosedale with Anthony. Went well. Lasted around 3 hours, definitely over the allotted time.

08/01/2019 – Meeting downtown in Dallas to attend presentation by Dr. Clay to introduce MTM study to HIV specialty pharmacists.

08/02/2019 – Visit 3 Point of Care testing at participants home. Finished some remaining CRF documents after returning to the office.

08/05/2019 – Team meeting this morning concerning upcoming recruitment efforts and division of consenting/visits. Continued literature review. Created excel spreadsheet for organization.

08/06/2019 – Harambee updates meeting this morning at 0730. Consenting visit downtown at Dallas Cedar Springs Walgreens location. Set up Lyft ride for tomorrows 0830 consenting visit.

08/07/2019 – 4 consenting visits at Rosedale Walgreens. Trouble continues with Lyft drivers and trying to find this location. Karen and I met to determine a method to try and get more reliable Lyft drop-offs. Also, attended Samaritan House presentation for recruitment. 1800 last consenting visit. Got home quite late.

08/08/2019 – Left 0630 to Dallas for 9 potential participants at Prism, starting at 0830. Traffic leaves less to be desired. Left for an added consenting visit in Dallas at Cedar Springs.

08/09/2019 – Team meeting this morning at 0700. Left immediately afterwards after compiling CRF documents for consenting visit. Left for Dallas to attend consent visit at Cedar Springs Walgreens. Had an additional consenting visit over at Prism. Ryan joining in and will be guiding him.

08/12/2019 – Covering Visit 2 at Rosedale Walgreens. Covered an additional consenting visit at Rosedale at around 1500. Drove back to UNTHSC campus to drop off documents and write of CRF documents.

08/13/2019 – Had team meeting this morning. OFFICE DAY! Catching up on the endless paperwork. Left at 1700.

08/14/2019 – Consenting visit at Rosedale Walgreens at 0830. Had to rush to meet next visit downtown in DALLAS. Went well super tired. Drove back to Fort Worth for Samaritan House Supper Club at 1600. Had to return to office to work on some CRFs. Got home late.

08/15/2019 – Covering Visit 2 at Rosedale Walgreens at 1000. Will be at office until 1730, then need to head over to Rosedale Walgreens again for consenting visit at 1800. Got home late.

08/16/2019 – Worked this morning in the office to call participants for scheduling and completing CRF documentation. Data entry training both at 1230 and 1530.

08/19/2019 – Covering visit 2 at Rosedale community pharmacy at 0900. Returned to UNTHSC office. To check pharmacy student Kevin on ability to do point of care testing and consenting. Karen will be joining me.

08/20/2019 – Office catch up day. Afterwards, continued literature review. Asking Ryan to help read through documents to speed up process. Review is taking long, only 4 studies thus far mention any best marketing recruitment at all.

08/21/2019 – Covering consenting visit at Prism in Dallas. Additional consenting visit at participants home in Dallas.

08/22/2019 – Covering Visit 2 at Rosedale Community Pharmacy. Had to return to UNTHSC to attend to an additional consenting visit at the Lewis Library. Participant did not show up after an hour of waiting.

08/23/2019 – Had to leave around 0530 to pick up lunch for meeting at Uptown Physicians Group downtown in Dallas. Karen and I had to present the MTM project to the group, so they know what to look to aid us in recruitment efforts. Meeting began at 0700, went well. I stayed in Dallas to cover Prism Health recruitment and Karen went back to Fort Worth to take care of additional consenting visits.

08/26/2019 – Covered a visit 2 at Rosedale Walgreens at 0950 and an additional visit at 1300. Both went well. Definitely have improved compared to when I initially started in terms of speaking ability with participants.

08/27/2019 – Covering a visit 2 at Rosedale Walgreens. Had to update CRFs at office once visit was completed. Need to order more materials for point of care. Will speak with Karen and Dr. Clay.

08/28/2019 – Was covering Prism in Dallas all day. Had multiple potential participants but no luck. Many failed to show up to provider appointment and one said no, and to ask them next time.

08/29/2019 – Again at Prism. Karen came by after a consenting visit over at Cedar Springs.

08/30/2019 – Had a consenting visit over at Prism at 1400. Spent morning looking over articles.

09/02/2019 – Covered paperwork at UNTHSC office. Worked on making folders for participants and discussed with Dr. Clay on how to structure my literature search.

09/03/2019 – Worked on documenting completed CRFs and finishing Visit 2 documentation.

09/04/2019 – Consenting participants at Prism Health North Texas Oak Cliff

09/05/2019 – Completed CRF for V2 and met participant for V2 appointment.

09/06/2019 – Consenting participants at Prism Health North Texas Oak Cliff. Traveled to Prism Health North Texas South Dallas for additional consenting, as more potential participants were identified.

09/09/2019 – Consenting visit scheduled at Prism Health Oak Cliff. Stayed at Prism for duration of the day to continue consenting potential participants.

09/10/2019 – Listened to NAC NIMHD online seminar while continuing paperwork at the UNTHSC office. Worked with CRC to start a data summary page on LabArchives of participants data points.

09/11/2019 – Consenting potential participants at Prism Health North Texas Oak Cliff.

09/12/2019 – Consenting potential participants at Prism Health North Texas Oak Cliff, due to higher volume of potential participants.

09/13/2019 – Consenting potential participants at Prism Health North Texas South Dallas location.

09/16/2019 – Had three visits today at Rosedale Walgreens. A visit 1 and two visit 2's. Went well but had issues with going over allotted time and cutting into other participants scheduled times.

09/17/2019 – Had a visit 2 at Rosedale. Then spent the rest of the day in the office. Had to organize folders and complete some CRFs.

09/18/2019 – Had to leave early for Prism Health Oak Cliff (Main Site) for early potential visits. Had a few that could potentially meet criteria, however, declined to take part.

09/19/2019 – Again at Prism. Nothing notable occurred. Reading literature in spare time.

09/20/2019 – Had a visit 2 at Cedar Springs that needed to be covered at 1000. Also had another consenting visit over at Prism Oak Cliff around 1300. Both went well, still normally taking 3 hours each.

09/23/2019 – Had a visit 2 downtown in Dallas at Cedar Springs Walgreens at 0900. Spent the remainder of time over at Prism Oak Cliff. Found an additional participant while there.

09/24/2019 – Had a team Database meeting this morning. Learning how to build a database for the MTM trial. Spent the afternoon organizing documents and CRFs.

09/25/2019 – Attended the Building Bridges Summit at Mabel Peter Carruth Center with Karen. The presentation went well, and they seem excited to help with the project and what it could achieve.

09/26/2019 – Had a visit 2 over at Rosedale Walgreens. Returned to UNTHSC to help Ryan with Visit 2 practice. Namely the point of care that is introduced from this visit onwards.

09/27/2019 – Covered a visit 2 at Prism Health Oak Cliff at 0930. Spent the rest of the day at Prism South Dallas.

09/30/2019 – Had a visit 2 at Rosedale Walgreens. Returned to UNTHSC afterwards to catch up on CRFs.

10/01/2019 – At Prism Health Oak Cliff to screen potential participants. Headed over to Prism South Dallas, as a potential participant was found.

10/02/2019 – Spent most of the day reading literature. Almost finished with literature reading.

10/03/2019 – Had a visit 2 over at Cedar Springs Walgreens at 1000. Spent the remaining day screening over at Prism Health Oak Cliff.

10/04/2019 – Had a 0900 consent visit at Prism Oak Cliff in Dallas. Spent remaining time at Oak cliff for the day.

10/06/2019 – Attended the Life Walk on Sunday in Dallas. Was quite an interesting experience.

10/07/2019 – Had a consenting visit at 1000. Followed by a Visit 2 at Rosedale.

10/08/2019 – Had a 1300 Visit 2 at Cedar Springs in Dallas. Went well. Spent reaming time at Prism Oak Cliff.

10/09/2019 – Attended a presentation for Dallas Ryan White Planning Council at 0900. Went well however, certain administrative issue remains a hurdle in accessing the patient population pool from Ryan White. I am unsure as to what they are. Attended to a visit 2 at Rosedale Walgreens following drive back to Fort Worth.

10/10/2019 – Covering Visit 2 at Rosedale this morning at 0900. Had another Visit 2 at Rosedale Walgreens. I was supposed to have a consent visit at Samaritan house, however, they cancelled and rescheduled.

10/15/2019 – Covered a consenting visit at Prism Health Oak Cliff in Dallas at 1100. Afterwards, I had to return to UNTHSC to do Medical Record Scanning. This is going to be an essential part of the data entry for the MTM study. Converting the medical records into electronic format.

10/16/2019 – I had a consenting visit at AIN in Dallas at noon. Went well, nice facility.

10/17/2019 – I had a visit 4 and visit 3 today at Prism Health in Dallas. They were at 1000 and 1300 respectively. Went well, stayed the afternoon to see if any additional participants came through.

10/18/2019 – Normal day at Prism Oak Cliff. Nothing extraordinary.

10/21/2019 – I had a visit 2 at Rosedale Walgreens at 1000. And a consenting visit at 1300 afterwards.

10/22/2019 – Medical record scanning all day.

10/24/2019 – Consenting visit at Prism Oak Cliff in Dallas at 0930. Left early to pick up a small breakfast and coffee. Spent the rest of the afternoon in Dallas screening potential participants.

10/25/2019 – I had an unusual consenting visit at a Denny's in Dallas. Participant was an hour late and the consent went for 3 hours. Spent afternoon at Prism South Dallas.

10/26/2019 – Attended the 2019 Harambee Festival in Dallas. Was an incredibly fun and exciting recruitment day.

10/31/2019 – Spent all day at Prism Oak Cliff. Had a possible 9 participants but none ended being able to be consented. Quite disappointing.

11/01/2019 – Two visits at Cedar Springs Walgreens in Dallas. They were at 1030 and 1400, respectively. Went well. Dropped off materials at UNTHSC around 1745. Traffic was horrible.

11/04/2019 – Had a visit 3 at 0830 at Rosedale Walgreens. Waited an hour and participant did not show. Worked on finishing last of literature review excel sheet and consolidating recruitment methods.

11/05/2019 – Medical record scanning most of the day.

11/08/2019 – Spent the morning at Prism Oak Cliff. I had a consenting visit at the participants home in Dallas.

11/12/2019 – Team meeting at 0900. Went well, update on recruitment efforts and some other areas where we might be able to recruit. Left for Dallas to cover Prism Health Oak Cliff participants.

11/13/2019 – I had a consenting visit at Prism Oak Cliff. Went to Parkland to pick up medical records for a participant. Drove back in the afternoon to UNTHSC to drop off medical records and headed home.

11/14/2019 – I had a visit 2 at 1000 at Oak cliff. Went well, some difficulty drawing blood from participant. Quite dehydrated. I had an additional two visit 3's at 1200 and 1500, respectively. Left in the evening to home.

11/18/2019 – Attended JPS Healing wings follow up information meeting at 0800. Had to leave early and help Karen pick up DONUTS for the providers. It was quite a great informal meeting. I had two back-to-back Visit 3's at Rosedale Walgreens from 1000-1600. Last visit 3 lasted quite a while.

11/19/2019 – I was at Rosedale Walgreens from 0930 to 1700. Quite a long day. I had 3 back-to-back visit 3's.

11/20/2019 – I was at Rosedale Walgreen again from 0930 to 1600. Left document for Karen on the desk in the office for tomorrow morning.

11/21/2019 – I was at Prism Health Oak Cliff in Dallas all day. Bounced between South Dallas location too, because of some participants.

11/22/2019 – Team meeting this morning at 0800. Left immediately after towards Prism Oak Cliff to catch potential participants coming in the morning.

12/06/2019 – Spent the morning at Prism Oak Cliff. Had a Visit 2 and performed point of care like usual. Went well. I am sure I have the hang of drawing blood now, even if participant is dehydrated.

12/09/2019 – I had a visit 2 at Rosedale Walgreens around 1100 this morning. Returned to UNTHSC to work on the CRF pile.

12/10/2019 – Team meeting this morning at 0900. Had to attend to a visit 3 at Rosedale Walgreens. Spent rest of day working on CRFs.

12/11/2019 – Spent day at Prism Health Oak Cliff in Dallas.

12/12/2019 – Attended APAA recovery staff presentation at 0800. Had to leave for Prism to screen participants.

12/13/2019 – BIRTHDAY! Spent the day screening participants at Oak Cliff.

12/14/2019 – Attended Kwanzaa Festival all day in Dallas.

12/16/2019 – I had a visit 3 at Rosedale Walgreens at 1000. Worked on CRFs the rest of the day.

12/17/2019 – At Prism since 0800 to screen participants for MTM study.

12/18/2019 – At Prism since 0800 to screen participants for MTM study. I had a Visit 3 at noon. Headed home afterwards. Dropped of documents at UNTHSC.

12/19/2019 – Two Visit 3's at Cedar Springs Walgreens. These were at 0900 and 1100. I had to pick up records at Parkland again. Took a while but got them! Left for UNTHSC and dropped off records.

12/20/2019 – Spent the day at Prism between Oak Cliff and South Dallas.

01/06/2020 – Team meeting at 0800. Nice to see Dr. Clay and Karen. Discussed strategy and new rounds of recruitment to begin.

01/07/2020 – I had a visit 3 at Rosedale Walgreens at 1500. Point of care was difficult due to participant being under the influence of some narcotic. Alerted pharmacist and agreed.

Attempted to complete visit activities as smoothly as possible. Made sure they got on Lyft back safety.

01/08/2020 – I was at Prism Oak Cliff all day. No notable occurrences.

01/09/2020 – I was at Prism South Dallas in the morning and then drove to Oak Cliff for a last-minute consent.

01/10/2020 – I was at Prism Oak Cliff all day. No notable occurrences.

01/14/2020 – I had a consenting visit today at Rosedale Walgreens at 1030. Returned to UNTHSC afterwards to work on CRFs and filing.

01/15/2020 – I had a visit 3 at Prism Oak Cliff at 0900. Stayed the rest of the afternoon as there were some potential participants in the afternoon.

01/16/2020 – I was at Prism Oak Cliff all day. No notable occurrences.

01/17/2020 – Spent the day at Prism South Dallas as there was quite a few potential participants coming in today. I managed to consent 2 more.

01/21/2020 – I had a 0900 visit 2 at Rosedale Walgreens. Spent the remaining day trying to organize the office with the new supplies and doing CRFs.

01/22/2020 – Team meeting this morning at 0800. Left for Prism afterwards and stayed the rest of the day in Dallas.

01/23/2020 – I was at Prism Oak Cliff all day. No notable occurrences.

01/24/2020 – I had a Visit 4 at Prism Oak Cliff at 1000 this morning. Headed back to UNTHSC afterwards to attend team meeting. Updated with data collection tool.

01/27/2020 – Team meeting this morning at 0800. Had to leave to attend to a Visit 3 at Rosedale Walgreens Pharmacy. Had a Visit 5 phone call interview (FIRST ONE). Scheduled participants separate point of care, per protocol.

01/28/2020 – I had a consenting visit down at Cedar Springs Walgreens in Dallas. Traffic was miserable. Left to attend networking meeting at Jefferson tower (prism administration building). Then drove back to cedar springs Walgreens to attend to a visit 2 at 1400.

01/29/2020 – I had a 1000 visit 2 appointments at Cedar Springs Walgreens. Spent the reaming afternoon at Cedar Springs for potential walk-ins.

01/30/2020 – Spent the day at Cedar Springs Walgreens in Dallas waiting for walk-ins.

01/31/2020 – Spent the day at Prism Health South Dallas for potential participants.

02/03/2020 – Team meeting at 0900. Had to attend to 1100 Visit 3 over at Rosedale Community Walgreens.

02/04/2020 – Office Day catching up on recruitment calling/reminders, filing and CRF completions.

02/05/2020 – I had a 1000 visit 3 appointment at Cedar Springs Community Walgreens. Spent the afternoon at the cedar spring's location for walk-ins.

02/06/2020 – I spent the day at Prism Oak Cliff all day. No notable occurrences.

02/11/2020 – I had a 1000 visit 3 appointment at Cedar Springs Community Walgreens. Spent the afternoon at the cedar spring's location for walk-ins.

02/12/2020 – Team meeting this morning at 0800. Left soon after to attend to a visit 3 appointment at Cedar Springs at 1000.

02/13/2020 – Spent most of the day at Prism Oak Cliff. However, drove to South Dallas as there was a potential participant.

02/14/2020 – Consented a participant at 0900 this morning in Dallas at their home. Went over to Prism Oak Cliff for potential participants.

02/17/2020 – Attended the APPE student meet and greet. Met Cam who will be working with us until March 27th. I had to leave at 1030 to make a 1100 visit 3 at Rosedale Community Walgreens.

02/18/2020 – I had to travel to Dallas to obtain records from both Parkland and a small primary care office. This ended up being an all-day experience. With the majority stuck in Dallas traffic.

02/20/2020 – Attended the wellness roundtables at the center for community cooperation. Dr. Clay spoke about the study to about 40 clients.

02/24/2020 – I had a visit 4 at Rosedale at 1000 and a visit 3 at 1200. Spent the afternoon sorting CRFs and calling participants.

02/25/2020 – I had a visit 2 at Cedar Springs Community Walgreens at 1200. Spent the remaining day waiting for walk-ins.

02/26/2020 – I had two visits at Cedar Springs Community Walgreens back-to-back. I had a visit 3 at 1000 and another visit 3 at noon.

02/27/2020 – I spent the day at Prism Oak Cliff all day. No notable occurrences.

02/28/2020 – I spent the day at Prism Health South Dallas for potential participants. Managed to consent 3 new participants.

03/02/2020 – I had two visits today. I had a visit 3 at 0900 at Rosedale Community Walgreens and a visit 4 at 1400. Both went well, and I can tell I am much better at communicating with participants and building a repour.

03/03/2020 – I had a visit 4 at Cedar Springs Community Walgreens. Drove to Prism Oak Cliff due to potential participants.

03/04/2020 – Spent all day in the office catching up on CRFs.

03/05/2020 – Spent the day in the office helping with data entry.

03/06/2020 – I spent the day at Prism Oak Cliff all day. No notable occurrences.

03/10/2020 – I had two visits at Cedar Springs Community Walgreens. I had a visit 2 at 1000 and a visit 3 at 1200. I then drove to Prism South Dallas for potential participants.

03/11/2020 – I had two visits at Cedar Springs Community Walgreens. I had a visit 3 at 1000 and a visit 4 at 1200. I then drove to Prism Oak Cliff for potential participants.

03/12/2020 – I had a visit 4 phone call at Rosedale Community Walgreens. Set up point of care appointment for next week.

03/18/2020 – Came back from bachelor party weekend for friend in Arkansas and everything is being closed and locked down due to COVID. Apparently switching to doing data entry.