

**Evaluating the Effectiveness of Third-Party Recruitment Campaigns  
in Small Site Management Organizations (SMOs)**

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Recruitment is often the most challenging aspect of a clinical trial. Finding the appropriate number of quality subjects takes time and may exhaust funds especially towards smaller site management organizations (SMOs). Standard recruitment strategies are often used such as physician referrals (patients given alternative treatments by being placed into clinical trials by their physicians) as well as database searches (extensive searches in patient networks by clinical researchers to find potential subjects). Both can be effective approaches but are often designed for larger research organizations with more available resources. One particular strategy, third-party recruitment, allows an outside company which specializes in marketing and recruitment to be assigned to finding potential subjects for clinical trials. This may reduce the burden of cost when allocating funds directly to this strategy rather than other recruitment strategies that may not work for smaller SMOs with limited resources and staff. Therefore, understanding which strategy is effective at enrolling subjects in a timely manner especially for SMOs with limited resources is vital for the continuation of clinical trials and their overall success to help improve scientific advancement. This study examined the process of recruitment in a small SMO with a focus on evaluating the effectiveness of third-party recruitment campaigns in comparison with standard strategies. Specifically, determine whether this strategy is better at acquiring more subjects to be enrolled compared to other strategies used for the same trials. It was hypothesized that third-party recruitment would be a more effective recruitment strategy for smaller SMOs with more limited resources compared to other standard approaches used in much larger organizations. This was done by comparing historical data from past

Nose, Throat (ENT) related clinical trials at two sites involving third-party recruitment and the other strategies such as physician referral and database searches. It was found from our sample that third-party recruitment was better at recruiting and enrolling in sheer numbers. From the disaggregated portion of the analysis, third-party had a significant effect on recruiting subjects compared to the other standard approaches. However, no other statistical significance was observed in recruitment and enrollment numbers between the two groups but the data do trend towards promising outcomes when using third-party recruitment. The no statistical significance may be due to the limited amount of clinical trials and or the total number of subjects used in this study. Third-party recruitment campaigns may show some promise to helping small SMOs with limited resources to successfully recruit in a timely and costly manner but future research is needed to further investigate its efficiency in recruitment using larger sample studies.

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in Small Site Management Organizations (SMOs)**

Internship Practicum Report

Presented to the Education Council  
of the School of Biomedical Sciences  
University of North Texas  
Health Science center at Fort Worth  
In Partial Fulfillment of the Requirements

For the Degree of

MASTERS OF SCIENCE  
IN CLINICAL RESEARCH MANAGEMENT

By

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Fort Worth, Texas

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## CHAPTER I

### INTRODUCTION

It is known that recruitment is often the limiting factor to clinical trials in most small site management organizations (SMOs), due to its high costs and high demand on time. A small SMO may be further limited due to having fewer resources, such as lower number of employees, funds, and available time. These factors may restrict their ability to recruit compared to larger research organizations. This unfortunately results in delaying the progression of scientific discoveries for the intended populations of these clinical trials. Therefore, an understanding of recruitment strategies to acquire participants is essential to improve the ongoing process of clinical trials for small research organizations. A study done by Harris *et al.* (2003) evaluated the differences in recruitment from proactive (in person study staff or healthcare workers) to reactive (marketing and spreading awareness of information about trials) recruitment strategies. The reactive recruitment strategies such as disseminating information for potential subjects to find and call a study hotline reported higher recruitment numbers, enrollment rates, and were more cost effective. Implementing these types of reactive recruitment strategies into clinical trials can provide a more effective, more efficient, and less costly way of finding subjects to enroll. For that reason, a possible benefit for these SMOs could be to primarily use third-party recruitment campaigns, an outside company that specializes in marketing and finding potential subjects for clinical trials, to save time and perhaps money in their recruitment process. This research project analyzed past trials to evaluate the effectiveness of third-party recruitment used at a small SMO with multiple studies at two different sites. This was done by comparing and contrasting third-party recruitment campaigns with other standard strategies such as physician referrals or database searches on different trials used at two clinical sites. Each trial provided the numbers of



participants recruited, those who were then enrolled, and the percent enrolled. The findings from this research may help influence smaller SMOs decisions to use third-party recruitment as one of their selective choices instead of multiple strategies that exhaust recruitment funds. Furthermore, employing third-parties may reduce the burden of recruitment (cost and time) to a smaller and limited SMOs during clinical trials.

## CHAPTER II

### BACKGROUND AND LITERATURE REVIEW

Successful planning and management of a recruitment plan is essential for the success of site management organizations (SMO). This includes piloting strategies, monitoring recruitment via data tracking systems, and hiring quality staff. Over decades of clinical trials, research companies have developed many recruitment strategies varying from occupational screenings and utilizing patient registries to direct mail, radio, and TV media outlets (Lovato et al., 1997). This research will discuss three main standard recruitment strategies used in the SMO for this research practicum: third-party recruitment campaigns, physician referrals, and database searches.

Third-party recruitment campaigns are outside companies that specialize in spreading awareness about clinical trials and finding potential subjects. This often includes using advertising services such as social media platforms, radio, and/or TV. Anyone interested could then contact a representative to answer some pre-screening questions. The representative will send any potential subjects contact information to the site where researchers can then choose to contact and make arrangement for screening visits based on the answered questions and

availability. The advantages of third-party recruitment campaigns are that it allows researchers to dedicate their time to other aspects of a clinical trial. Depending on the trial and its specific criteria, recruitment can be a challenge. These companies are also beneficial in recruiting patients from all diverse backgrounds which is crucial to the generalization of clinical research (Milo et al., 2019). Third-party recruitment may be costlier for the sponsor or SMOs with a fixed recruitment budget compared to the other two strategies evaluated in this research. These companies often charge SMOs a fee per referral or guarantee a number of referrals for a set fee. However, recruitment requires a large team to actively work in finding patients such as using flyers, staff networks, and posting ads on social media in order to be successful (Milo et al., 2019). A small SMO may not have the resources or time to achieve those standards.

Physician referrals is another effective recruitment strategy. These referrals are mostly from the clinics of the investigators running the trials. A physician at the clinical research site may find their patients an alternative option when their situation fits the criteria of a particular study. Referrals may also be sent by other doctors at clinics usually in nearby areas. Physicians send their patients to clinical trials in hopes to get the treatment and care they need that they are otherwise not able to give them at their clinics. Physicians can send doctor-doctor letters to inform other clinics in the area about ongoing trials and to see if their patients may fit the criteria of the study and/or may be willing to participate. The advantages of this recruitment strategy are that it is free and patients are more likely to meet enrollment criteria due to the referring physician being familiar with the study criteria. Unfortunately, it is often a challenge to get physicians to refer their own patients for clinical trials for several reasons. Doctors may only prioritize their clinical practice and are not willing to give up their patients. They may also opt out due to the present risk or possible complications a trial may have on their patient. This

strategy is very dependent on the physician's contributions to clinical research (Embi et al., 2005).

Database searches are in depth searches conducted by researchers at the SMOs themselves. When available, researchers may utilize the clinic patient database or network to find potential subjects for their trials. Researchers will search and make contact with those who may qualify. This is a very time-consuming process for a SMO but very cost effective. This strategy is also dependent on the database itself which may be limited to find potential subjects. Databases alone may be difficult or inadequate to find the necessary information to recruit some subjects (Maria et al., 2000).

#### SPECIFIC AIM

The specific aim of this study was to examine the process of recruitment in a small site management organization (SMO) with a focus on evaluating the effectiveness of third-party recruitment campaigns. Specifically, to determine whether this strategy is better at acquiring more subjects to be enrolled in a timely manner compared to other strategies used in trials. The research gathered and determined the number of subjects recruited, then enrolled, and percent enrollment by third-party recruitment campaigns compared to other standard strategies.

#### SIGNIFICANCE

Recruitment is an essential component for clinical studies and may often be the limiting factor to success of a trial. A low rate of trial enrollment strongly correlates with limited

improvement in treatment population outcomes (Unger *et al.*, 2016). Therefore, the recruitment phase must be well understood and carefully planned in order to establish the success of clinical trials and their ongoing findings to help advance medical treatment and care to intended populations. Interestingly, Abernethy *et al.* (2009) found only 31% of trials were recruited to the planned target time with the majority of cost of the study arising from the recruitment phase alone. Recruitment issues can lead to delays or even premature terminations of clinical trials. According to the National Institute of Health (NIH), nearly 80% of clinical trials in the U.S. do not meet their deadlines, further increasing research costs (Desai, 2020). As for any SMO, this can be the most time consuming and resource depleting process. For that reason, different recruitment strategies may vary depending on the resources available of a SMO (Laura *et al.*, 1997). Smaller SMOs may be restricted to certain strategies and struggle to find subjects for their trials without exhausting funds. As of recently, SMOs are increasingly becoming limited in funding to conduct clinical trials (Isadora *et al.*, 2019). Therefore, the efforts to quantify and reduce recruitment costs are needed more than ever. Understanding which recruitment strategy is the most effective could allow a SMO to invest primarily in one or two strategies to minimize costs.

## MATERIALS AND METHODS

In order to evaluate the effectiveness of third-party recruitment campaigns, a retrospective analysis on past clinical trials found at a smaller site management organization (SMO), Berkson Medical. This study included two different sites involving eight clinical studies. Historical data were collected using the SMOs electronic storage system for each clinical trial

with differing or mixed recruitment strategies. This was done by comparing and contrasting third-party recruitment campaigns with the other two main strategies, physician referrals and database searches. Two clinical sites were used to combine data to provide a larger sample size for some of the studies, using the same protocol and procedures. All patient identifiers were removed and given a number. Out of the eight studies, four of them employed only one recruitment strategy and were removed from analysis. Aggregated data for each study were combined and proportion of subjects enrolled from recruited were calculated. Disaggregated data were analyzed using a Chi-Squared and a non-parametric test, Kruskal-Wallis, was used to analyze the aggregated measures (number of participants recruited, the number of participants enrolled, and the percent enrollment). The data were analyzed using the software Systat 13 using the recruitment strategy as the independent variable considering an alpha of 0.05.

## RESULTS

Data were gathered from eight completed clinical trials conducted at two different sites. Figures 1 and 2 show the clinical trials found at each site and how many subjects were recruited from the different recruitment strategies (third-party vs. other where other is representative of the standard recruitment strategies: physician referrals and database searches). A total sample of 152 subjects was used in this study. At Site 1, only five studies were found at this site (Figure 1). Two studies had mixed recruitment strategies while the other three studies only contained other standard recruitment strategies (Other). A total sample of 46 subjects were recruited at this site from these studies. At Site 2, only six studies found at this site (Figure 2). Three studies had mixed recruitment strategies while the other three studies only contained other standard

recruitment strategies. The total sample of 106 subjects were recruited at this site from these studies.

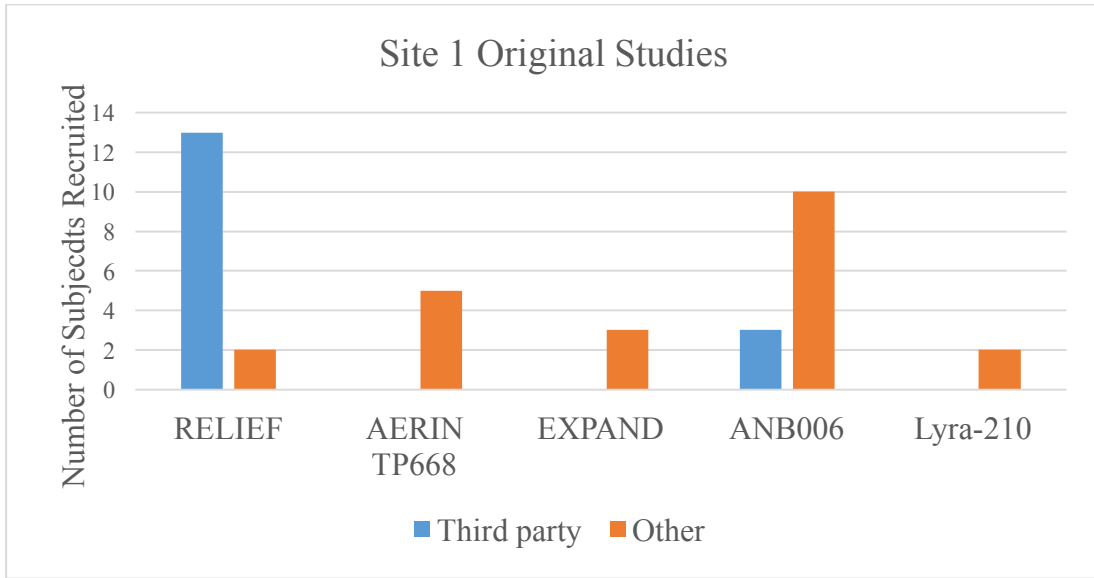


Figure 1: Number of subjects recruited in each original study at site 1.

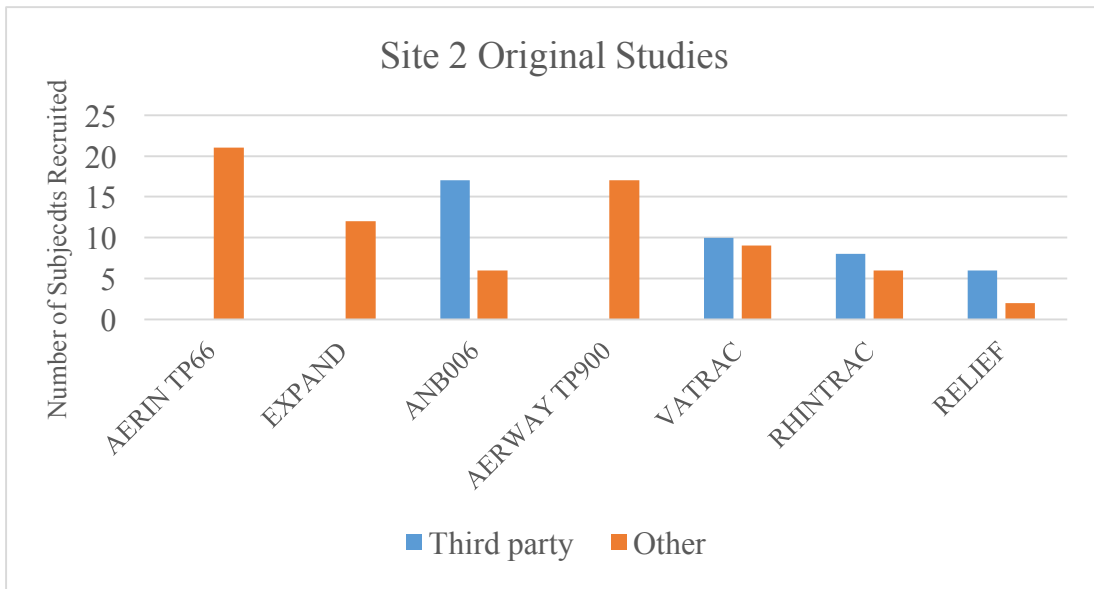


Figure 2: Number of subjects recruited in each original study at site 2.

Only the studies with mixed recruitment strategies containing both third-party and other were selected for analysis. This excluded four studies bringing down the number of clinical trials

used to four with a total sample of subjects of 92. The tables below show only the clinical trials with mixed recruitment strategies found at each site. Site 1 of exclusive studies are shown in Figure 3. Only two studies found at this site both of which have mixed recruitment strategies. The total sample of 36 subjects were recruited at this site from these two studies. Site 2 of exclusive studies are shown in Figure 4. Only three studies found at this site with mixed recruitment strategies. The total sample of 56 subjects were recruited at this site from these two studies.

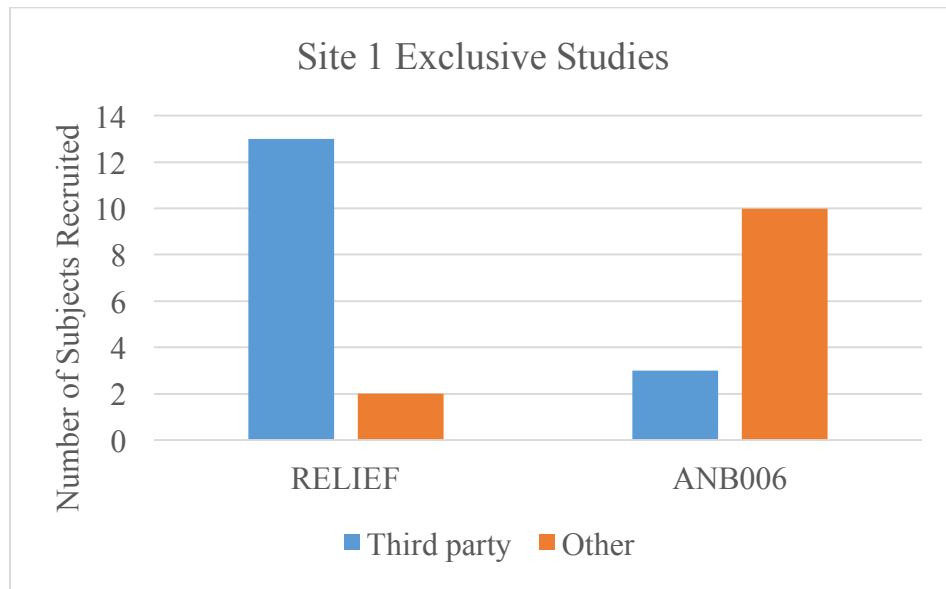


Figure 3: Number of subjects recruited at site 1 for studies with mixed recruitment strategies.

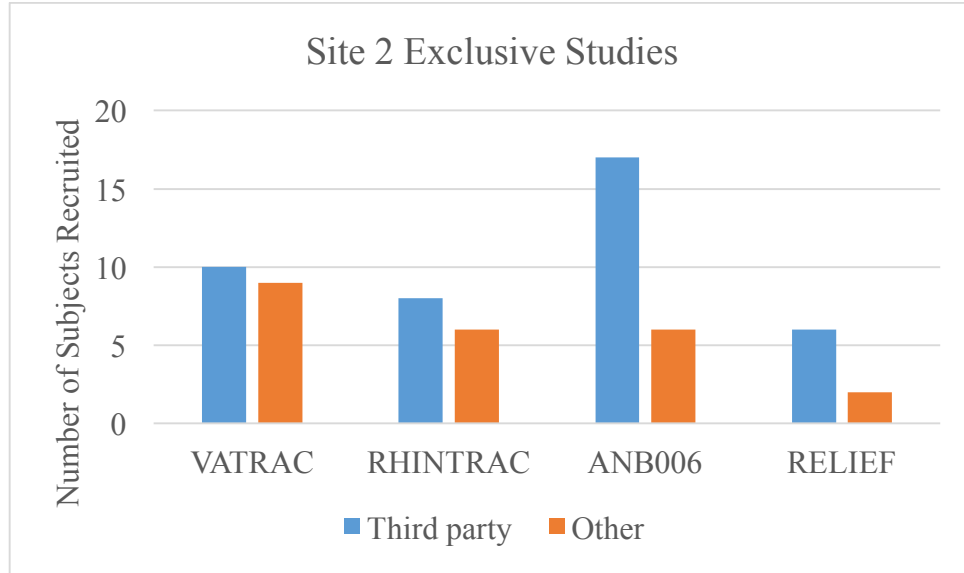


Figure 4: Number of subjects recruited at site 1 for studies with mixed recruitment strategies

A summary of the disaggregated numbers can be found in Table 1 outlining how many participants were recruited and how many enrolled depending on the recruitment strategy.

**Table 1. Number of participants**

Strategy	Other and Third-party	Other only	Third-party only
<b>Recruited</b>	92	35 (38%)	57 (62%)
<b>Enrolled</b>	55 (60%)	20 (57%)	35 (61%)
<b>Not enrolled</b>	37 (40%)	15 (43%)	22 (39%)

From this data, more individuals were recruited via third-party (62%) than other strategies (38%). An analysis of this frequency distribution using Pearson Chi-square revealed a significant difference between the two strategies ( $p=0.022$ ). However, in terms of enrollment numbers, there did not seem to be a difference between the strategies, third-party (61%) compared to other strategies (57%). This was confirmed with a Pearson Chi-Square analysis with Strategy as a factor ( $p=0.686$ )



Figures 5-7 depict the aggregated measures from the four exclusive studies used to assess the differences between third-party and other. Using a nonparametric test Kruskal-Wallis, it was analyzed and found no significant effect of the strategy used in all three measurements: recruitment ( $p=0.261$ ), enrollment ( $p=0.196$ ), and percent enrollment from recruitment ( $p=0.872$ ). The average recruited in third-party was  $9.3 \pm 2.1$  while the other was  $6.2 \pm 1.3$  (Figure 5). The average enrolled for third-party was  $5.7 \pm 1.7$  while other was  $3.5 \pm 1.2$  (Figure 6). The percent enrollment from recruitment for third-party was  $58.4 \pm 15.8$  while other was  $60.9 \pm 14.1$  (Figure 7).

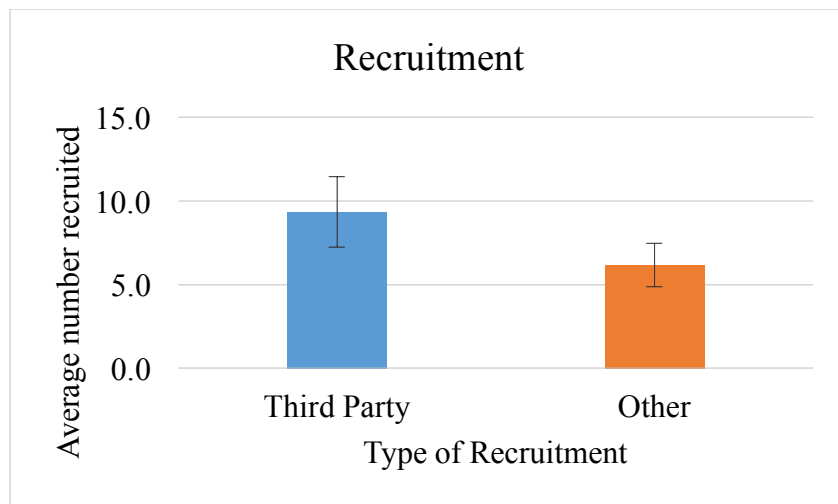


Figure 5: Average number of participants recruited between Third-Party and Other.

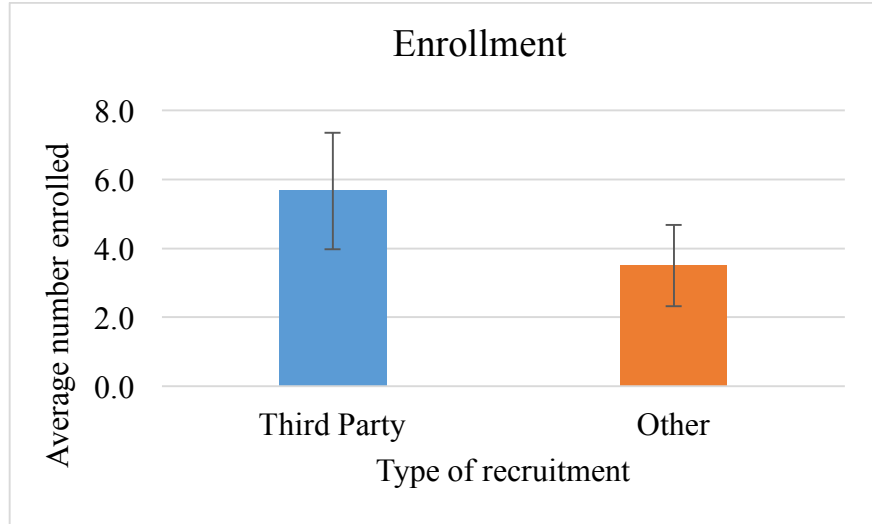


Figure 6: Average number of participants enrolled between Third-Party and Other.

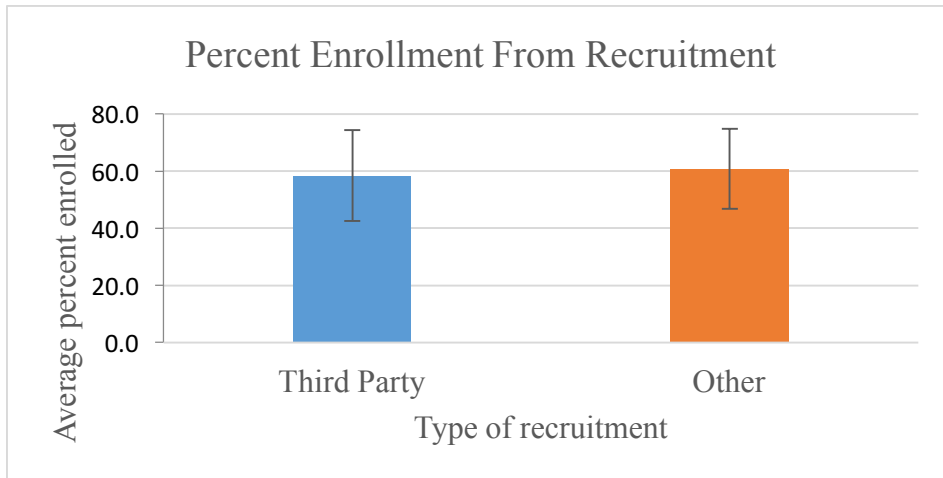


Figure 7: Average percent enrollment from recruitment between Third-Party and Other

## DISCUSSION

The data found in this study showed promise for smaller SMOs to use third-party primarily as the main recruitment strategy. When the four clinical trials were disaggregated and analyzed using Pearson Chi-Square analysis, it was found that third-party had a significant effect

on recruiting subjects compared to the other standard strategies. However, there was no effect on the enrollment numbers between the two groups. This data suggests that third-party was more effective at recruiting subjects. The data also show that slightly more people were enrolled in the studies from the third-party recruitment strategy, however it was not significant. The lack of significance could be due to a relatively low sample size, and increasing the data pool could answer this question more definitively.

When used the aggregated measures from the four exclusive studies, this study found that on average, third-party recruited three more patients than other strategies and enrolled about two more. The differences were not significant again but the data do trend towards promising outcomes when using third-party recruitment.

From the sample of this study, third-party seems to show better results for recruiting subjects. A possible reason for the effective recruitment might be the strength of a great marketing team spreading awareness through communities about ongoing clinical trials. The team of marketing experts may have more staff and are tasked to only finding potential subjects of a trial compared to research staff who are responsible for the entirety of a clinical trial. This is very encouraging especially when a SMO with limited resources may not have the time or effort to find enough subjects to recruit in a timely manner. It is also hopeful that recruiting high enough numbers may eventually reach target enrollment numbers. This may help explain the higher average enrollment numbers found in third-party compared to the other strategies.

While third-party recruitment seems better at recruiting and enrolling in sheer numbers, the transformation from recruitment to enrollment does not seem to be impacted by the recruiting strategy. There are many possible factors that may have led to these results. Firstly, as explained previously, the limited number of clinical trials used and the low sample size in these studies

may not have been enough to detect a true effect. Another explanation is that third-party recruitment may not be as effective as it was once thought. It does show promise that it would bring more potential subjects to screen but may not be as effective for enrollment compared to physician referrals and database searches where staff are more trained and equipped to find better fit candidates. The effectiveness of this recruitment strategy could also vary depending on the marketing company hired by the SMO or sponsor of the trial. Certain companies may just be better at recruiting subjects with higher enrollment numbers compared to others. A factor of cost may play into the outcome of what third-party a SMO can afford to meet their recruitment needs for their trials. Certain costs associated with different companies may have some variability and effectiveness in their recruitment measures. Another possible influence could be the research organization itself which could be more fit to certain recruitment strategies that meet their needs with resources and the type of clinical research done at their site. The hope is that third-party may be a more advantageous recruitment strategy but more research is needed to further investigate the comparison between third-party and other standard methods.

This study had some limitations due to the low sample size used to evaluate differences between third-party and other standard recruitment strategies, physician referrals and database searches. Since four of the eight past clinical trials only contained other recruitment strategies, lacking the third-party recruitment, it was decided to not include them in the analysis. This was to accurately investigate the differences between the two groups and avoid any bias that may have resulted with the skewed data. Another limitation is the generalization of this study to only ENT related clinical trials. This research evaluates recruitment strategies at two ENT sites on certain prevalent conditions found in this field. Other diseases or conditions not ENT related may differ in recruitment strategies such as which standards used, necessary budgets for a given trial,

and the behavior or attitude of the targeted populations. Certain populations may be easier or harder to recruit thus spending on recruitment may vary depending on the trial indication population. For example, subjects with conditions of high severity or disability may actively seek to find clinical trials that may help with their condition. Also, certain diseases with higher prevalence and/or awareness may have greater budgets to use for clinical trials and thus more resources to recruit subjects. More investigation into other fields of clinical research with varying diseased populations should be investigated in future research.

Certain factors this study wanted to evaluate but were not able due to the limited resources available at this smaller SMO was the duration of enrollment periods and costs associated with each strategy. As emphasized previously, the time it takes for a study to reach their enrollment target could lead to higher costs and delays, potentially delaying the time to product approval or premature termination of the trial. Understanding each strategies' effects on the duration of enrollment, the time it takes to enroll sufficient subjects, would be useful for SMOs depending on their time-frame goals for their trials. The costs associated with recruitment and their overall burden on the budget of a trial is also very important to understand when evaluating recruitment strategies. Conducting a cost analysis of each strategy and their outcomes in recruitment and enrollment numbers would have been hugely informative to determine third-party's cost-effectiveness compared to other strategies. Investigating the duration of enrollment and a costs-analysis of each strategy would have been interesting factors in this study to further evaluate the effectiveness of third-party compared to other standard strategies used in recruitment.

## SUMMARY AND CONCLUSION

The difficulty of completing clinical trials in a timely manner has much to do with recruitment. The cost and the high amount of effort and planning to successfully recruit the appropriate number of subjects for trials is a growing struggle especially with smaller site management organizations (SMOs) with limited funds and staff. Third-party recruitment campaigns show some promise to helping small SMOs with limited resources to successfully recruit in a timely and costly manner. This study found third-party was effective in recruiting and enrolling more in numbers compared to other strategies. Third-party had a significant effect on recruiting subjects in the disaggregated portion and had on average more recruited and enrolled compared to the other standard approaches. Even though much of the data had no significant differences between the two groups, it does trend toward promising outcomes when using third-party. Yet more research with larger samples of data and more factors of consideration such as duration of enrollment period and cost analysis of recruitment strategies is needed to fully understand third-party recruitment compared to other approaches.

Future research should further investigate the effect of third-party recruitment compared to other standard recruitment strategies used in clinical trials. A continuation of this research to a broader application using a larger sample size involving more clinical trials is recommended. Future studies should attempt to find more effects from third-party has on smaller research companies to find if any improvement in recruitment measures as well as understanding the cost benefit of this strategy. An additional measurement, duration of each recruitment strategy to reach target enrollment, could be interesting to investigate as it could provide some insight to the efficiency of certain strategies and their effect on completion of clinical trials without delays. Also, understanding third-party recruitment in many specialties and fields of research is highly

recommended. Whether the effects of third-party recruitment are the same in different fields of clinical trials would be interesting to understand and would help generalize results to a larger population. Furthermore, more studies should examine the outcomes of third-party recruitment has on larger clinical research organizations with more staff and resources to find whether other factors such as budget play a more influential role in recruitment compared to recruitment strategies alone.

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## CHAPTER III

### INTERNSHIP SITE

My research internship practicum was completed at Berkson Medical on various ongoing clinical trials at multiple sites in the DFW area. Current active sites are ENT and rheumatology clinics conducting trials involving chronic sinusitis, nasal polyps, sensorineural hearing loss, tinnitus, rheumatoid arthritis, giant cell arteritis, and lupus. My role consists of coordinator activities including recruitment, informed consent process, clinical visits and procedures, source documentation, AE monitoring, and maintaining regulatory documents.

#### a) Patient recruitment

I am responsible for following up with referrals sent to our sites from our third-party recruitment companies as well as physician referrals. My task is to go through the referrals list to find potential candidates for our trials. I will then contact individuals to see if they could answer some additional prescreening questions. If I believed this patient might qualify for the study, I would schedule a screening visit at the clinic. Another recruitment task I do is database searches using our sites EMR system to try to find any potential subjects that may fit a study's criteria. Again, I would contact individuals to find if they are interested in partaking in a clinical trial and schedule for a screening visit.

#### b) Preparing and assisting in patient visits

My task involves printing out all the necessary documentation and forms for the patient visit including informed consents and source documentation. I assemble all subject's charts for upcoming study visits. My duties also involve assisting in patient visits which include completion of source documentation, asking and helping answering questions for the particular study, administering study questionnaires, recording medical history and concomitant

medications, measuring and recording vitals and ECGs, processing bloodwork, and recording physician assessments and procedures. Some procedures such as endoscopies, drug injections, audiograms, and otoscopies. In order to be fully prepared, I must know each of our studies protocol and be familiar with the tasks done on each visit. One study I am the un-blinded coordinator and must be the only research coordinator present for all subject visits imaging procedures and uploads.

c) Organizational tasks

An important daily task is to keep all patient visits, studies, and data information organized. This includes having binders, filing cabinets, and electronic documents storage to organize all information for various studies and its subjects. Labeling and organization are key to running a successful clinic trial. Monitors visit our sites on a regular basis to ensure continual compliance at the site. I help answer questions and gather the necessary paperwork for our monitors in order for them to review subject records, regulatory documents, and query resolutions.

d) Data Collection and management, source documentation, AE monitoring

My responsibilities involve collecting subject data on source documentation and uploading information collected from each visit to the sponsor's electronic data capture (EDC). Data such as a subject's medical history and medications, physical assessment, and recorded measurements such as endoscopy, audiograms, and subject surveys. It is essential to upload all the necessary information in a timely manner to send to our sponsors for review and approval, upholding compliance, and to show the completion of each visit. I often must go back to add new information and resolve queries generated by the monitor or data management team. For each given study, there may be several online portals used by the sponsor to enter subject's data for each visit. Each portal requires formal training in order to understand how to fully use and

operate correctly. I was also given the role to create paper source documentations for two of the clinical trials. This included using Word and Adobe to create a source document that had all the objectives and documentation necessary for each visit for the trial.

e) Maintaining regulatory documents

Another role is to keep up to date on new informed consent for studies, IRB changes and approvals. I must be well informed with these changes and be being able to discuss these to our patients. This involves each subject enrolled in that particular trial to be re-consented and sign the updated information. Site staff credentials including training and delegation logs for each study must be updated and filed. Some examples are CVs, licenses, certifications, current protocols, investigator brochures, study correspondence, and newsletters.

## APPENDIX A: Internship Practicum Journal

Monday, August 22, 2022

- Introduction to the site (Fort Worth ENT & Sinus)
- Acquainted with site manager of Berkson Medical (Karyn Willyerd) and rest of staff at the site
- Worked on onboard process such as signing papers, printing documents, assign folders.
- Discuss some of my roles for this internship and brainstormed ideas for my research thesis proposal
- Read protocol for FX-322 trial – asked questions, informed about current standing with trial
- Patient visit 1 for FX-322 Trial – observed and assisted in obtaining informed consent, demographic and medical history paperwork, audiogram diagnostic, physical exam and vital signs, and finally otoscopy with Dr. McIntyre

Tuesday, August 23, 2022

- Patient visit 6 for FX-322 – observed and assisted in obtaining questionnaire data, updated medical history, audiogram measurement
- Uploaded data from patient visit into electronic sources

Wednesday, August 24, 2022

- Worked on certification of Transportation Dangerous Goods, Good Clinical Practice (GCP), C-SSRS
- Researched proposal ideas for thesis
- Started PowerPoint for research proposal

Thursday, August 25, 2022

- Prepared for patient visit 1 for FX-322 – printed necessary paperwork and organized in binder
- Patient canceled appointment
- Printed out certifications and filed in my folder
- Discussed more ideas about thesis proposal and realistic proposals and limitations
- Read protocol for Archive – asked question, informed about current standing with trial

Friday, August 26, 2022:

- Prepared for patient visit 1 for Archive – printed paperwork and organized in binder
  - o Observed informed consent process, past medical history and vitals which included blood taking and EKG, endoscopy procedure, follow up visit scheduled
- Assisted in uploading all paperwork into electronic sources

Monday, August 29, 2022:

- At McKinney site: ENTTEX

- Organized, printed, assembled contact info pamphlets for recruitment
- Reviewed some literature on possible ideas for research proposal
- Patient visit 6 for Archive – printed paperwork and organized in binder
- Observed/assisted endoscopy, blood draws, smell test, review medical history, injection of placebo or treatment drug, prepared blood smear slides, packaged lab work

Tuesday, August 30, 2022:

- Prepared for patient visit 1 for FSX-322 – printed out paperwork, assembled into binder
- Patient canceled visit
- Prepared for visit 1 for GSC study – printed out and assembled all consent forms, gather all other necessary papers into binding
- Read protocols for FX-322, ORCHID (Benralizumab) for further understanding
- Worked on research proposal for next week

Wednesday, August 31, 2022:

- Opened shipment from sponsor – corticosteroids for nasal polys study
  - o Learned information on shipping process and standards of recording temperature logs, handling of products, return shipment
- Prepared for patient visit 1 for Orchid and Anchor (GSX) - printed consent forms, HIPPA documents,
- Met with primary faculty advisor to discuss progress on research proposal ideas
- CRIO eSource training
- Patient visit 1 for Orchid:
- Assisted/observed in informed consent procedures
- Vitals, lab work, EKG,
- Conversation in expectations of trials and help answer any question to the subject
- Endoscopy and physician assessment
- Prepared urine and blood work into appropriate tubes, packaged, brought to FedEx to ship to lab

Thursday, September 1, 2022

- Patient visit 1 for orchid
- Assisted in vitals, patient history, informed consent, EKG and bloodwork, set up eDiary, endoscopy and physician assessment
- Recorded and uploaded necessary documents to e-sources and assisted in data management to the sponsor
- Patient cancelled visit 1 for Anchor (GSX)

Friday, September 2, 2022

- Met with primary faculty advisor for research proposal
- Worked on presentation for research proposal
- Training and onboard with eSource

Monday, September 5, 2022

- Labor Day

Tuesday, September 6, 2022

- Prepared for patient visit 3 for FX-322
  - o Assisted in audiogram, update patient information/history
  - o Observed randomization and injection of treatment or placebo to patient
- Uploaded patient visit to E-source
- Research proposal meeting (1<sup>st</sup> CRM meeting) for approval of research idea

Wednesday, September 7, 2022

- Drove out to Allen Rheumatology site for patient visit
- Prepared and assisted for patient visit for M20-466 – rheumatoid arthritis study
  - o Update patient info
  - o Assisted in patient questionnaire & lab work
  - o Observed physician assessment – joint count & injection of drug/placebo
  - o Recorded data to E-source/portal
- Drove to McKinney ENTTex site for patient visit
- Patient canceled for Orchid
- Found patient study visits windows for months of December – January to understand conflicts with holidays
- Created Excel sheet for Lyra-210 - timeline/subject study visit windows

Thursday, September 8, 2022

- Organized binders of previous patient visits, shredded past trial documents, created binder cover headers for several studies
- Continued to work on training for online portals and E-sources for access of trials
- Worked on research proposal paper
- Prepared for 2 patient visit for tomorrow– printed out necessary paperwork (informed consent, medical history, procedures list etc.) & placed in binder

Friday, September 9, 2022

- Prepared for patient visit 2 for FX-322
  - o Charged phone for audio recording
  - o Double checked all paper work ready
- Assisted for visit 2 for FX-322
  - o Updated patient history and medications
  - o Observed audiogram and inputted data to our source documents
  - o Observed and assisted in endoscopy and physician assessment
- Uploaded all data from patient visit to find if qualified for randomization (visit 3 of placebo/drug) - qualified
- Prepared for patient visit 1 for Lyra-210 study
  - o Paperwork all printed out and assembled into binder ready to use
  - o Read protocol to familiarize myself with new study
- Patient visit 1 for Lyra-210
  - o Assisted in informed consent forms and process, medical history, patient medications, vitals and bloodwork

- Observed endoscopy and physician assessment
- Uploaded all data and patient info in E
- source
- Assembled labs into proper tubes and packaged – went to FedEx to ship

Monday, September 12, 2022

- Prepared for patient visit 1 for GSK
  - Printed all informed consent forms and other necessary paperwork and put into binder – ready to use
- Training for frequency study –5 certifications achieved to gain access to electronic source documentation for 2 studies (GSK and FX-322)
- Assisted for patient visit 1 for GSK
  - Observed patient history, medications, informed consent process, vitals, EKG, bloodwork, endoscopy

Tuesday, September 13, 2022

- Prepared for patient visit 6 for FX-322
  - Printed out all ICF, source documents, procedure forms etc. and assembled into binder ready to use
- Monitor for FX-322 – assisted in gather all necessary files and paperwork as well as to answering any updated status on clinical trial
- Patient visit 6 for FX-322
  - Assisted in informed consent process, updated medical history and medications, vitals, physician assessment (otoscopy)
  - Uploaded all data from visit into protocols and electronic Esources for sponsor

Wednesday, September 14, 2022

- Sent research proposal rough draft to faculty advisor
- Prepared for patient visit 1 for GSK (anchor)
  - No show
  - Attempted to call and reschedule
- Monitor visit for Lyra-220 study – assisted in gathering necessary paperwork and answering questions on trial
- Training and certification for a portal to conduct and upload ECGs

Thursday, September 15, 2022

- Monitor visit for Orchid – discussed recruitment approaches and overall status of trials at Fort Worth ENT site
- Got access to EMR for McKinney ENTTex – database searches to look for potential candidates for Lyra-210 study
- Met with CEO of Berkson medical for lunch – get to know each other, discussed my role in the company

Friday, September 16, 2022

- Filed some updated regulatory information- IRB committee list several studies



- Recruitment database searches in EMR McKinney ENTTex – looked for potential subjects for Lyra-210 study
- Met with recruitment for Lyra studies – introductory meeting and training to use online recruitment portal

Monday, September 19, 2022:

- Prepared for patient visit for Lyra-220 study
  - o Printed the updated informed consent forms and other necessary paperwork for the visit
- Got access to Lyra-210 and Lyra-220 Electronic Source portals
  - o Did the necessary training to obtain certifications
- Patient visit 6 for Lyra-220 – updated medical history, vital signs and blood work, endoscopy, questionnaires
- Input patient visit into portal and prepared bloodwork for shipping

Tuesday, September 20, 2022

- Drove to ENT site in McKinney for 2 patient visits
- Prepared for both patient visits – printed out necessary paperwork and reviewed protocols for the studies and the objectives for the specific visits
  - o Patient no show for GSK visit 1
- Worked on second draft of research proposal
- Patient visit 6 for Orchid – updated vitals, patient history and medications, assisted in bloodwork, observed endoscopy and injection of treatment drug/placebo, prepared blood for lab and packaged, reported an AE (worsening of intended conditions)

Wednesday, September 21, 2022

- Prepared for patient visit 1 for GSK
- Signed off on training for RHINTRAC and VATRAC for preparation of scheduling and conducting year checkup via phone
- Created info pamphlets for Fort Worth and McKinney ENT sites
- Patient visit 1 for GSK
  - o Informed consent process
  - o Medical history and medications
  - o Vitals, EKG, bloodwork
  - o Endoscopy
  - o E-Diary set up
- Uploaded all data into Esources, shipped off bloodwork, assembled paperwork in binder of patient visit
- Delivered patient package to FedEx to ship to lab

Thursday, September 22, 2022

- Worked at home
- Online training and recruitment tasks
- Sent my research proposal to my entire committee team for feedback
- Started to make the necessary edits for my research proposal to be sent in by September 30<sup>th</sup>

Friday, September 23, 2022

- Prepared for patient visit 1 for Lyra-210
  - o Printed out paperwork – informed consent forms and medications/history documentations
- Patient visit 1 for Lyra-210
  - o Assisted in informed consent process, review and enter medical history and medications, vitals and bloodwork, set up and observed endoscopy
- Organized and assembled patient information from visit into binder
- Reviewed past visit for GSK subject – did not qualify
  - o Endoscopy, blood work and EKG reviewed and signed by doctor

Monday, September 26, 2022:

- Sent emails to subjects in VATRAC and RHINTRAC studies to schedule a the 24-month phone call checkup
- Prepared for patient visit 3 for FX-322 – printed informed consent forms, follow up forms, randomization and injection procedure forms
- Prepared for patient visit 1 for Orchid – printed necessary informed consent forms
- Assisted with 24 month follow up phone call visit for VATRAC – answered surveys, reviewed past medical history and medications, any changes in symptoms and conditions
- Use ENTTex EMR system to find potential subjects information for contact for upcoming Lyra studies – recruitment purposes
- Began mailing out recruitment pamphlets to potential subjects for Lyra-210 & 220

Tuesday, September 27, 2022:

- Prepared for patient visit 3 for FX-322 (randomization and injection of drug/placebo)
  - o Got mic and recording set in the booth for audiogram
  - o Paperwork all checked and assembled
- Patient visit 3 for FX-322 –
  - o Audiogram
  - o Uploaded patient information into Esource
  - o Randomization of drug/placebo process
  - o Injection
- Patient no show for Orchid
- Discussion with my site manager on research proposal

Wednesday, September 28, 2022:

- Called to get medical records for patients
- Database searches with EMR of ENTTex to find potential subjects for Lyra studies
- Prepped for FX-322 visit 4 for Monday

Thursday, September 29, 2022:

- Off

Friday, September 30, 2022:

- Off

Monday, October 3, 2022:

- Training for a portal for GSK
- Prepared for patient visit 4 for FX—322 – printed out paperwork, prefilled in information
- Patient visit 4 for FX-322
  - o Audiogram
  - o Questionnaires and updated on medical history and medications, any changes from last visit
  - o Otoscopy
- Entered data from visit to EDC and uploaded necessary videos and information to sponsor portals

Tuesday, October 4, 2022

- Filed patient information in binders
- Corrected queries for FX-322 trial
- Prepared for patient visit 7 for GSC – printed out necessary paperwork and assembled into binder
- GSK visit 7 – updated on medical history and past/current medications, assisted in bloodwork procedures and shipment, physician assessment including endoscopy
  - o Uploaded patient visit information in EDC and sponsor portal

Wednesday, October 5, 2022

- Lyra study closing visit – printed out paperwork, reviewed past medical history and conditions, assisted in bloodwork procedures and shipment
- Uploaded data from patient visit into EDC and sponsor portal
- Filed all paperwork in binder
- Team meeting – all 3 CRC's including myself present
  - o Updated on current clinical trials – issues, duties, progress
  - o Discussed future plans and scheduling until end of the year

Thursday, October 6, 2022

- Drove to McKinney ENT site
- Meeting via zoom with monitor for RHINTRAC and VATRAC - necessary training to be granted access to EDC for follow up phone visits
- Prepared for GSK screening visit – printed out ICF and all the necessary paperwork
- GSK screening visit – assisted in informed consent process, entered past medical and medications, assisted in bloodwork procedures and shipment, vitals (including EKG)
  - o Uploaded data from visit into EDC and sponsor portal

Friday, October 7, 2022

- Followed up on patient for GSK – did not qualify
- Filed and organized patient and trial binders
- Discussed my duties for next week (site manager will be gone)

Monday, October 10, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Printed out received lab work from Lyra study & filed in study binder
- Uploaded new lab results to Lyra study and assigned the PI to evaluate and sign off
- Prescreening and recruitment for Lyra 210 and 220 – finding new potential subjects through McKinney EMR system
- Training for past trials: RHINTRAC and VATRAC, in order to do the 36 month, follow up phone call visits

Tuesday, October 11, 2022

- Arrived at McKinney ENT site
  - o Prepared for GSK visit 4 – printed out paperwork and assembled into binder
  - o Prepared for Orchid visit 7 - printed out paperwork and assembled into binder
- Patient visit 4 for GSK – assisted in updating medical history, medications, vitals, EKG, and blood collections and processing
- Patient visit 7 for Orchid – assisted in updating medical history, medications, vitals, EKG, endoscopy, blood collections and processing
  - o Uploaded video to sponsor portal

Wednesday, October 12, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Set up accounts to access E-Diary sources for FX trial
- Granted access to EDC for VATRAC and RHINTRAC for follow up phone calls
- Sent medical records requests for a possible patient for Lyra study
- Sent out emails and follow ups to those in past trial: VATRAC and RHINTRAC to schedule 24-month phone call visits
- Reviewed pre-screening questions and attempted to contact Lyra referrals via phone and email to try to schedule a screening visit
- Prescreening potential subjects using McKinney site EMR system – prepare to mail in flyers to addresses

Thursday, October 13, 2022

- Arrived at McKinney ENT site
  - o Prepared Lyra 210 – printed out paperwork and assembled into binder
- Patient visit screening for Lyra 210
  - o Assisted in vitals, medication and past medical history, blood work collections and processing/shipment, endoscopy
  - o Data collection and upload to EDC and sponsor portal

Friday, October 14, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Reviewed pre-screening questions and attempted to contact Lyra referrals via phone and email to try to schedule a screening visit
- Reviewed, responded, corrected queries from FX-322 patient visit
- Prescreening potential subjects using McKinney site EMR system – prepare to mail in flyers to addresses
- Scheduled 24M follow up phone call for VATRAC

Monday, October 17, 2022:

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Conducted 36-month phone call visit for VATRAC
  - o Reviewed past/current medications – updated dosage and changes
  - o Added any new health conditions or clinical visits
  - o Answer several survey questions
- Reviewed pre-screening questions and attempted to contact Lyra referrals via phone and email to try to schedule a screening visit
- Organized and file source documents for several of our studies
- Reviewed and corrected open queries for FX-322 trial in preparation for monitor visit

Tuesday, October 18, 2022:

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Reviewed 24 M visit for VATRAC – printed out AE document & scheduled next phone call visit
- Reviewed pre-screening questions and attempted to contact Lyra referrals via phone and email to try to schedule a screening visit
- Phone call visit for VATRAC – discussing adverse event and document an AE form
- Assisted monitor for FX-322 with answering and corrected queries, finding necessary information, and answering any questions
- Called and scheduled patient referral for a screening visit in Lyra study

Wednesday, October 19, 2022:

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Scanned and sent delegation and temperature logs at our site to monitor
- Prepared for Orchid screening visit – printed out informed consent forms and other necessary forms for visit
- Patient did not show up for screening visit
- Packaged and shipped bloodwork of Lyra study
- Called and scheduled patient referral for a screening visit in Lyra study
- Sent out text messages to referrals for Lyra studies
- Conducted a 24M phone call visit for VATRAC – updated medications, any changes in medical history or new diagnosis, several surveys

Thursday, October 20, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Called and scheduled patient referral for a screening visit in Lyra study (6 patients scheduled)
- Conducted a 24M phone call visit for VATRAC – updated medications, any changes in medical history or new diagnosis, several surveys
  - o Recorded it on paper and entered data into the EDC
- Filled in excel document of past Lyra subjects to send to sponsor for reimbursement

Friday, October 21, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)

- Prepared for lyra-210 screening visit – printed out ICF and all necessary forms
  - o Prepared lab kits, COVID test, etc.
- Screening visit for Lyra-210
  - o Assisted in informed consent, inclusion/exclusion criteria, blood collections and COVID test, vitals, endoscopy
  - o Input all data into our database and EDC
- Called twice for a 24M phone call visit for RHINTRAC – had to reschedule for the next week

Monday, October 24, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared for patient screening visit for Anchor (GSK) – printed out ICF, demographic and medical history forms, set up tablet, checked blood work tubes etc.
  - o Patient no show due to bad weather
- Emailed to reschedule in 24 M phone visit for RHINTRAC
- Contacted Lyra-220 referral to follow up on prescreening questions and schedule a screening visit
- Continued on Lyra recruitment – followed up with referrals via text message, email, and calling patients to ask follow up questions and schedule them in for screening visits for the following weeks
- Answered queries for Lyra-220 subject in EDC

Tuesday, October 25, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Conducted 24M phone call visit for RHINTRAC – updated medical history and medication, completed several surveys, updated subject on trials standing, answering any questions
- Prepared for patient screening visit for Lyra-210 – printed out informed consent form, demographic and medication/history forms
- Patient screening visit for Lyra-210
  - o Assisted in ICF process, vitals, past medication and history, blood working, endoscopy
  - o All patient info recorded and input into our EDC and sponsor portal
- Prepared for another screening visit for Lyra-210
- Patient screening visit for Lyra-210
  - o Assisted in ICF process, vitals, past medication and history, blood working, endoscopy
  - o All patient info recorded and input into our EDC and sponsor portal
- Dropped off packaged bloodwork to FedEx for shipment to lab

Wednesday, October 26, 2022

- Arrived at McKinney site
- Called a Lyra-220 referral, asked prescreening questions, scheduled them for a screening visit for the following week
- Training session on zoom with clinical research associate for clinical trial: RELIEF and AERWAY

- Scanned DOA forms and letters for my research project – organized each forms for each trial into folders in preparation to send to IRB for approval
- Reviewed GSK endoscopy of 2 patient visits to time stamp start and stop times for each nostril

Thursday, October 27, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Sent emails to schedule 24M phone call visit for RHINTRAC and VATRAC
- Prepared for patient visit for Lyra-210 – printed out ICF documents and other necessary demographic, medication and past medical history forms
- Patient visit for Lyra-210
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - o Assisted in inputted data from patient visit into EDC and shipment of lab specimens
- Meeting with rest of the staff with the Lyra recruitment team – updated them on referrals and Round Table discussion about the pros and cons of the study thus so far

Friday, October 28, 2022

- Worked on recruitment for Lyra-220 using the McKinney site EMR database - searched for potential subjects

Monday, October 31, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared for patient visit for Lyra-210 – printed out ICF documents and other necessary demographic, medication and past medical history forms
- Patient visit for Lyra-210
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - o Assisted in inputted data from patient visit into EDC and shipment of lab specimens
- Prepared for patient visit for Lyra-220 – printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - o Assisted in inputted data from patient visit into EDC and shipment of lab specimens

Tuesday, November 1, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Sent emails to schedule 24M phone call visit for RHINTRAC and VATRAC
- Conducted a 24M phone call visit for RHINTRAC – updated medical history, medications, and answered several survey questions
  - o All data was recorded on paper and then later inputted into EDC
- Sent text messages, emails, and called referrals for a Lyra studies
  - o Scheduled 2 patients for a screening visit
- Rescheduled two of our patient visits today for later dates

Wednesday, November 2, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared for patient visit for Anchor-2 (GSK)– printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Reviewed GSK protocol and screening visit procedures in preparation to run patient visit
  - o Patient no show – attempted to call to reschedule
- Sent out mailings to potential Lyra-220 patients for McKinney site
- Conducted a 24M phone call visit for VATRAC – updated medical history, medications, and answered several survey questions
  - o All data was recorded on paper and then later inputted into EDC

Thursday, November 3, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Called a Lyra-210 referrals, discussed about the trial, asked more pre-screening questions and scheduled for the following week for a screening visit
- Prepared for patient visit for Lyra-210 – printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - o Assisted in inputted data from patient visit into EDC and shipment of lab specimens
  - o Brought shipment to fedex
- Conducted a 24M phone call visit for VATRAC – updated medical history, medications, and answered several survey questions
  - o All data was recorded on paper and then later inputted into EDC
  - o Had to report an SAE due to hospitalization from COVID last March

Friday, November 4, 2022:

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Sent medical records requests from our Lyra-210 screening subject
- Mailed the rest of the Lyra-220 flyers to potential subjects from the McKinney site
- Conducted a 24M phone call visit for VATRAC – updated medical history, medications, and answered several survey questions
  - o All data was recorded on paper and then later inputted into EDC
  - o Had to report an AE due to current sinus infection

Monday, November 7, 2022:

- At McKinney site for several patient visits
  - o Prepared for patient visit for Lyra-220 – printed out ICF documents and other necessary demographic, medication and past medical history forms
    - Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
    - Assisted in inputted data from patient visit into EDC and shipment of lab specimens



- Prepared for seventh visit for GSK (anchor) - printed out ICF documents and other necessary demographic, medication and past medical history forms
  - Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - Assisted in inputted data from patient visit into EDC and shipment of lab specimens
- Conducted a 24M phone call visit for VATRAC – updated medical history, medications, and answered several survey questions
  - All data was recorded on paper and then later inputted into EDC
  - Had to report an SAE due to hospitalization from COVID last March
- Got IRB approved to begin gathering data for research practicum
- 

Tuesday, November 8, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Called a Lyra-220 referral, asked prescreening questions, scheduled them for a screening visit for the following week
- Inputted all of the 24 M phone call visits for VATRAC and RHINTRAC into Berkson logs for billing purposes
- Worked on converting electronic sources version to paper for Lyra-210 in preparation to leaving EDC in the next year

Wednesday, November 9, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared for patient visit for Lyra-220 – printed out ICF documents and other necessary demographic, medication and past medical history forms
  - Both patients rescheduled
- Received study drug, COVID tests, and study flyers for various ongoing clinical trials
  - Confirmed received shipment on sponsor portal
  - Printed, signed, and filed confirmation into regulatory binders
  - Recorded in lab/equipment log
- Called a Lyra-210 referrals, discussed about the trial, asked more pre-screening questions and scheduled for the following week for a screening visit
- Scheduled randomization/procedure day for both Lyra patients
- Went to storage unit to drop off previous study boxes & grab extra packaging for upcoming patient visits

Thursday, November 10, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Called a Lyra-210 referrals, discussed about the trial, asked more pre-screening questions and scheduled for the following week for a screening visit
- Rescheduled several patients who cancelled this week

Friday, November 11, 2022

- Off

Monday, November 14, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Set up RHINTRAC 24 M phone call visits for this week
- Called a Lyra-210 referrals, discussed about the trial, asked more pre-screening questions and scheduled for the following week for a screening visit
- Sent email to monitors on details regarding Lyra screen fails subjects and areas of improvement for the third party referral campaign
- Sent reminder text to Lyra-220 subject for screening visit tomorrow
- Prepared for ninth visit for GSK (anchor) - printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - o Assisted in inputted data from patient visit into EDC and shipment of lab specimens

Tuesday, November 15, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Conducted a 24M phone call visit for VATRAC – updated medical history, medications, and answered several survey questions
  - o All data was recorded on paper and then later inputted into EDC
- Lyra Therapeutics monitor visit at Fort Worth site
  - o Assisted with answering queries and finding necessary documentations/paperwork for the visit
- Scheduled Lyra-220 patient for screening visit
  - o Communicated to sponsor to ensure transportation costs were covered
- Prepared for screening visit for Lyra-220 - printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - o Assisted in inputted data from patient visit into EDC and shipment of lab specimens

Wednesday, November 16, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Sent medical records request forms to PCP to obtain needed information from subject yesterday
- Prepared for screening visit for Lyra-210 - printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - o Assisted in inputted data from patient visit into EDC and shipment of lab specimens
- Prepared for screening visit for Lyra-220 - printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan

- Assisted in inputted data from patient visit into EDC and shipment of lab specimens

Thursday, November 17, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared for screening visit for Lyra-210 - printed out ICF documents and other necessary demographic, medication and past medical history forms
  - Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - Assisted in inputted data from patient visit into EDC and shipment of lab specimens

Friday, November 18, 2022:

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared and conducted visit 4 of FX-322
  - Audiology session
  - Updated medication, survey questions etc.
  - Inputted all data into EDC
- Prepared for randomization for Lyra-210 patient
  - Assisted in vitals, bloodwork, questionnaires
  - As unblinded coordinator – assisted physician in procedure by assembling device and implantation, recording endoscopy, inputting data from visit
- Prepared for randomization for Lyra-220 patient
  - Assisted in vitals, bloodwork, questionnaires
  - Assisted physician in procedure by assembling device and implantation, recording endoscopy, inputting data from visit

Monday, November 19, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Conducted a 24M phone call visit for RHINTRAC - updated medical history, medications, and answered several survey questions
  - All data was recorded on paper and then later inputted into EDC
- Called more Lyra referral patients to discuss trial, ask prescreening questions, scheduling for a screening visit
- Inputted previous patient visits into EDC and correct ongoing queries
- Prepared and conducted patient visit 3 (post randomization/procedure visit) for Lyra-220
  - Updated medical history and medications
  - Obtained blood samples

Tuesday, November 20, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Inputted patient visit data into EDC for Lyra-210
- Received lab shipment from studies – open, documented, organized
- Prepared for screening visit for Lyra-210 - printed out ICF documents and other necessary demographic, medication and past medical history forms

- Morning patient no show
- Afternoon patient:
  - Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - Assisted in inputted data from patient visit into EDC and shipment of lab specimens
- Conducted a 24M phone call visit for RHINTRAC - updated medical history, medications, and answered several survey questions
  - All data was recorded on paper and then later inputted into EDC

Wednesday, November 23, 2022

- Office closed
- Worked on gathering data for research practicum

Thursday, November 24, 2022

- Office closed
- Worked on gathering data for research practicum

Friday, November 25, 2022

- Office closed
- Worked on gathering data for research practicum

Monday, November 28, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Received drug shipment from Lyra study:
  - Opened/checked for any damage/turned off temperature monitor
  - Signed documentation, printed temperature logs, emailed back to sponsor
  - Documented drug log in regulatory binder
- Prepared for screening visit for Lyra-220 - printed out ICF documents and other necessary demographic, medication and past medical history forms
  - Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - Assisted in inputted data from patient visit into EDC and shipment of lab specimens
- Conducted 24M phone call visit for VATRAC – reviewed medical history, current medications, new diagnosis, answered several surveys
  - Inputted data into EDC
- Prepared for visit 10 for GSK (anchor)
  - Assisted in bloodwork, ECG, completing questionnaires, reviewing current medications and symptoms
- Packaged blood work and dropped off at FedEx

Tuesday, November 29, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)

- Prepared for screening visit for GSK (anchor)- printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Patient no show
- Prepared for screening visit for Lyra-210- printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - o Assisted in inputted data from patient visit into EDC and shipment of lab specimens
- Conducted 24M phone call visit for VATRAC – reviewed medical history, current medications, new diagnosis, answered several surveys
  - o Inputted data into EDC
- Packaged blood work and dropped off at FedEx

Wednesday, November 30, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared for screening visit for Lyra-210- printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - o Assisted in inputted data from patient visit into EDC and shipment of lab specimens
- Packaged blood work and dropped off at FedEx

Thursday, December 1, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Sent medical record request to several PCP's regarding our patients in Lyra Studies
- Sent PCP notifications to our Lyra patients who requested it in the ICF forms
- Prepared for screening visit for Lyra-210- printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Patient no showed
- Prepared for screening visit for Lyra-210- printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - o Assisted in inputted data from patient visit into EDC and shipment of lab specimens
- Packaged blood work and dropped off at FedEx

Friday, December 2, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared for visit 5 for FX-322- printed out source documents and questionnaires for visit
  - o Prepared for audiology session
  - o Inputted all audio/visual recordings from session as well as data from otoscopy, questionnaires, and audiology session into EDC

- Prepared for visit 7 for FX-322- printed out source documents and questionnaires for visit
  - o Prepared for audiology session
  - o Inputted all audio/visual recordings from session as well as data from otoscopy, questionnaires, and audiology session into EDC

Monday, December 5, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared for unscheduled visit for Lyra-210 patient due to sinus infection
  - o Endoscopy and physician assessment
- Worked on source documentations for Lyra study – transition from electronic to paper source

Tuesday, December 6, 2022

- McKinney site for procedure/randomization for Lyra-220
  - o Assisted in vitals, bloodwork, endoscopy, procedure, input of data, answering any questions
- Prepared and assisted in Orchid Visit 8
  - o Questionnaires, update on medications, review health status

Wednesday, December 7, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Received several shipments
  - o Unpackaged
  - o Checked for complete and undamaged products
  - o Documented and signed off
- Sick day

Thursday, December 8, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Received several shipments
  - o Unpackaged
  - o Checked for complete and undamaged products
  - o Documented and signed off
- Charged video/audio equipment for 2 audiology sessions for tomorrow
- Printed out all necessary source documents for 2 FX-322 visits
- Printed out and prepared for randomization/procedure day for Lyra-210
- Worked on data collection for research practicum

Friday, December 9, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared for randomization for Lyra-210 patient
  - o Assisted in vitals, bloodwork, questionnaires
  - o As unblinded coordinator – assisted physician in procedure by assembling device and implantation, recording endoscopy, inputting data from visit

- Prepared for visit 5 for FX-322- printed out source documents and questionnaires for visit
  - o Prepared for audiology session
  - o Inputted all audio/visual recordings from session as well as data from otoscopy, questionnaires, and audiology session into EDC
- Prepared for visit 6 for FX-322- printed out source documents and questionnaires for visit
  - o Prepared for audiology session
  - o Inputted all audio/visual recordings from session as well as data from otoscopy, questionnaires, and audiology session into EDC
- Conducted 3-week phone call visit for Lyra-220 patient
  - o Updated any AE, medications, and checked for completion of surveys

Monday, December 12, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Printed weekly reports, IRB approval, updates on regulatory info and filed into appropriated study binders
- Finish inputting data from last week's FX-322 visit into EDC
- Sent email updates to sponsor regarding Lyra referral's and randomization dates
- Restarted video/audio equipment for FX-322 study in order to upload the audiology sessions last week
- Worked on gathering data for research practicum

Tuesday, December 13, 2022

- Drove to McKinney
- Joined a zoom call from sponsor involving RHINTRAC and VATRAC extension of the study
- Received study drug for Lyra-220
  - o Unpackaged, verified correct and undamaged drug, sent temperature logs to sponsor, and recorded in regulatory log
- Assisted in training new remote clinical research assistant
- Assisted in Lyra-220 screening visit - printed out source documents and questionnaires for visit
  - o Assisted in vitals, bloodwork, questionnaires
- Worked on gathering data for research practicum

Wednesday, December, 14 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Received study drug for Lyra-220
  - o Unpackaged, verified correct and undamaged drug, sent temperature logs to sponsor, and recorded in regulatory log
- Emailed delegation log to sponsor for Lyra-210
- Re-uploaded audio visits for FX-322 trial
- Prepared and conducted visit 4 Lyra-220
  - o Update of medication and past medical history, vitals, bloodwork, endoscopy

- Inputted data from patient visit into EDC and shipment of lab specimens

Thursday, December 15, 2022

- Went to Central Market to get Dry Ice for monthly shipment of blood specimens and nasal swab secretions for our studies
- Packaged lab specimens accordingly and called for pickup
- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Re-uploaded several audio sessions for FX-322
- Worked on source documentation for Lyra studies
- Worked on gathering data for research practicum
- Conducted a 24M phone call visit

Friday, December 16, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Calling Lyra referrals to ask pre-screening questions and scheduling for screening visits for upcoming weeks
- Emailing monitors weekly updates regarding our Lyra patients and their upcoming procedure dates
- Correcting ongoing queries in EDC for FX-322
- Worked on gathering data for research practicum

Monday, December 19, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Printed and filed received lab specimens for Lyra studies
- Re-uploaded FX-322 audio sessions
- Called to confirm subjects for their Lyra-210 visits for this week
- Worked on creating source documents for Lyra visits (transition from electronic to paper sources)

Tuesday, December 20, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared and conducted procedural/randomization for Lyra-221
  - As unblinded coordinator - update of medication and past medical history, vitals, bloodwork, endoscopy
  - Assisted PI in procedure of sham/drug device implant
  - Uploaded endoscopy videos and documentations to portals for sponsor review

Wednesday, December 21, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Worked on sending out flyers for rheumatology site for Giant Cell Arteritis trial
- No show for Lyra-210 Screening visit

Thursday, December 22, 2022

- Called and discussed the clinical trial to several referrals, asked pre-screening questions and Scheduled them for upcoming screening visits for Lyra study
- Scheduled upcoming screening visits for Lyra study



- Scheduled upcoming screening visits for Lyra study
- Worked on sending out flyers for rheumatology site for Giant Cell Arteritis trial

Friday, December 23, 2022

- Scheduled a physician referral
- Worked on sending out flyers for rheumatology site for Giant Cell Arteritis trial
- Worked on creating source documents for Lyra visits (transition from electronic to paper sources)

Monday, December 26, 2022

- Holiday off

Tuesday, December 27, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Scheduled upcoming screening visits for Lyra study
- Called to confirm subjects for their Lyra-210 visits for this week
- Answered and corrected queries for FX-322 EDC and source documents
- Completed source documents for Lyra-220 subject

Wednesday, December 28, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared for s screening visit for Lyra-210- printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Both no shows
- Worked on creating source documents for Lyra visits (transition from electronic to paper sources)
- Called to schedule a Lyra referral – asked pre-screening questions and scheduled for screening visit
- Shipped monthly blood specimens for Lyra studies

Thursday, December 29, 2022

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Worked on creating source documents for Lyra visits (transition from electronic to paper sources)
- Prepared for screening visit for Lyra-210- printed out ICF documents and other necessary demographic, medication and past medical history forms
  - o Assisted in ICF process, update of medication and past medical history, vitals, bloodwork, endoscopy, CT scan
  - o Assisted in inputted data from patient visit into EDC and shipment of lab specimens
- Prepared and assisted in visit 11 GSK (ANCHOR) visit
  - o Updated ICF and signature, update on medication and new diagnoses, bloodwork, endoscopy

Friday, December 30, 2022

- Discussed a Lyra referral about trial, asked pre-screening questions, and scheduled screening visit for next week
- Completed Lyra-220 subject week 6 phone call visit
- Day Off

Monday, January 2, 2023

- Day off

Tuesday, January 3, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Worked on completing the rest of source documents visits for Lyra studies
- Conducted a screening visit for Lyra-220
  - o Printed out ICF and all necessary documentations
  - o Informed subject of trial and answered all questions
  - o Subject DNQ
- Prepared and assisted in randomization/procedure visit for Lyra-210
  - o Assisted in vitals, bloodwork, questionnaires
  - o As unblinded coordinator – assisted physician in procedure by assembling device and implantation, recording endoscopy, inputting data from visit

Wednesday, January 4, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Confirmed appointments for our two screening visits for tomorrow
- Continued to work on visits for Lyra paper sources
- Scheduled times for McKinney patients in Relief for 24M phone call visits
- Organized patient visits into separate binders as transition from EDC to paper sources

Thursday, January 5, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Conducted a screening visit for Lyra-220
  - o Printed out ICF and all necessary documentations
  - o Informed subject of trial and answered all questions
  - o Assisted in vitals, bloodwork, sinus CT, endoscopy, questionnaires
  - o Uploaded all information into EDC and filled out paper sources
  - o Sent PCP records request
- Following up with Lyra referrals on portal
- Reschedule no show subject for today

Friday, January 6, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Following up with Lyra referrals on portal
- Scheduling screening visits for Lyra studies
- Contacting and scheduling RELIEF subjects at McKinney site for their 24M phone call visits
- Transferred electronic PDF's of multiple clinical trials from our electronic source to electronic storage and flash drives as transition to paper sources.

Monday, January 9, 2023

- Bought dry ice for specimen shipment
- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Packaged specimen and shipped to Lyra study lab (MedPace)
- Attempted to following up with Lyra referrals on portal
- Attempted to contact and scheduling RELIEF subjects at McKinney site for their 24M phone call visits
- Talked to our qualified screening patient for Lyra-220
  - o Scheduled eye exam for next week and the procedure/randomization visit
- Scheduled a Lyra-210 referral
- Received and documented shipment for GSK (anchor)
- Conducted a screening visit for Lyra-220
  - o Printed out ICF and all necessary documentations
  - o Informed subject of trial and answered all questions
  - o Assisted in vitals, bloodwork, sinus CT, endoscopy, questionnaires
  - o Uploaded all information into EDC and filled out paper sources
  - o Sent PCP records request
  - o Patient no show
- Training for GSK (Anchor) for uploading endoscopes
- Worked on gathering extra data for my research practicum
- GO FROGS! (national championship game tonight)

Tuesday, January 10, 2023

- At McKinney site
- Scanned and sent electronic documents for VATRAC and RHINTRAC to folders for sponsor collection
  - o Include 12M phone visits, 24M phone visits, AEs/SAEs, and Medication lists for each patient
- Assisted in GSK patient visit V7
  - o vitals, bloodwork, updated medications, endoscope

Wednesday, January 11, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Updated Lyra-referrals – attempt to make contacted to new referrals and dropped all referrals unable to reach
- Sent scheduling reminders to our subjects in our trials with upcoming visits
- Sent a primary care notification fax to our qualified Lyra-220 subject
- Emailing Orchid IT team to gain access to uploading imaging portal and MyTrial portal
- Uploaded yesterday's Lyra-210 screening subjects' sinus CT and endoscope video
- Reviewed Primary care physician's medical records of our Lyra-220 subject to cross check medication, surgeries, and any other medical history

Thursday, January 12, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)

- Sent updated reminders of daily journals and upcoming visits to Lyra subjects
- Sent laboratory request to MedPace for Lyra studies – ordered more screening visit kits & pregnancy tests
- Conducted a 24M phone call visit for McKinney study RELIEF – updated medications, reviewed symptoms, answered questionnaires
  - o Inputted data into EDC
- Prepared and conducted Lyra-210 week 8/ V3
  - o Updated medications, current health status, endoscope and questionnaires
- Prepared and conducted Lyra-210 screening visit
- Sent medical records request to primary care of Lyra-210 subject

Friday, January 13, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Conducted a screening visit for Lyra-220
  - o Printed out ICF and all necessary documentations
  - o Informed subject of trial and answered all questions
  - o Assisted in vitals, bloodwork, sinus CT, endoscopy, questionnaires
  - o Uploaded all information into EDC and filled out paper sources
  - o Sent PCP records request
- Conducted a 24M phone call visit for McKinney study RELIEF – updated medications, reviewed symptoms, answered questionnaires
  - o Inputted data into EDC
- Received study kits and other lab resources from GSK – unboxed, validated, and organized

Monday, January 16, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Contacted Lyra screening subjects to notifying them of their status with the clinical trial – either qualified and scheduled upcoming visits or did not qualified and discontinued them from the study
- Attempted to make contact with some of the referrals in portal for the Lyra-study
- Attempted to make contact with RELIEF subjects to schedule for 24-month phone call visit
- Called to conduct week 8 phone visit for Lyra-220 subject
  - o Updated medications, checked questionnaire upload, reviewed any AEs and uploaded to EDC

Tuesday, January 17, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Attempted to make contact with RELIEF subjects to schedule for 24-month phone call visit
- Contacted Lyra subjects to notifying them of their upcoming visits including randomization/procedure next week
- Organized and separated subject visits into individual binders
- Received lab kits from Lyra-210 – unpackaged, sorted, and noted in regulatory binder
- Scheduled my research practicum defense date

Wednesday, January 18, 2023

- Went to McKinney site
- Contacted a Lyra-210 screening subject to inform of not qualifying for the trial
- Contacted a Lyra-220 subject to remind to complete daily diaries and answer any questions or issues with the study
- Scanned and sent electronic documents for VATRAC, RHINTRAC, and RELIEF to folders for sponsor collection
  - o Include 12M phone visits, 24M phone visits, AEs/SAEs, protocol deviations, Medication lists for each patient
- Assisted in Lyra-220 screening visit
  - o Vitals, bloodwork, updated medications, endoscope

Thursday, January 19, 2023

- Received news of subject in Lyra-220 tested positive for COVID-19
  - o Documented as an AE and informed subject of the protocol procedures
- Conducted a 24M phone call visit for McKinney study RELIEF – updated medications, reviewed symptoms, answered questionnaires
  - o Inputted data into EDC
- Rescheduled GSK screening subject for next week
- Had company lunch meeting – discussed yearly updates, upcoming changes for the company, and news ways to improve

Friday, January 20, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Contacted Lyra-210 subject for unscheduled visit for next week
- Scanned and sent electronic documents for RELIEF Fort Worth site to folders for sponsor collection
  - o Include 12M phone visits, 24M phone visits, AEs/SAEs, protocol deviations, Medication lists for each patient

Monday, January 23, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Contacted to get update on Lyra-220 subject status with COVID-19 infection
  - o Added information to AE form
- Sent medical records request to PCP and ENT of subject in Lyra-210
- Updated source documents for Lyra studies
- Scheduled two procedure visits with our Lyra subjects
- No show with GSK/Anchor patient

Tuesday, January 24, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Conducted 24M phone visit for RHINTRAC
  - o Updated medications and history, questionnaires and inputting rest of the data onto paper and electronic sources into EDC

- Prepared and assisted on randomization/procedure visit for Lyra-220
  - o Update history and medications
  - o Questionnaires
  - o Nasal endoscopy
  - o Device with drug implantation
  - o Blood collections pre and post procedure
  - o Inputted data into EDC
- Conducted unscheduled visit for Lyra-210 patient – possible infection
  - o Reviewed history and updated medications
  - o Endoscopy and evaluated patient status
- Packaged blood specimens and shipped to lab

Wednesday, January 25, 2020

- Off day – Med school interview

Thursday, January 26, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Conducted visit 3 (day 3) of Lyra-220 subject – collected PK blood work and prepared for shipment
- Arrived in Allen at rheumatology clinic – assisted in move in day

Friday, January 27, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Went through past several weeks of source visits from our Lyra study in preparation for monitor visit next week

Monday, January 30, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Monitor visit to review Lyra studies
- Snow day

Tuesday, January 31, 2023

- Snow day

Wednesday, February 1, 2023

- Snow day
- Contacted patients regarding rescheduling visits

Thursday, February 2, 2023

- Contacted patients regarding rescheduling visits

Friday, February 3, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Monitor visit to review Lyra studies
- Uploaded RELIEF patient documents to sponsor portal for Fort Worth site
- Conducted a 24M phone call visit for VATRAC
  - o Updated medication and new conditions/AEs

- Questionnaires
- Inputted data of visit on source documents and EDC
- Created paper source documents for later visits of Lyra-210
- Conducted Visit 3 of Lyra-210 subject – updated information and collected PK blood samples

Monday, February 6, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Contacted subjects for tomorrow's appointment
  - Two subjects in Lyra-210 will be randomized/procedure
  - Lyra-210 subject for 8-week visit
- Reviewed monitor visits notes and corrected queries

Tuesday, February 7, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Lyra-210 procedure day for 2 subjects
  - Update history and medications
  - Questionnaires
  - Nasal endoscopy
  - Device with drug implantation
  - Blood collections pre and post procedure
  - Inputted data into EDC
- Lyra-210 week 8 visit
  - Updated medical history, endoscopy, questionnaires
  - Inputted all data into EDC and paper source documents

Wednesday, February 8, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared and conducted Lyra-220 week 12 visit
  - Reviewed monitor queries, confirmed information with subject and corrected
  - Questionnaires, update medical history, blood draw, endoscopy
  - Inputted all data into EDC and paper source documents
- Assisted in GSK screening visit
  - Printed out all ICF papers and necessary documentation
  - EKG, blood work, endoscope, shipment of blood specimen

Thursday, February 9, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Sent medical record request to GSK subject in screening
- Added confirmed conditions and medications from patient visit for Lyra-220 subject into source documents and EDC
- Community outreach member for Orchid study – in person site visit to discuss possible new recruitment methods and ways to improve in awareness of clinical trial
- Updated new version of source documents for Lyra-210

Friday, February 10, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Organized papers ready for PI signatures
- Printed and filed sponsor documents for Fort Worth site

Monday, February 13, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared for GSK screening visit – patient no showed
- Updated Lyra-210 source documents
- Attended virtual training session for AERWAY with topic: SAE reporting

Tuesday, February 14, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared and conducted Lyra-210 week 8, visit 3 visit
  - o As unblinded coordinator, conducted endoscope and completed necessary documentation for source documents and EDC
- Filed necessary paperwork of several studies in site regulatory binders

Wednesday, February 15, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Monitor visit for Lyra-210 and preparation for sponsor audit next week
  - o Corrected queries, organized and filed paperwork in regulatory binders
- Contacted GSK screening patient to notify status in trial
  - o Scheduled randomization visits to receive drug/placebo

Thursday, February 16, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Monitor visit for Lyra-210 and preparation for sponsor audit next week
  - o Corrected queries, organized and filed paperwork in regulatory binders
- Completed an NTF form for a subject in the VATRAC study since visit was conducted after study exit

Friday, February 17, 2023

- Day off

Monday, February 20, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Sent medical records request for GSK study patient
- Prepared for the Lyra auditor visit – made sure all files in correct binders, everything completed, all queries corrected

Tuesday, February 21, 2023

- Arrived at McKinney site to assist in 2 visits
- Filed VATRAC and RHINTRAC 24-month phone call visits into appropriate binders
- Assisted with visit 9 for GSK study



- Questionnaires, updated con meds and history, endoscopy, blood collection, data input
- Assisted with end of trial visit for Orchid
  - Questionnaires, updated con meds and history, blood collection, data input
- Processed, packaged, and shipped blood specimens for both trials

Wednesday, February 22, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Met with Lyra auditor to discuss status of trial and if any changes or updates need to be made
- Conducted week 8 visit for Lyra-210
  - Updated con meds and history, blood collection, endoscope, questionnaires, AE reporting
- Met with faculty advisor at UNTHSC campus to discuss data and analysis for my research practicum

Thursday, February 23, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Conducted week 4 visit for Lyra-220
  - Updated con meds and history, blood collection, endoscope, questionnaires
  - Inputted all data into EDC and corrected queries
- Worked on my data and analysis for research practicum

Friday, February 24, 2023

- Attempted to contact new Lyra-210 referrals
- Attempted to contact VATRAC subjects to schedule for 24-month phone call visits
- Worked on my data and analysis for research practicum
- Worked on updating source documents for Lyra studies

Monday, February 27, 2023

- Worked on updating source documents for Lyra studies
- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Attempted to contact new Lyra-210 referrals
- Attempted to contact VATRAC subjects to schedule for 24-month phone call visits
- Assisted with week 13 visit for GSK (anchor)
  - Questionnaires, blood processing and packaging, endoscope
- Screening visit for Lyra-210
  - Informed consent, medical history and Con Meds, blood work, endoscope
  - Inputted data and uploaded CT and endoscope images to portal
- Shipped GSK and Lyra blood specimens

Tuesday, February 28, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Bought Dry Ice, packaged frozen blood specimens, shipped to sponsors lab
- Worked on my research practicum report

Wednesday, March 1, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Filed temperature logs and printed new month to file in folder
- Bought Dry Ice, packaged frozen blood specimens, shipped to sponsors lab
- Send medical records request for GSK subject
- Worked on my research practicum report

Thursday, March 2, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Worked on research practicum report
- Conducted Lyra-210 week 8 visit
  - o Endoscope, questionnaires, review Con Meds and medical history
  - o Uploaded images and inputted data into ECC

Friday, March 3, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Worked on research practicum report & sent draft to faculty advisor
- Completed 24M phone call visit for VATRAC – updated Con Meds and medical history, questionnaires, and uploaded to EDC

Monday, March 6, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Contacted GSK patient for more details recording their PCP in order to obtain medical records
- Send Lab request to Lyra for new blood specimens tubes
- Completed Lyra-220 week 6 phone visit
  - o Updated Con Meds and medical history, questionnaires, inputted data into EDC

Tuesday, March 7, 2023

- Went to McKinney to assist two patient visits
- Assisted in GSK patient visit
  - o EKG, blood work and packaging, updated history, questionnaires, and filing
- Screening visit for Orchid no showed
- Completed 24M phone call visit for VATRAC – updated Con Meds and medical history, questionnaires, and uploaded to EDC

Wednesday, March 8, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Printed and filed regulatory documents, monitoring reviews, and site correspondents to several study regulatory binders
- Called Lyra-referrals to schedule screening visits
- Prepared for GSK visit 2/randomization day
  - o No showed; rescheduled for next Tuesday

Thursday, March 9, 2023

- Worked on research practicum report
- Called Lyra referrals asked them prescreening questions, discussed the trial and requirements and scheduled them in for screening visit

Friday, March 10, 2023

- Lyra screening subject rescheduled for next Monday
- Worked on research practicum report
- Called Lyra referrals asked them prescreening questions, discussed the trial and requirements and scheduled them in for screening visit

Monday, March 13, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Sent reminders to two Lyra subjects to continue to do their dairy diaries and discussed the importance of compliance
- Tried to contact more Lyra-referrals via email and phone for both Fort Worth and McKinney sites
- Completed week 16 telephone visit for Lyra-220
  - o Updated Con Meds and history, questionnaires, reviewed any changes in symptoms or possible AE's, inputted data on paper source and into EDC
- Prepared and conducted Lyra-210 screening visit –
  - o Printed out paperwork and organized into binder
  - o ICF, medical history and medications, vitals & blood work, CT scan, endoscopy, blood processing and packaging, inputted data and images into EDC

Tuesday, March 14, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Completed progress note for a missed patient visit for relief study
- Worked on research practicum project
- Prepared and conducted GSK visit 2 (randomization)
  - o Updated Con Meds and history, reviewed study criteria met subject, questionnaires, ECG and vitals, bloodwork, endoscope
  - o Processed blood specimens, packaged, shipped to lab
  - o Inputted data into paper source and EDC

Wednesday, March, 15, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Sent lab equipment request for GSK study
- Corrected RELIEF queries on sponsor portal
- Contacted Lyra-referrals for Fort Worth and McKinney sites
  - o Sent available times to schedule for screening visit
- Worked on research practicum
- GSK monitor for drug disposal visit

Thursday, March 16, 2023

- Worked on research practicum & sent to faculty advisor

- Scheduled three Lyra-210 referrals to McKinney site for screening
  - o Contacted, asked pre-screening questions, discussed about clinical trial subjects, obtained patient information and put in our schedule

Friday, March 17, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Completed tasks from auditor of Lyra for 220 subjects
- Printed and filed documents in regulatory binders of several ongoing studies
- Moved all FX-322 trial into storage box as trial is completed
- Training session with eClinPro - a new online source documentation

Monday, March 20, 2023

- Worked on research practicum edits and sent it back to faculty advisor
- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Prepared and conducted Lyra-210 screening
  - o ICF process, demographics, medical history and medications, vitals, blood work, endoscopy, CT scan
- Contacted Lyra-210 referrals for McKinney site – waiting to reach back to schedule for screening visit
- Answered and corrected queries in EDC for Lyra-220

Tuesday, March, 21, 2023

- Worked on making final adjustments for research practicum project
- Contacted more Lyra-210 referrals for McKinney site
- Created paper source documents for end of treatment for Lyra-220 in preparation for upcoming visits

Wednesday, March 22, 2023

- Worked on making final adjustments for research practicum project in preparation to send to rest of committee members by tomorrow
- Contacted more Lyra-210 referrals for McKinney site and schedule two more screening visits
- Created paper source documents for end of treatment and study for Lyra-220

Thursday, March 23, 2023

- Sent my final Research Practicum Report to my committee in preparation for my defense in 2 weeks
- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Printed and Filed regulatory documents
- Obtained PI signatures from patient visits and filed into subject binders
- Unpackaged new lab equipment from GSK study
- Lyra-210 visit no show due to COVID infection

Friday, March 24, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Obtained PI signatures from patient visits and filed into subject binders

- Created paper source documents for end of treatment for Lyra-220 in preparation for upcoming visits

Monday, March 27, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Created paper source documents for end of treatment for Lyra-220 in preparation for upcoming visits
- Worked on presentation for thesis
- Prepared and conducted Lyra-210 week 16 visit
  - o Updated medical history and medications, questionnaires, endoscopy, inputted data into EDC and paper source

Tuesday, March 28, 2023

- Arrived at McKinney clinic to assist in GSK screening visit and visit 11
  - o Endoscopy, questionnaires, bloodwork and processing, updating medical history and medications
- Cleaned out the drug freezer
- Signed off as one of the un-blinded coordinators for Lyra-210 at McKinney site
- Worked on thesis presentation

Wednesday, March 29, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Assisted with Monitor visit for Lyra studies
  - o Helped clarify any questions and answered queries
- Prepared and conducted Lyra-210 screening visit
  - o ICF, medical history and medications, questionnaires, blood work and processing, CT scan, endoscopy, uploading images and data into EDC and paperwork
- Updated exclusion/inclusion criteria for Lyra on paper source

Thursday, March 30, 2023

- Arrived at McKinney site to assist in Lyra-210 week 16 visit and screening visit
  - o Un-blinded coordinator – endoscopy, uploaded images to EDC
  - o Assisted in other tasks at visit such as bloodwork, updated medical history and medications, questionnaires.
- Worked on thesis presentation

Friday, March 31, 2023

- Worked on thesis presentation
- Sent out emails/texts to Lyra-210 referrals
- Lyra protocol 3 amendment training session

Monday, April 3, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Worked on answering Lyra-220 queries

- Sent out emails/texts to Lyra-210 referrals to ask pre-screening questions and schedule for screening visits
- Worked on thesis presentation

Tuesday, April 4, 2023

- Worked on practicing thesis presentation
- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Scheduled Lyra-210 screening visits for this and the following weeks
- Conducted a 24M phone call visit for RHINTRAC
- Conducted week 20 Lyra-220 visit – updated medical history and medications, blood draw, scheduled the end of treatment visit
- Got dry ice, packaged stored blood specimen, shipped to lab

Wednesday, April 5, 2023

- Recorded daily temperature logs (refrigerator, freezer, room temperature)
- Sent out emails/texts to Lyra-210 referrals to ask pre-screening questions and schedule for screening visits
- Conducted Lyra-210 week 8 visit – updated medical history and medications, endoscopy, inputted data from visit
- Practiced thesis presentation

Thursday, April 6, 2023

- Rehearsed thesis presentation in the morning
- Presented thesis presentation
- FINISHED MY INTERNSHIP!