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Maximizing Patient Recruitment

Sneha Rangu
University of Pennsylvania

Annie Maxwell
University of Pennsylvania

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Maximizing Patient Recruitment

Summary

- Having well-constructed recruitment pathways are vital in research. Clinical trials that fail to meet recruitment/enrollment goals may have substantial delays, or small sample sizes resulting in decreased study power, and even early termination.
- There are many diverse sources for patient recruitment, including clinics, community outreach, institution resources, and traditional media/social media outlets.
- To optimize recruitment methods during the study and meet enrollment goals, create a system to track progress, and follow recruitment rates.
- It is important to clearly articulate how staff will approach patients and from what source they will recruit them from. This is to avoid discrepancies and protocol deviations among staff when recruiting subjects.

Maximizing Patient Recruitment

Sneha Rangu and Annie Maxwell

Summary

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Introduction

Patient recruitment is a key determinant in a clinical trial's success. As many as 86% of clinical trials do not meet recruitment goals within their proposed time frame, resulting in inconclusive results and ultimately failing to improve patient outcomes. It is imperative to consider recruitment timelines in the early stages of creating a study; for example, during the planning and budgeting stages. On the other hand, one must also be aware that unexpected barriers to recruitment may arise during the study, which may require carefully planned recruitment methods to be modified or revised. In many cases, these modifications will require IRB approval, resulting in unplanned delays to the study timeline. With clear and realistic recruitment goals from the start, you are more likely to see study completion without unanticipated delays or added costs.

How to Create Recruitment Goals and Graphs

Once study procedures and an overall timeline are created for your study, you can begin setting recruitment goals and developing a schedule to meet these goals. Recruitment goals will vary for

each study. It is important to distinguish the difference between recruitment goals and enrollment goals. Your study team will need to recruit many more people than enrolled in order to hit the target enrollment number. For example, only 50% of those consented may meet your eligibility requirements after conducting additional screening measures following initial interest from the patient. That 50% will then be enrolled into your study. The following are useful resources to create recruitment goals, timelines, and graphs:

- Study time and events table (see Chapter 6 on Methods, Time and Events Tables)
- Attrition table (see Chapter 8 on Inclusion/Exclusion Criteria)

Dividing your recruitment and enrollment goals into monthly or quarterly blocks will allow for changes as time goes on. Recruitment may be slow in the beginning, so gradually increasing your goals is reasonable. Below is an example of a recruitment graph for a study that has continuously failed to meet recruitment goals (Figure 1). Under Figure 1, there is also an example of a recruitment graph for a study that started slow in recruitment, but gradually met recruitment targets (Figure 2). On these graphs, please note that the number of consented subjects exceeds the target enrollment because many consented subjects are not eligible to be enrolled since they may not meet all of the study inclusion/exclusion criteria. A Google Sheet to create recruitment graphs and calculate numbers is under Practical Guides/Worksheets. This Google Sheet can be updated weekly to reflect recruitment numbers for the specific month.

Figure 1. Recruitment Graph for Study that is Continuously Under-recruiting Subjects.

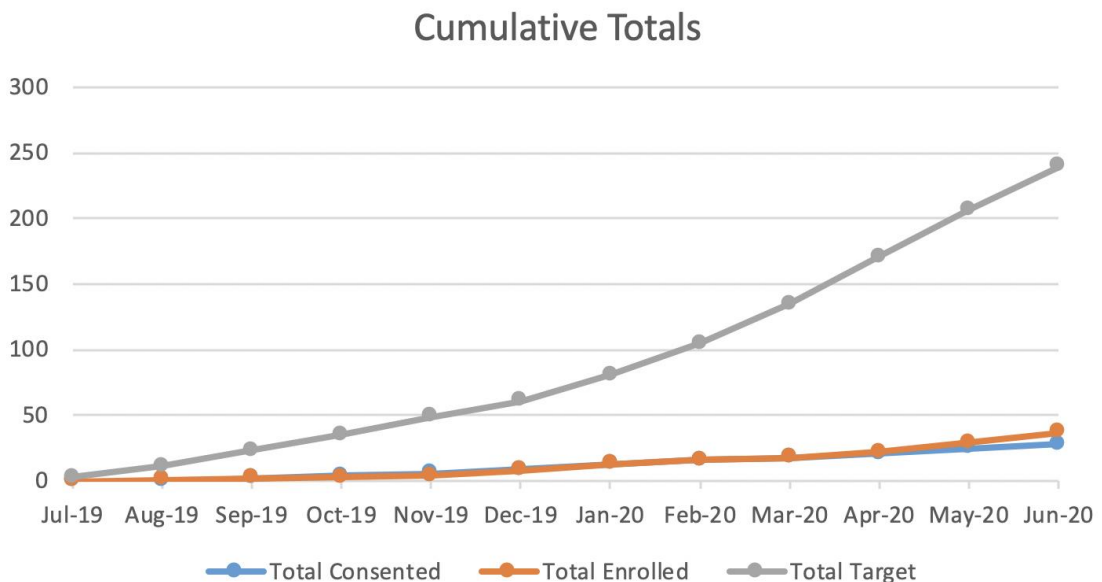
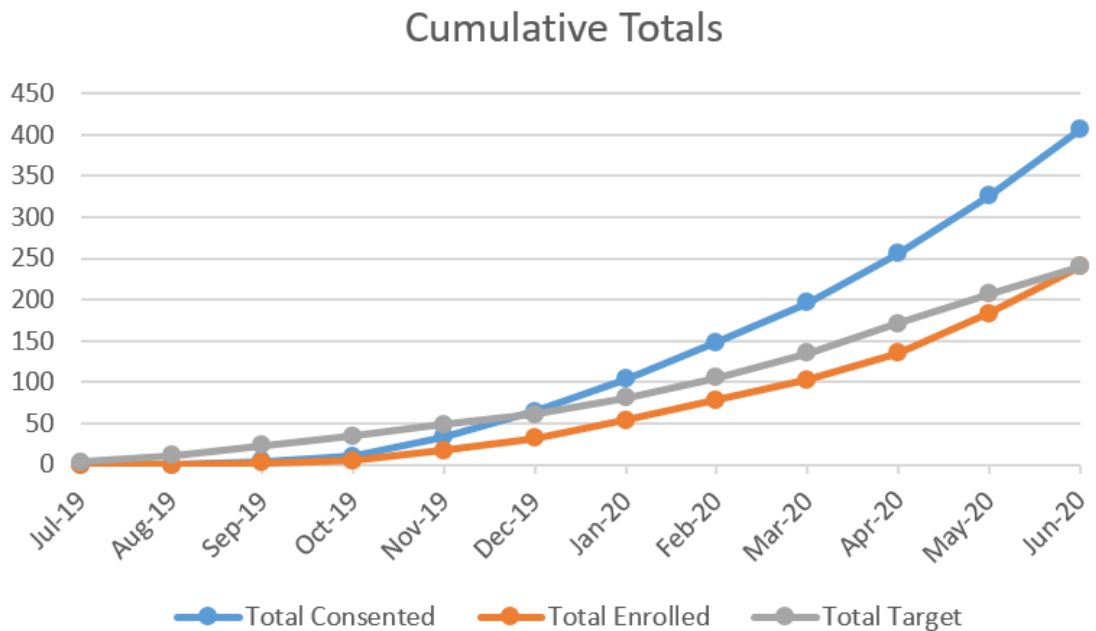


Figure 2. Recruitment Graph for Study that Started Slow in Recruitment, but Eventually Met Recruitment Targets.



The consented number needs to exceed the total enrolled number because studies generally need to consent more subjects than the study enrolls in order to meet enrollment targets (i.e. due to screen failures during the consent process).

The following sections include items to consider when creating recruitment goals and timelines.

Target population

Your target enrollment number depends on your study's purpose and aims. For example, if your study focuses on cognitive impairment in older adults, your enrollment target may be higher compared to the enrollment target for a study on a rare genetic disease in newborns.

Resources/tips to better understand your target population include the following:

- Search the literature for similar studies to get a sense of an appropriate enrollment target
- Query the electronic medical record (See Chapter 9)
- Use the U.S. Census Bureau to get an idea of the profile data in your surrounding community

If your study requires in-person visits, your recruitment may require more staffing than for a study conducted online. Additionally, if your study requires in-person visits and you are only enrolling a certain demographic, for example Hispanic/Latinos ages 55 to 85, then you can use

the U.S. Census Bureau to obtain the profiles of residents in your area. Completing prior research on your target population is key in incorporating realistic recruitment goals into your timeline.

Proposed budget and subject compensation

The budget is also a key aspect of the proposal that needs to be referenced when creating recruitment goals. Prior to beginning recruitment, review the budget for your project and pay special attention to what portion of the budget you have designated for recruitment. The recruitment budget is typically outlined in the grant proposal, however, if there is no budget outlined in the grant or your study is not grant-funded, then you will need to discuss a budget with the PI and reallocation/distribution with a business administrator.

All research subjects are volunteers, so compensation is often, though not always, an important component of participation. If compensation is an element of the study, you should base payment on the amount of time and effort expended by the subject. While compensation amounts should be effort-based, payment structure or amount should not cause undue influence or coerce patients into participation. Minimum wage is often an acceptable criteria for compensation.

There are many ways to compensate subjects. Options include:

- Lotteries
- Gift cards (i.e. Amazon, Visa, food stores such as Wawa, etc.)
- ClinCards (debit cards) - payment cards issued by many institutions
- Checks

To see which option yields more subjects, you can consider creating different arms for compensation. Many studies that seek to learn more about effective incentivization or behavioral economics will utilize different compensation paradigms across study arms.

Compensation is not the only cost to consider when planning for recruitment. The cost to enroll a single subject includes compensation, but also includes the cost of involved staff time and required study implementation and procedures. After approximating the cost per subject, use this number to calculate the approximate total amount needed to meet your overall enrollment target.

Keep in mind that the budget may not cover the projected cost of recruitment. This could be because the budget was not calculated prior to the grant submission or because the recruitment method/study procedures have since been revised and now require more funding. If the recruitment budget cannot cover recruitment costs, then either the budget will have to be re-distributed, the target enrollment will have to be reduced, or other costs will have to be offset. If this is not assessed periodically to ensure you are on track, then you may not have enough funds to meet study recruitment goals as the study end-date approaches.

Common reasons for disinterest in target population

While many people are interested in participating in research, there is a large number of people that will choose not to get involved. Understanding the common reasons for disinterest/refusal will keep you well prepared when setting recruitment goals. Reasons for declining participation may be found in published literature, as many studies have evaluated common reasons for refusing participation in clinical research studies. Common reasons for refusal include:

- Travel difficulties
- Insufficient subject compensation
- Lack of interest in study procedures after learning more
- Procedures are too time-consuming
- Unavailable to participate due to weekday obligations (i.e. work, taking care of family members, etc.)
- Concerns about study risks

Solutions to these issues include:

- Arrange transportation with local cab services or rideshare services like Uber
- Pilot different compensation arms to see the optimal compensation amount to yield participants
- Offer meal vouchers during study visits
- Have a flexible study visit schedule -- include evening and weekend hours

Additionally, if you live in an area with seasonal variation (i.e. the Northeast region the United States), then there may be fluctuations in recruitment rates on a monthly basis. Thus, when creating a recruitment timeline, it is important to consider the effect of temperature changes and holiday seasons on subject interest. Overall, recognizing common reasons for rejecting participation in clinical research studies will increase your chances of meeting your enrollment target and avoiding any delays or additional costs.

Examples of Recruitment Pathways

There are many ways to advertise your clinical research study to recruit participants. Recruiting subjects can take place in person, within the community, over the phone or online and through social media. Research institutions typically have many resources available that can offer guidance for recruitment. It is important to note that adding recruitment pathways to your study will require Institutional Review Board (IRB) approval. Below are successful methods used to recruit patients for research studies.

Experts in the field

The principal investigator (PI) on your study will likely have many years of experience in your area of topic. Routinely meet with your PI to discuss the success of past recruitment pathways. Similarly, identifying an expert in your topic can help improve your recruitment plan. You can identify such experts during your literature search. In some cases, researchers versed in your topic will be located near you. If they are not, you can also reach out to them through email. The knowledge you gain from experts and the lessons they have learned from conducting studies will be invaluable.

Clinic/providers

If your study enrolls patients with a specific disease, it may be helpful to recruit directly from specialized clinics. Below are examples of ways to engage with clinics/providers:

- Brochures
- Flyers
- Direct referrals from physicians and other healthcare providers

For example, if your study focuses on cognitive impairment in the elderly, you can place brochures or flyers in memory clinics and centers. Once you have engaged with the clinic staff, consider engaging with healthcare providers in the clinic. Healthcare providers, such as physicians and nurse practitioners, can directly identify patients for you that may be interested and eligible for your study. Make sure to provide doctors and staff an easy way to refer patients to your study. Below is an outline of a 2-page packet for referrals.

- First page: For providers
 - Provide space of providers to write down the name and medical record number (MRN) of patients during the patient's clinic appointment
 - This is necessary so you can identify patients in the electronic medical record (EMR) after the provider sends the sheet back to the study team (with name and MRN)
- Second page: For patients
 - Provide a brief description of your study with study contact information
 - Providers will hand these out to patients during a clinic appointments for the patient to take home and they may contact you if interested

You may wish to modify this packet, but the simpler it is for providers to refer patients to you, the more patients you are likely to obtain through this pathway.

It may take months to launch this pathway. You first need to identify clinics; often they have a medical director or administrative director that is in charge of research engagement and it may take several days or weeks to get an initial meeting with them. It may then take days or weeks to schedule an introduction presentation. Thus, start planning early and approach clinics that will give you the highest yield (i.e. clinics that include your target population, clinics that are near

your geographic region, etc.) and identify at least one point-person/expert in these clinics that can be a go-to person for questions and implementation concerns.

Once you have established a relationship with clinics and providers, it is important to have sustained engagement. Below are examples:

- Follow-up visits
- Thank-you emails and letters
- Lunches
- Small thank-you items like chocolates, donuts, etc.

Also keep in mind that you may need to reach a subject in multiple different ways before they finally decide to engage. It is important to be persistent but not to be overly intrusive or annoying.

Electronic medical record

The electronic medical record (EMR) is also a powerful recruitment method. You can use the EMR to find potential subjects by:

- Using International Classifications of Diseases (ICD) codes specific to diagnoses to create a patient list in the EMR
- Finding contact information for potential subjects (using the “demographics” tab)
- Viewing upcoming schedules for clinics that treat your disease of interest (useful for in-person recruitment at clinics)

Additionally, many institutions have data groups that can create large lists of potential subjects using the EMR. For instance, the University of Pennsylvania has the Data Analytic Center which can create patient reports based on a criteria list you create (demographic variables, ICD codes, etc.). Furthermore, there may be data tools that exist at your institution that allow for aggregate search queries. For example, the University of Pennsylvania has PennSeek. PennSeek allows for:

- Refinement of search criteria and immediate review of identified cohort data
- Identification of providers that see patients with the disease of interest; these providers can be ideal to engage with for recruitment
- Creating recruitment goals

Using the resources of the EMR and patient databases can also help you generate your target enrollment number. If the EMR and patient databases show only a 1000 people with the specific disease you are targeting, then it would be unreasonable to have a target enrollment number greater than 1000. More detailed information about the EMR can be found in Chapter 9.

Community recruitment

Although there are many clinical pathways to meet recruitment goals, the community at large also serves as a useful avenue. Many people are open to learning more about research studies during their free time. You can place flyers and brochures in popular local buildings such as:

- Libraries
- Coffee shops
- Fitness centers
- Grocery stores
- Bus stops
- Senior centers

In addition, giving presentations at local communities such as senior centers, libraries, and even congregations can reach many interested subjects. Focus the presentation on the general topic of the study, and then introduce the specifics of the research study towards the end of the presentation. Set some time aside at the end of the presentation to answer questions, engage with the audience and collect contact information from interested participants. Recruiting for your study at these centers also provides a chance to relay vital health information to the wider community and to demystify research. Most of all, it also makes information about your study's topic accessible to community members who may have not had exposure to it otherwise.

Institution resources

As previously mentioned, your institution likely has many resources that can help in developing recruitment pathways. There are central offices at institutions that are designed to support the management and conduct of clinical research while promoting compliance. For instance, the University of Pennsylvania has the Office of Clinical Research (OCR). The OCR works with research teams to provide workshops and training sessions on different recruitment avenues they offer. The staff on the OCR team have a very diverse skill-set and have had years of experience in optimizing patient recruitment while adhering to research policies and regulations.

Additionally, institutions may provide a platform to create a website for your study. For example, the University of Pennsylvania utilizes iConnect to share research studies to the public online. iConnect allows you to provide a brief description of your study, inclusion/exclusion criteria, and study contact information. Interested subjects can also fill in their information to be contacted by study staff. Platforms like iConnect allow study staff to keep track of the number of potentially interested subjects and also have helpful analytics features. If a platform like iConnect does not exist at your institution, consider creating your own study website to generate interest online.

Peer referrals

The power of word of mouth can be capitalized on in research studies. Many business companies use word of mouth marketing to increase sales in their products. Likewise, you can apply this approach to clinical research studies. Provide currently enrolled subjects and those who have completed study procedures with a business card with study contact information. When the enrolled and completed subjects meet their family and friends, they can introduce the research study and speak about their positive experience. Hearing about the research studies from a trusted source may make others more likely to participate in your study. You can also consider compensating participants for meaningful referrals to your study. This may encourage them to refer the study to their friends and family, and also make them feel recognized for their time and efforts. Keep in mind that peer referrals, also called “Finders Fees” will be scrutinized by the IRB. Generally speaking, most IRBs will not approve of a finders fee if payment is contingent upon the enrollment of the person referred.

Paper referrals are most suitable for clinical research that requires in-person visits (when the card can easily be shared) or when the study population is older people or those with mild cognitive impairment. These populations may be less comfortable with technology and may prefer the simplicity and familiarity of a paper card.

Referrals can also be easily made online. People who view online ads on Facebook or other social media sites will often share the study with friends or shared interest groups on their own volition.

Traditional marketing and social media

Similar to brochures and flyers, advertisements are a great way to get the word out about your research studies. Below are key media outlets:

- Radio
- Television
- Newspaper
- Newsletters
- Magazines
- Craigslist
- Facebook
- Google Ads
- Billboards/Large signs in high traffic areas (ex: on public transit)

Radio/television

One mode of traditional media that can be useful is the radio. Identify a station that your target population listens to in order to maximize your time and money spent on the advertisement. It is also important to identify the best times to run your advertisements. For example, if you are targeting people with insomnia, it may be useful to run most of the advertisements during the late-

night hours. You can also utilize television programs similarly to market research studies. Most of all, be sure to verify the number of viewers that each radio station and television program generates before moving forward with your advertisement. This will avoid any unwanted costs that are associated with a failure to plan ahead. There is usually a point-person at a given publication/station/network that can help you plan a marketing campaign. Be aware that marketing campaigns usually require minimum run-times or a minimum budget.

Newspaper/newsletter/magazine

Similarly to radio and television ads, you can use newspapers, community newsletters, and magazines for printed advertisements. Reach out to your local newspaper to see if they have space to include your study as an advertisement. This will likely have a cost associated with it. On the other hand, many community centers such as senior centers have newsletters that they send to members. Sometimes community centers will advertise your study at no cost. You can utilize magazines that include information about your disease of interest to advertise a brief description of your study. Like newspapers, magazine companies will likely charge a fee for your study's advertisement.

Craigslist

While newspapers and magazines can run printed advertisements, Craigslist is a web-based classifieds platform that you can use to advertise your study online. The cost is based on the type of advertisement and the location of your advertisement. Alternatively, there is a "volunteer" section where free posts can be listed. Note that the volunteer section has more specific rules, particularly around compensation, and Craigslist may remove your study posting if it deems the post non-compliant with these parameters. For example, you cannot list the same "volunteer" post in multiple cities as Craigslist will view the posts as spam. Below are brief instructions on how to post a Craigslist advertisement:

1. Choose a location. If your study takes place in Los Angeles, choose Los Angeles as your city and other surrounding areas.
2. Create a post in the "gigs," "et cetera," or other relevant section.
3. Provide a brief study description and be sure to include study contact information.
4. Provide compensation amounts in both the description and the "pay" field on the Craigslist form.
5. Pay using a personal credit card. You will need to make reimbursement requests so be sure to keep a full log of all purchases, including receipts.
6. Posts will stay on the site for 30 days, after which they will expire. Craigslist will give you the option to re-post. It may be pertinent to repost before the 30 days ends, as the further from the front page the ad is shown, the fewer people will see it. Most responses from the ad will occur within the first 3 days of posting.

Facebook

The growth of social media has been immense in the last few years. Facebook, the most commonly used social media platform, has over 2.4 billion users.² While many businesses use Facebook business accounts to sell their products, research teams can utilize similar approaches to promote their research studies.

Facebook advertisements use targeted ads to reach desired demographics. For example, if you are only recruiting patients from New York City, you can set your advertisement to appear for people listed living in New York City on Facebook. This is applicable for demographic variables such as age and gender, as well. The advertisement can also target people with certain interests and groups. If you are studying an intervention in pregnant women, then consider having your advertisement target Facebook groups created for pregnant women. You can also build a study page to provide a brief description of your study and create a community of people interested in your area or topic. Your research institution may already have a dedicated Facebook page for sharing research trials. For example, The University of Pennsylvania has a Facebook page called “Clinical Trials @ Penn.” Users on Facebook can share this page with others and spread the word of your research study.

Google Ads

Similarly, Google Ads is a platform where advertisers pay to display brief advertisements within the Google Search Engine and on certain websites. At the time of publishing, Google Ads come in two forms: “smart” ads and fully customizable campaigns. Both of these ad types have pros and cons, but in general, if you are new to online marketing and/or do not have time to devote to the daily management of your online advertisements, then the smart campaign is probably the best choice. There are keywords you can enter and when people search these words in Google, your study’s advertisement will appear. For instance, if you are studying the effect of exercise programs in diabetic patients, keywords may include: “exercise,” “diabetes,” “treatment for diabetes,” and “lowering blood sugar.” Google has a multitude of helpful articles and FAQ articles that explain all aspects of the ad-making process.

Facebook and Google Ads both have helpful analytics that tell you about your ads’ performance, including the number of interactions, calls, and the types of people your ads are reaching. It is also important to note that Facebook and Google Ads charge you for the amount of “clicks” the advertisements generate (or by relevant interactions as defined by your campaign). Budgets set for online advertisements are cost caps, meaning if your budget is \$20 a day, your ads might only cost \$15 one day and \$17 the next. Though you may be charged less than the budgeted amount, daily costs will never exceed the \$20 limit. Always refer back to your budget to set aside enough funds for these advertisements. Keeping up with the latest trends in technology will certainly increase your chances for successful patient recruitment.

How to Track and Refine Recruitment

Funnels: the importance of a diversified approach

Recruitment funnels are different avenues of recruiting subjects and are a useful tool as described in a Michael J. Fox Foundation slide presentation.³ You may think of a recruitment funnel as one specific recruitment source. Each funnel should have a number and written name for easy identification. Funnels that start with the number should share a general theme. For instance, you can group funnels that start with the number one as clinics, and funnels that start with the number two as social media outlets. Examples of funnel names include “1.0_Memory Clinic,” “2.0_Facebook,” “2.1_Google Ads,” “3.0_Senior Center,” and so forth. If you have several memory clinics that you are recruiting from, be sure to distinguish by location.

Additionally, each recruitment funnel should have a one-page description on its unique process of subject recruitment. These documents will serve as a reference sheet for staff when recruiting potential subjects from a particular source. As a study progresses, you may need to adjust procedures for a specific recruitment method, and these changes should be reflected in the one-page funnel description. On the other hand, if a recruitment source is no longer a viable option, mark the funnel as archived to avoid confusion among staff (i.e. ARCHIVE_1.0_Memory Clinic). A template to create recruitment funnels is under the Practical Guides/Worksheets section.

Database reports to track success

You can also add recruitment funnels to your research database as a key variable field. When a staff member identifies and screens subjects, he or she can then tag the subject with the funnel used to find them. You can then run reports to see how effective that funnel has been. Research databases such as REDCap contain features that can help you track recruitment, such as REDCap’s data report feature. After adding “Funnel Number” as a field in your database, you can then choose to filter subjects by a specific funnel. An example of filtering for a source is below (Figure 3).

Figure 3. Filtering for a Recruitment Source.

The screenshot shows a filter configuration interface. At the top left, there is a red triangle icon and the text 'Filters (optional)'. To the right, there is a header 'Operator / Value'. Below this, there are two filter rows. The first row is labeled 'Filter 1' and contains the text 'funnel_run_number "Funnel Run Numt' followed by a dropdown arrow and a red 'X' icon. The operator is '=' and the value is 'M2_1.3_Sleep_Lab_Q'. The second row is labeled 'Filter 2' and contains the text 'funnel_run_number "Funnel Run Numt' followed by a dropdown arrow and a red 'X' icon. The operator is '=' and the value is 'M2_1.2 Sleep Lab Epi'. There is also an 'OR' dropdown arrow to the left of the second filter row.

Filters (optional)		Operator / Value	
Filter 1	funnel_run_number "Funnel Run Numt	=	M2_1.3_Sleep_Lab_Q
OR	Filter 2	=	M2_1.2 Sleep Lab Epi

Although using funnels in your research database is an easy way to keep track of where subjects are coming from, some platforms have an auditing system built in. The previous section about examples of recruitment pathways discussed that Facebook and Google Ads can track the advertisement’s success. Funnels can track recruitment generally in databases, but platforms such as

Facebook and Google Ad have tracking features that can provide a more in-depth analysis (time at which people view the advertisement, demographic variables, etc.). iConnect has a similar tracking feature that you can utilize across multiple types of campaigns. Using a combination of site-specific analytics, general reports, and in-depth analyses can help you navigate the nitty-gritty challenges of recruitment.

After creating recruitment reports and analyses, it is crucial that you take the time to routinely evaluate the results. Holding weekly recruitment meetings with study staff will help refine recruitment methods as time goes on, and develop new innovation pathways. For example, if you see that clinic referrals are providing more subjects than community presentations, then it may be pertinent to focus on adding more clinics to the recruitment roster, and to decrease the resources and time spent on community presentations. Reflecting on and revising recruitment strategies frequently will allow the study to adjust to changes and to identify potential setbacks before they cause major delays, problems, or expenditures.

Refusal survey

Even though there are common reasons for disinterest in research studies, it is still helpful to understand why people from your specific patient pool decline to participate. For those patients that decline participation, consider a few follow-up questions. This will enable you to modify recruitment methods in real-time. For instance, if 50% of those who are not interested in your study state the main reason for not wanting to participate is travel, then you can consider arranging for transportation through cab services. The best way to refine methods is by getting feedback from the population you are recruiting from. Making it easier for them to participate in the study will likely increase their interest levels and your recruitment numbers. Incorporating this refusal survey in your research database will allow you to analyze data more quickly than collecting data on paper. While it is useful to gather this information, patients may refuse to answer the survey and research staff must respect a patient's autonomy in research procedures. Keep in mind that the use of any type of survey, including a refusal survey, will need approval from the IRB. Below is an example of a refusal survey used in a clinical trial.

Administered as an open-ended format.

Options:

They will be asked to volunteer their reasons ---please check the reasons below when they explain. If they do not offer any reason, please read the name of the general categories (Compensation, Procedures, etc.) and that may help prompt them to explain further.

Question:

Could you please identify the reasons why you are not interested in participating in this research study?

Concerns regarding Compensation/Time:

- I am not compensated enough for my time
- I do not have time to commit
- Lack of lunch or other meals
- My study partner is not compensated enough for their time
- My study partner is not available
- My study partner is no longer available

Concerns regarding Procedures:

- I do not want to have a blood draw
- I don't really understand the study
- I don't think this study will benefit me
- I am afraid of study procedures (i.e. I don't want to have a brain MRI scan because I am claustrophobic or brain PET scan because of radioactive tracer)

Concerns regarding Travel:

- I don't want to drive into the city
- I'm traveling/moving
- Lack of transportation
- Parking too difficult

Miscellaneous:

- My doctor asked me not to be in the study
- I can't take my treatment/medications when I'm traveling
- Other
- Refused to answer

How to Train Staff on Recruitment

After selecting recruitment sources and creating a plan/timeline, the entire study team must be trained on proper recruitment procedures before engaging with potential subjects. After reviewing recruitment procedures, it is best to go through a practice run of the entire recruitment process with study staff, from start to finish. A mock practice run will help supervisors and research staff pinpoint parts of the process that need adjustment or additional training. A mock

recruitment run-through will also ensure that the databases, necessary applications, and workflow are properly working. Below is a helpful guide to consider when training study staff on recruitment.

Steps include:

1. Create a script for study staff to follow when asking patients to participate in the study.
2. Practice recruitment pathways themselves; walk through/roleplay funnel pathways so that staff understand each recruitment source.
3. Roleplay initial engagement with subject: have one staff member act as the “eligible participant” and another staff member act as the “research coordinator.”
 - a. Have both study staff members switch roles.
4. Go through the main consent and go through each of the questionnaires/assessments. If this interaction is being conducted by telephone, the “research coordinator” should send the link to the questionnaires and main consent via email to the “eligible participant.” This is to test if the database and applications are correctly working.
5. By the time the “eligible participant” answers the surveys and consent, ask the “research coordinator” to thank the “eligible participant” and to leave the room to assess the answers and randomize participants in a particular arm of the study (if randomization is applicable). If this interaction is through the phone, just assess the answers and randomize them thereafter.
6. Once this is complete, have the “research coordinator” verbally communicate and/or assist the “eligible participant” with the intervention.
 - a. Examples: Give the login instructions, provide a demonstration on how to set up the intervention, etc.
7. Have both staff members refer to the Time and Events table (see Chapter 6) to confirm they understand the study timeline and can communicate this to potential subjects.
8. At the end of this roleplay session, both staff members should be able to clearly articulate the purpose of the study, how the study is conducted, and why they are talking to potentially eligible participants.

While training staff members, encourage direct engagement by frequently pausing and asking questions. Alternatively, you may also ask other study personnel to oversee training and/or take notes during training sessions. This will minimize the negative effects of passive involvement in training sessions. It is also imperative to conduct routine training on recruitment procedures with staff to ensure there are no protocol deviations. Whenever there are changes to recruitment procedures, be sure to change study documents accordingly to avoid confusion among staff. Having an easy to understand recruitment structure for your study team will allow for smooth and efficient patient recruitment.

Practical Guides/Worksheets

Supplement 1: Template for Recruitment Graphs, provided by Sneha Rangu and meant to function for your specific study.

<https://docs.google.com/spreadsheets/d/1M8CtqrqC1L24kGvKkrbpG05vuY3HiUY9/edit?dls=true>

Supplement 2: Template for Recruitment Funnels, provided by Sneha Rangu and meant to function for your specific study.

https://docs.google.com/document/d/1VK6zG20wyh0igGHcNsHUz9hPXXKSHHiC_xifbZSPMmQ/edit

Conclusion

Successful clinical research can lead to transformative innovations in patient care. But this can only happen if the study can meet recruitment targets. Thus, you should place careful consideration on developing the recruitment plan, the backbone for meeting your study's aims. Creating a robust recruitment structure is a process; successful recruitment in a human subjects research study requires brainstorming, researching, tracking, and revising. It is equally important that all members of the study team are involved in the development of the recruitment plan. A streamlined and easy-to-follow recruitment approach for both patients and staff will increase the likelihood of meeting successful study completion. Maximizing study participation is one of the greatest challenges in research, but by exploring different recruitment methods and strategies prior to study initiation, you will be able to create a patient pool necessary for your study's purpose.

Resources

A Google Sheet checklist to assist with preparing your research proposal is available and includes a section with specific checklist items related to this chapter:

https://docs.google.com/spreadsheets/d/1Z5AvaQwQPawZ6OTEPmK0_QF6PAvhHICwwyjm1bdvzI/edit#gid=0 (a copy is also available at the end of this book). We encourage you to copy this master Google Sheet checklist to your Google Drive and edit it.

1. Patient Recruitment Timelines: <https://trialfacts.com/patient-recruitment-timelines-why-they-should-be-important-to-you/>
 - This resource provides information about the reasoning behind creating a patient recruitment timeline and the benefits of it.
2. Social Media: <https://www.mesm.com/media/1343/using-social-media-for-clinical-trial-recruitment.pdf>

- This resource provides helpful tips for planning social media recruitment campaigns, including steps to receive approval from your institution and/or social media websites.
- 3. Craigslist Ads: <https://productelevator.com/2017/08/31/how-to-recruit-user-research-participants-from-craigslist/>
 - This resource provides a step-by-step guide on how to recruit subjects from Craigslist, and supplies an example result.
- 4. Metrics to track/consider: <https://www.antidote.me/blog/clinical-trial-patient-recruitment-5-metrics-to-track>
 - This resource provides five key metrics to analyze when tracking the success of your patient recruitment.
- 5. Helpful Google and Facebook Guides: <https://trialfacts.com/facebook-advertising-patient-recruitment/> and <https://www.patientcentra.com/patient-recruitment-insights/google-social-media-improve-clinical-trial-recruitment>
 - These two resources explain key features and advantages of Facebook and Google Ads that researchers can utilize when recruiting patients through these services.

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<https://www.sciencedirect.com/science/article/pii/S155171441730753X> (86% statistic in intro)
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<https://www.openaccessjournals.com/articles/improving-patient-participation-in-parkinsons-clinical-trials-the-experience-of-the-michael-j-fox-foundation.pdf>
 (Michael J Fox recruitment funnels)

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