Patient Recruitment in Clinical Trials: Steps to Develop a Successful Enrollment Strategy
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Introduction

Recruiting study participants is arguably the most critical part of the clinical trial process; but it’s also one of the most challenging. During Forte’s 2017 national survey of over 900 clinical research professionals, recruiting enough participants to trial was identified as one of the top three pain points in clinical trial conduct.

So, why is it that such an important element of clinical research is also one of the most difficult to execute?

Strategic preparation is critical to successfully recruiting and enrolling qualified participants to a clinical trial. All too often research institutions take on a study without dedicating the necessary resources (time, effort and money) to develop an effective recruitment strategy, relying on their industry sponsor to already have a plan in place, or believing institutional name recognition will bring potential participants knocking. This approach to patient recruitment can result in low and slow patient accrual that negatively influences the clinical trial.

Under-enrolling studies come with a number of consequences that affect all stakeholders—sites, sponsors, patients and the general public. Not only can keeping low accruing trials open waste time and money, but it also diminishes the scientific validity of the study and raises ethical concerns for participants already enrolled.

To proactively prevent low accrual, it’s imperative for research institutions to build patient-recruitment strategies that are well-planned and fit within protocol budgets and timelines. This eBook outlines best practices to help your organization develop and implement successful pre-recruitment practices, build and launch strategic advertising campaigns and use metrics to identify and prevent under-enrollment.
Determining feasibility

Patient recruitment is a significant consideration when determining whether or not your team can agree to take on a study. The type of study, the number of participants required for a particular protocol, the available number of patients to recruit from and your ability to screen those patients are only a few of the factors to take into account during the feasibility assessment.
Explore your database of potential participants

The highest-quality and least-expensive participants to enroll are the ones that come from your institution’s own database. Individuals in your database already have a relationship with your organization, they’re familiar with your institution’s research and are likely interested in participating in research. For these reasons, any recruitment strategy you deploy should begin with an internal focus.

Search your EMR

Conduct an analysis of your electronic medical records (EMR), with IRB approval as needed, to see how many participants are already coming in with the desired qualifications:

- Do you have an adequate population to accrue the required number of participants?
- Are you reasonably able to reach these potential participants?

- Is the population adequately representative for the protocol?

It’s also important to determine if and/or how many protocols with similar criteria are already open at the institution. Competing studies can complicate your recruitment efforts by limiting your eligible participant population.

Engage area physicians

Assess which physician networks and hospitals would be willing to help you recruit through referrals.

- Do these organizations have sizable populations of potentially qualified patients?
- What is your plan to encourage referrals?

Physician referrals are invaluable to patient recruitment efforts, as they are one of the most efficient means of finding and enrolling qualified patients. However, some physicians may be concerned they will lose their primary care patients if they refer them to a trial. Be sure you have a plan in place to work with physicians and effectively communicate your efforts and intentions.
Assess past enrollment performance

Data is incredibly valuable to completing an accurate feasibility assessment. If you’ve conducted similar studies in the past, look at how well you accrued patients to those trials. This assessment could include studies you’ve conducted with the same sponsor or sponsor type, same trial phase and/or the same condition. Understanding your past performance will help you determine a more accurate and feasible enrollment estimate and will allow you to adequately manage finances and staff resources if you take on the study.

Understanding the right metrics to use to predict enrollment begins by knowing the questions you’re trying to answer. When assessing the enrollment of past studies, a few common questions include:

• How many total participants did we accrue to this trial?
• Did this trial meet target enrollment?
• What did our accrual timeline look like?
• Were there any delays caused by low or slow accrual?
• How many screen failures did we see for this study?
• What recruitment campaigns were utilized in the study?
While the path to uncovering the most effective metrics to measure your operational performance requires significant consideration, here are a few common metrics that can be useful when assessing past performance to determine feasibility:

**Number of participants enrolled**
This metric tells you how many total participants you accrued to a trial (consented and eligible). You're likely to accrue a similar number of people for similar studies, particularly those in the same therapeutic area.

**Open to enrollment to first participant in**
Find out how long it took to enroll your first participant to trial. If it took a significant amount of time to accrue one person, it could indicate that a different recruitment method is needed or that this is a difficult study type to accrue to. Use this metric as a starting point for additional investigation into past problem areas.

**Percent target enrollment met**
Use this metric to see if and how much of the enrollment goal was achieved for past studies. If this percentage is low, it doesn’t bode well for future studies with similar criteria.

Metrics are a powerful tool to help you make educated decisions about study opportunities. Take past performance into consideration before you agree to a study so you (and the sponsor) can be confident you’re capable of achieving the required enrollment numbers.

**Tip**: Provide an honest enrollment estimate to your sponsor up front. Giving your sponsor numbers that are unfeasible for your population could set your site up for failure before you even activate the study.
Ask your sponsor feasibility questions

If the clinical trial is sponsor-funded, there are a number of questions that are necessary for you to ask to gain a better understanding of what will be required of your site. Here are a few that are most significant for enrollment planning:

• When did you open the trial to accrual?
• How many sites are currently accruing participants?
• How many sites within XX miles are accruing to this study?
• How many participants have been accrued already?
• Will you give us a ready-made recruitment plan?
• If yes, have materials for this plan already been IRB-approved?
• How successful has the recruitment campaign been?
• What is the recruitment budget?

• Will we need to develop our own internal tools in addition to, or as a replacement, to yours to get the population we need?

The number of sites currently accruing patients can be particularly significant when assessing enrollment feasibility. If there are multiple sites actively enrolling participants to the same study, and you’re the sixth or seventh site opened in your area, it’s possible the pool of participants could already be depleted.

Tip: Go onto ClinicalTrials.gov and see which institutions are open to enrollment for this study in your area.
Conduct a SWOT analysis

As a research team, analyze the strengths, weaknesses, opportunities and threats (SWOT) of a protocol, both specifically for enrollment as well as the many additional aspects of a trial, to help your site identify potential issues and drawbacks before you agree to take on the study. The SWOT analysis is a common tool used in many industries to help individuals and organizations consider all of the potential impacts of a decision before it is made. With the help of your research team, determine 3-4 points that fit into each of these categories:

- Strengths
- Weaknesses
- Opportunities
- Threats
**Strengths**

In this section, consider what appeals to you about the protocol and how it emphasizes your internal site strengths. For example, discuss:

- What about this protocol do you think will work well at your site?
- Does your site specialize in this therapeutic area?
- Does the public recognize your organization for its expertise in this area of research?
- Have you previously accrued an adequate number of participants for similar studies?
- Do the eligibility requirements align accurately with a significant portion of your participant population?

**Weaknesses**

Like the strengths, this section should focus on how the protocol relates to the internal weaknesses of your site. For example, discuss questions like:

- Does your site have the resources to accrue an adequate number of participants?
- Are there trials open to enrollment that could compete with this study?
- Have you previously seen low enrollment for this type of disease?

**Opportunities**

In this section, determine external opportunities that exist for your organization as well as any other peer institution. For example, consider:

- Could this protocol advance treatment options and/or prevention for the studied condition?
- Will taking on this study bring your institution substantial return on investment (i.e., recognition, capital, experience, etc.)?
- Would taking on this study increase your database of people potentially eligible for additional trials?

**Threats**

Like opportunities, this section should focus on the external threats for your institution as well as your peer institutions.

- Would this study be competing with other open trials in your geographic area?
- Is the protocol exploring a common condition that is widely researched?
- Are other institutions more known for research in this therapeutic area?
Chapter 2

Building an advertising strategy

Marketing and advertising have become more sophisticated in past years, and you’re now able to spend advertising dollars more intelligently. Whereas with traditional marketing you would blast a single product and message to the masses, you now can deliver specific and targeted messages that resonate with a specific group of people. Personalized messages drive people to take action much faster than a message for the masses.

So, who is that specific audience? The keys to marketing aren’t your logo or the colors you use—it’s knowing your audience inside and out. Once you know your audience, you can begin to craft the right strategy and message to reach that the right participants.
Define your target audience

Before you start reaching out to potential participants, take the time to research and understand who it is you’re trying to reach with your recruitment efforts—what is your target participant population?

Answer these questions to maximize the effectiveness of your recruitment plan:

Who is your ideal participant?
The inclusion/exclusion criteria associated with the protocol is a good place to start when answering this question. Identify the target demographics of your ideal participant, including factors such as gender, age, location as well as specific protocol requirements. Determine where the peak prevalence/incidence rates are, and let that information guide your recruitment strategy.

However, be careful not to limit your reach too much. If your specifications become too narrow, it may be tough to market to that group; keep your defined population as high-level as possible.

Where does your ideal participant go for information?
To know where to publish ads to promote a trial, you need to know where your audience will see them. What channels do they visit?

Demographics often play a key role in where a patient is most likely to search for information. For example, a 19-year-old patient is probably more likely to search social media sites, whereas a 70-year-old patient may find information in a newspaper. Choose the information outlets you know your audience will be using, eliminating the need to advertise in places that will provide little to no results.
How does your ideal participant engage with advertisements/content?

To increase the likelihood that your ideal participant will pay attention to your study ads, you need to know what types of content they are most likely to engage with. Is your audience more likely to download something? Or would they rather hold a pamphlet in their hand? Do they prefer to read a blog post? Or are they more likely to watch a video ad?

Think about how your target audience would engage with the content you are looking to provide. Multiple internal and external factors can affect the type of content a patient is most drawn to, including literacy, attention span and available time. Adapting study ads into the easiest and most enjoyable format for your ideal participant will likely provide better results.
Develop messaging that resonates with your audience

Again, delivering a message that resonates begins with knowing your audience. Look back at your target participant population and determine what might motivate them to participate in your clinical trial.

- Are they seeking new treatment?
- Will they benefit from the medical exams that will be provided free-of-cost throughout the study?
- Is lack of health insurance inhibiting their treatment options?

Also consider whether or not your target population is motivated by altruistic reasons.

- Is it motivating for people to know they’re contributing to the research community?
- Do they know someone affected by the study disease?

Take your identified motivators and try to find the most meaningful message for that population. Determine what message will drive your ideal participants to find out more about your trial. All the while, remember that your messaging must be IRB-approved and void of any potentially coercive content.

**Tip:** Don’t be afraid to explore the emotional side of advertising to provide relevant and resonating messages for your population.
Establish your online advertising database

As you’re engaging with potential participants it’s important to collect their email addresses. This allows you to follow up with them to provide additional information and content that could lead them to take action and agree to participate in your trial. Even if the participant isn’t interested in the study you’re promoting now, they might be interested in a future study you conduct.

However, it’s important to note that you need to gain an individual’s permission if you want to communicate with them via email. The Federal Trade Commission (FTC) has very clear rules about email communication in the CAN-SPAM Act. Permission is clear consent from the individual to receive marketing communication in the future. This can be accomplished by adding a checkbox to your email sign-up that clearly states an opt-in to your email communication. For example: “I agree to receive e-mails from X company for information about future studies and organization news.”

Tip: It’s good practice to be up-front with your participants when it comes to email advertising by letting them know what they can expect from you. This helps build trust with those in your database and could influence their choice to engage with your site in the future.
Create compelling and valuable content

Instead of pushing information on your population, deliver helpful and valuable content that attracts the right participant. Think about what content is helpful for your population. What can you provide potential participants that they will be grateful for?

Delivering content that’s genuinely useful for your target population builds trust with potential participants. Having already gained value from your content, they may be more likely to take action and learn more about your study. A blog can be a very easy way to create content on your website that continues to bring people back to your site and encourages engagement. Blogging is also a great way to connect with your community in general and share the purpose of why your organization conducts clinical research.

Tip: Participant quotes and social proof are a great way to encourage positive perception of your site. A common statistic says 90% of people will believe social proof from someone they don’t even know as opposed to an advertiser.
**Tip:** It’s also important to think outside of the box when determining where to put your advertising materials. While the essential 3 L's and 3 P’s could get your message in front of the right people, a different tactic may prove more engaging and encourage greater action from your ideal participants, such as mailing a brochure along with people’s water bill to build far reaching awareness.

**Know where to put your advertising materials**

Once you have your messaging and advertising materials, you need to know where to put them to connect with the right population.

Consider tactics for building clinical trial awareness by developing an understanding of your target population and placing advertising materials where they live, learn, labor and pay, pray, play. This framework was developed by Karen Brooks, PhD candidate at Trident University, and she calls it the 3 L’s and 3 P’s. Its principal is that exploring the everyday actions and priorities of your ideal participant can help you think deeper about how and where it’s best to reach them with your messaging. If you know your audience well enough, you know where all of these places are.
Deliver a clear call to action

A critical part of any advertising campaign is a clear call to action. Determine what you want people who see your advertising to do and make sure it’s very clear what their next step is.

- Do you want them to call and sign up for more information about the trial?
- Should they attend an info session you’re hosting?
- Would you like them to provide their email address?

Tip: Your call to action should be obvious enough that if someone skims your content, whether it’s a blog post or brochure, they know what action they should take. Make it as easy as possible for your ideal participants to take the next step.
PATIENT RECRUITMENT IN CLINICAL TRIALS

Chapter 3

Launching your recruitment campaign
Determine where to spend your money

One of the most important aspects of your recruitment campaign is your budget. When budgeting for recruitment advertising, you always want to create context by defining your goal. Ask yourself, how important is this protocol to your site this year? What is the potential return for your organization?

Where to put your dollars

There are many targeted marketing options today that allow you to be hyper-specific about the population you are targeting and eliminate wasted advertising. When building your budget, try to set aside funds for:

- Paid ads
- Social media
- Google ads
- Local TV
- Magazine and radio
- Print materials
Google AdWords is another good place to put your dollars. This tool allows businesses to purchase keywords or phrases that trigger ads to appear on the search results page. When used well, it can be very successful for gaining awareness, as it allows you to be strategic with keywords unique to you.

**Tip:** If applicable, contact your institutional public relations team or communications center. Talk with them and see if they’re willing and able to partner with you to spread the word about your clinical trial. It’s possible they’ll help you advertise, or at the very least, give you best practices for your campaign.

**Saving costs with free resources**
There are a lot of low to no cost advertising options out there that can help you get your message to the right individuals, including:

- **Organic social media:** Social media that you don’t put dollars behind
- **SEO:** Optimizing your web content to include specific phrases and words you know people are searching for to increase your chances of being indexed on the Google search platform
- **Email campaigns:** Once you have someone’s email, you can contact them for free or low cost
- **Word of mouth:** Social proof is incredibly valuable, particularly when coming from someone the individual knows.
Prepare your advertising materials

Creating your advertisements is a big step in getting your campaign up and running. Use the messaging you developed in the previous steps to build well-crafted advertising materials that appeal to your target population.

Develop the creative for your campaign
You know your target population, you have your messaging, now it’s time to put together creative imagery that resonates with the right individuals. Free tools like Canva allow you to easily create custom graphics for everything from social media posts to business cards to flyers.

Remember to update your creative to meet the requirements of each separate channel. For example, the images on a brochure are going to require different dimensions than a Facebook post. However, while each channel may require different graphic elements, the look and feel of your campaign should be consistent across all materials.

Update your website
It’s likely many of the call-to-actions in your web content will be to visit your organization’s website for more information. Before you post your advertisements anywhere, ensure your website has the necessary information prospective participants need to make the decision to participate. Include information about your research site and the clinical trial as well as contact information for the right staff members. Make it as easy as possible for people to take next steps.

Internally communicate the launch
Don’t underestimate the importance of communicating your advertising campaign internally at your organization. Notifying your site staff, as well as other institutional departments, that you’re advertising for a particular study can encourage sharing and word-of-mouth recommendations, dramatically increasing your advertising reach.
Schedule Social Media posts and ads
If you’ve decided your target population is likely to engage with ads on social media, it’s important to consider these tips to help build successful posts:

Make sure your message is appropriate for the idiosyncrasies of each platform: Not only does each platform have unique message requirements (Twitter limits the number of text characters to 140), but your audience uses each platform for different reasons. Alter your message to align with the reason individuals use each platform. For example, a post on Facebook may be more sociable and visual, whereas a post on LinkedIn may be more formal and discussion-based.

Be familiar with each platform’s algorithm for posting on people’s timelines: For example, Twitter posts can be quickly buried in a matter of minutes, while LinkedIn posts tend to resurface for weeks.

Have a schedule for when and what you will be posting to each platform: Don’t be afraid to post a variety of different versions of your ad on the same platform throughout a designated time period. This can help guarantee more people see your ad and allow you to experiment to see which ads are more successful.

Meet the image requirements for each different platform: This will ensure your creative elements display correctly and nothing is skewed or misinterpreted.

There are a lot of free tools you can use to get your social media ads out there, including the platforms themselves. If your site has a company page on Facebook, LinkedIn and/or Twitter, you can easily create and track the progress of your post engagement as a page administrator. Hootsuite is another free tool that allows you to schedule posts for multiple platforms in a single location and provides growth and engagement analytics.
Gain regulatory approval for recruitment materials

It takes a lot of work to get everything you need to start your recruitment campaign on the right track. But, along with developing a strategy to provide the most relevant advertising to your target population, you also need to ensure compliance. It’s essential to make sure all of your recruitment efforts fall in line with your IRB and other institutional policies.

What to get approved

Do your advertising materials need IRB approval? The answer is very likely, yes. As a general rule of thumb, any material that you will be putting in front of a potential study participant needs to have prior IRB approval.

Doctor-to-doctor and researcher-to-doctor communication likely needs IRB approval, as well (check with the IRB of record). For example, if you were to send information about a protocol (inclusion/exclusion criteria, etc.) to physicians to encourage participant referrals.
**Best practices for gaining approval**

When submitting your recruitment materials for approval, it’s best practice to also submit the type of media you’ll be using. Give the IRB a sense of not only of the information you’re presenting to potential participants, but also the context that it’s in. If possible, include pictures, mock-ups and/or scripts when appropriate.

You’ll also need to submit a plan for how you’ll be using the materials. Provide the who, what, when, where, why and how for everything you submit. Tell the IRB:

- How the materials will be used
- Who the intended audience is
- What you’ll be using to display them
- When and where they will be used
- Why you chose this medium

This comprehensive information will give your IRB the necessary context to help them approve your campaign.

**Tip:** Be “specifically vague” about where things will be located. Including specific websites, social media sites and physical locations for approval means those are the only IRB-approved locations for your advertising materials.

Certainly, tell your IRB necessary location information, but don’t limit yourself by being unnecessarily specific in where the materials will be posted. For example, instead of saying you’re going to post an ad on “www.favoriterecruitmentsite.com” say you’re going to post the ad on “recruitment websites such as www.favoriterecruitmentsite.com, www.otherrecruitmentwebsite.com, etc.”
Chapter 4

Tracking your progress
Know your conversion rate

Tracking the appropriate data is key to both ensuring your advertising campaign is successful and preparing you for the next phase of recruitment. Organizing the follow up of your recruitment campaign is critical to seeing return on your invested efforts; and knowing how many participants you should expect to accrue will help you estimate the amount of time and resources you should arrange for tasks such as screening and scheduling visits with participants.

Understand what to expect

Take a look at both your protocol feasibility assessment and your advertising strategy to determine the goal, milestone and conversion rate for your recruitment advertising campaign.

- **Goal**: How many participants do I need to accrue to this trial in order for it to be successful?
- **Milestone**: How many people do I need to view my advertising materials in order to reach my goal?
- **Conversion rate**: The percentage of individuals that view your advertising materials and ultimately qualify and agree to participate in your study.
Finding your conversion rate

Determining the conversion rate for your recruitment campaign can help you establish the amount and scope of your advertising, and inform your strategy for distribution and channel. It can also give you a better understanding of the amount of resources you can expect to dedicate to follow-up tasks. The more you track and measure your conversion rates, the better prepared you'll be for the individuals that respond to your recruitment campaign.

The best way to get an accurate estimate of your conversion rate is to look back at the data for similar studies conducted at your institution. However, if you’re starting out with no historical data, a 10% conversion rate is a pretty realistic general starting estimate. For example, if you know your goal is to accrue 100 ideal participants for your study, you may need to reach about 1,000 people with your advertising materials for a 10% conversion rate.

When estimating your conversion rate, it’s also important to take into account factors such as:
- Ineligible, screened respondents
- Referrals that decide not to participate
- Potential trial dropouts
Preparing for participants

Following up with interested respondents in a timely manner is critical to accrue enough qualified participants. For some sites, this follow up is the point of failure for their recruitment efforts. Often in these cases, the site is not adequately prepared for the amount of effort required to process referrals and/or pre-screen individuals, leading to lost participants and wasted resources.

Review the strategy you established for your advertising campaign to help you develop an effective plan for responding to incoming participants. Ask yourself:

- Are you conducting broad, traditional media campaigns and are expecting a large influx of respondents?
- Are taking a targeted approach to your social media advertising and expecting a smaller more specified group of respondents?
- Will respondents require primary and/or secondary prescreening from your site?
- What is your expected frequency of respondents over time?

A well-established plan can streamline the process for screening participants and scheduling visits, and help you avoid feeling overwhelmed by a potentially increased workload.
Best practices for higher conversion rates

Throughout the process of your recruitment campaign it’s important to keep track of your conversion rates to ensure your strategy is effective and you’re allocating resources to the right tasks. If you find your conversion rate for the study is surprisingly low, take the time to understand the root cause of the problem. Is it a lack of information about the recruitment strategy from your sponsor? Was study staff unprepared for the frequency of calls coming in from participants?

Consider these best practices to avoid common missteps in recruitment follow-up:

Ensure you have the necessary resources: Look over your recruitment campaign and outline your plan and process for following-up with incoming participants. Include considerations in your plan like frequency of calls, number of available visit times and dedicated work effort.

It’s also important to ensure your plan is adequately supported financially.

If you’re working with a sponsor that has a recruitment campaign, try to understand what they’re going to be doing to build awareness and when. Are they going to be launching a national TV ad? Or are they going to do targeted community outreach events during certain months of the year? Make sure you have the staff and appointments available to coincide with their recruitment strategy.

Understand the pre-screening process: If you’re conducting your own site-initiated recruitment campaign, prepare your prescreening script to sufficiently rule out individuals that are unqualified and have it approved by the IRB. Determine what staff will be following up with incoming respondents for prescreening.
When working with a sponsor, get as much information about the prescreening process as possible. Find out if they’re going to have an online pre-screener or a call center. Ask to see the script to make sure you really understand the criteria they can realistically filter out, and what you’ll need to screen out at a secondary level. Prepare your secondary screening script and gain necessary IRB approval. Understand what type of prescreening funds are going to be available to you. If you have to prescreen 40 patients on the phone to get one scheduled, that’s work effort on your part that’s often not included in your budget.

**Determine a threshold for “turning off the funnel”:** Expect that the percentage of conversions will likely be low and determine a reasonable limit for stopping or revising the recruitment process. If you’ve prescreened 50 referrals and haven’t accrued any of them to the trial, it may be time to reassess your recruitment strategy.

It’s also important to determine a limit for your efforts when working with a sponsor. Keep lines of communication open and provide your sponsor with feedback to help them fine-tune the message, channels and other elements of their advertising strategy.
Avoiding recruitment disaster

Tracking conversion rates is one way to preemptively avoid operational problems during patient recruitment. However, managing follow-up for incoming participants is just one element of your recruitment campaign that could cause problems.

It’s critical that you regularly meet with your research team to proactively troubleshoot problems throughout the course of your patient recruitment campaign and ensure your trial is on track for success. Unless you’re taking a solid look at a study during regularly scheduled meetings, a failing protocol could go unnoticed among more successful protocols. Determine a frequency for your meetings and stick with it—be it weekly or daily, depending on work schedules.

During these meetings with your team, review:
- How many people your staff has screened
- How many they’ve accrued
- What the screen fail rate is and if it is changing
- The rate of people they’re screening and if that has changed

If there’s a decrease in the amount of people you’re accruing and/or the amount of people being screened, it could mean your population pool is drying up and you may need to amplify your advertising campaign to reach your target accrual number.

Tip: Research analytics tools can help you stay in touch with the progress of your study accrual. Having a comprehensive way to visualize your data can help you and your team easily identify and address problem areas in your recruitment campaign before they cause further damage to the success of your study.
Conclusion

Recruiting participants can be an arduous process, but starting with a well thought out plan and optimizing your efforts can save your organization time and money. As one of the top challenges in clinical research, patient recruitment requires strategic preparation on the part of research institutions to ensure a clinical trial is on the right track before it is even opened to accrual.

Effective pre-recruitment practices, a strategic advertising campaign and a thorough use of metrics can help you prevent under-enrollment and ultimately meet your recruitment goals. Take a look at the following page to find more resources to help you develop effective practices for patient recruitment and other essential clinical research operations.
Find more content at ForteResearch.com

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