inHealth
We Own Enrollment

7 Questions

To Ask Before Hiring A Patient Recruitment Partner

(And bonus content at the end too!)

00
Introduction

Clinical trial success hinges on finding the right patient recruitment solution—and asking potential partners about expertise, experience, and engagement methods can help you learn quickly whether they're the right partner for you.

1. How do you ensure diversity in representation?
2. Do you have a full-funnel communication strategy?
3. How secure is your patient data collection?
4. Does your approach change depending on the study TA?
5. What key metrics do you use in your patient enrollment?
6. What is your patient screening process?
7. What are your contingency plans if we don't hit enrollment?

★ Bonus Content! 1nHealth's Rubric for good answers

01
Diversity

How does your patient recruitment company ensure diversity in representation in clinical trial participants?

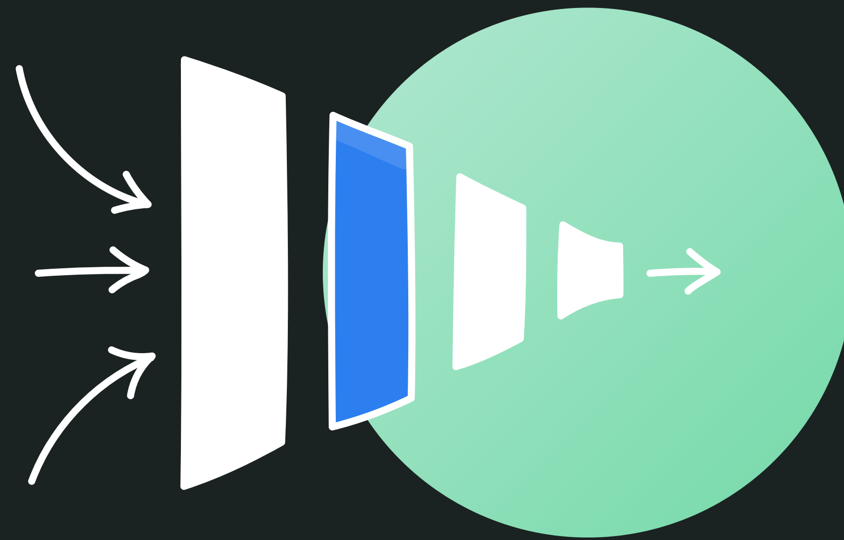
DEI—or diversity, equity, and inclusion—is a key component for any clinical research trial. The more diverse your participants, the more applicable your findings will be to the broader population. The U.S. Food and Drug Administration agrees, issuing new draft guidance in the hopes that it will help enroll more patients from underrepresented minority populations saying “despite having a disproportionate burden for certain diseases, racial and ethnic minorities are frequently underrepresented in biomedical research.”

While some demographics have to fit within a specific range (such as age or locale) your next patient recruitment company should be as proactive as possible in bringing you a diverse participant pool, so make sure you ask specific questions including:

- What are your outreach methods for underrepresented populations within the community?
- How do you overcome certain cultural barriers, such as language or social etiquette?
- Can you provide examples of how you’ve overcome participant diversity challenges in previous enrollment campaigns?

02

Comprehensive



Do you have a full-funnel communication strategy to maximize patient engagement and ensure enrollees actually join the clinical study?

It's crucial that there's consistent communication with participants and follow-up during the entire process. Patient recruitment requires a full-funnel communications plan, and identifying a potential participant with a compelling ad is only the first step.

Once a patient displays interest, following up with relevant health information, offering to answer any questions they may have about the trial itself, and friendly reminders to fill out any medical authorization forms or pre-screening documents increases the likelihood they will join your clinical study. Discover more about a patient recruitment company's communication plan with questions such as:

- What communication channels do you use to reach potential participants, and how do you leverage digital technologies to maximize your efforts?
- How much time elapses between each of the steps in your patient follow-up strategy?
- How flexible are you in modifying your communication strategies based on the progress of the recruitment process?

03
Security

How secure is your patient data collection, and what steps do you take to ensure that you're HIPAA-compliant through the entire process?

One of the most frequent challenges we see in patient enrollment is the fear that a participant's health data won't be kept safe and secure.

Ensuring that a recruitment company's methods are in compliance with HIPAA is crucial for protecting the privacy of potential enrollees.

Here are some questions you can ask to measure how responsibly your next recruitment partner is in gathering health data:

- How do you gather, store, and transmit participant health data in a way that complies with HIPAA regulations?
- What steps do you take if there's been a security breach?
- What do you do with patient data once the trial is completed?

04

Consistency

Does your approach to patient recruitment change depending on a specific therapeutic area of study?

Your patients are online no matter what. Insider Intelligence predicts that 90% of North Americans will be internet users by the end of 2024. Patient recruitment is now therapeutic-agnostic, which means that sophisticated digital targeting strategies and compelling advertising are at a premium—as compared to expertise in a specific therapeutic area of study.

Ask these targeted questions to discover if your patient recruitment company is the right fit for you:

- What are some examples of clinical trials in diverse therapeutic areas that you have successfully recruited for?
- What are some common challenges to patient recruitment across all therapeutic areas, and how have you overcome them in the past?
- What processes do you have in place for regular improvement across diverse therapeutic areas?
- Do you have previous positive results from a new translatability assessment? What elements of your strategy are repeatable?

05

Intentional

What key metrics do you use in your patient enrollment? How will your company measure “success” once the campaign is complete?

In short, what does your patient recruitment company think success looks like? For example, if your goal is to enroll a certain number of patients in a short amount of time, you’ll want to partner with a patient recruitment company that places a stronger emphasis on average recruitment rate and efficiency.

But if you have more lead time, a balanced approach with a higher initial reach, could be more helpful. In short, make sure you’re on the same page so that you’re focusing on metrics that directly affect the success of your study. Ask these questions to see if you and your potential partner are on the same page:

- What were the specific goals of your last patient recruitment campaign, and how did you achieve those results?
- Can you talk about a strategy or initiative you’ve recently employed that made a big difference in success rates?
- If you had an additional 12 months to achieve the results we discussed, how would that change your campaign strategy?

06
Thorough

What is your patient screening process? Do you have anything in place that will make it easier for site staff to onboard patients?

One of the most important aspects of patient-centric recruitment is effective communication.

Is it as simple as creating engaging digital ads and ensuring screening questions are easy to understand? Or has the patient recruitment company found that phone calls and mailers increase the likelihood they'll find quality enrollees?

Here are some questions to ensure your partner isn't spending unnecessary time and money attempting to engage patients:

- Do you have a specific screening process in mind for this campaign, or do you have a general screening process across all trials?
- Is the screening process fully automated before site referral, or do you have someone reaching out to patients with things like secondary phone screens and telehealth visits?
- Can you provide an example of a screening process that wasn't going according to plan and how you fixed it?

07
Risk Mitigation

Do you have contingency plans in place in case we don’t hit our enrollment numbers? Will it increase our budget or study timeline?

Even the best patient recruitment companies can encounter unforeseen challenges, no matter how experienced they are. The National Institutes of Health reported that “more than 80% of trials fail to enroll on time” leading to costly delays. You don’t need the NIH to remind you that delays are costly, but help in avoiding them in the first place is probably welcome.

That’s why learning how companies mitigate risks and navigate problems is important. How flexible are they with their processes? Are they experienced in making changes in the middle of their campaign? By asking questions that focus on their ability to overcome adversity, you can get an idea of how equipped they are to see your clinical trial enrollment through to completion:

- How do you proactively identify and assess risks that could impact patient recruitment?
- Can you provide an example of when you needed to make an adjustment mid-campaign to meet an enrollment deadline?
- What is your process in quickly ensuring that a change you want to make is in compliance with regulatory standards?

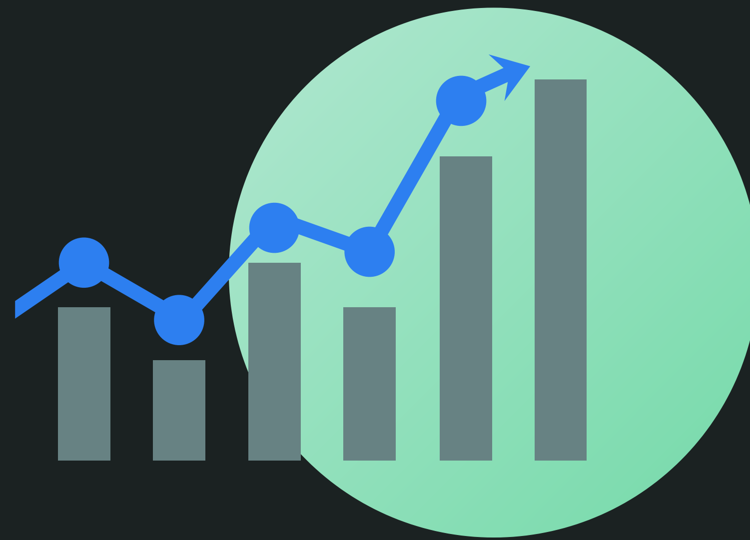
Bonus Content

You won't find this anywhere else!

Since you've made it this far, we thought it'd be nice to give you some bonus content.

What follows are some very pointed questions and a helpful rubric for evaluating answers—as well as dive deeper into additional themes and concepts that were mentioned. That way you're even more prepared for conversations with potential providers.

Representation



How will you ensure diverse representation?

Patient recruitment companies outlining their strategy is one thing. Ensuring representation in your clinical trial is another. If you're serious about representation, give firm targets and ask the company if they can include those in the budget. That way, the goals are clear and everyone's on the same page.

For example…
"We need a greater than 20% share of participants from groups historically underrepresented in research. Can you provide that?"

(And by the way, if you ask 1nHealth that question, we'll say yes—but be prepared for the budget to be higher.)

Safety

What's your current level of data security?

Anything less than a custom platform using secure cloud-based storage is likely in a gray area or worse. Ask potential providers how they store patient data, make them walk you through every step, and get specifics on all the software and solutions involved in the process.

Full-Funnel

Do you have a full-funnel communication strategy?

Imagine ordering something on Amazon and not receiving a confirmation email immediately after. You'd think something went wrong and that your purchase didn't go through. You'd be frustrated. You'd be refreshing your inbox every 30 seconds to make sure everything's alright. That's how patients feel when our follow-up communication is inconsistent and infrequent. Recruitment providers should aim for zero surprises as the standard, and every step of the journey should prepare a patient for what's coming next.

Communication should also be on the patients' terms, which usually means texting, emailing, and then calling—in that order. Adopting an omni-channel messaging approach ensures that patients are reachable no matter what.

Transparency

What metrics do you use?

Impressions and clicks are not meaningful, and form-fills are barely better. Unfortunately, “randomized per site per month” metrics can be meaningful but often lag so far that things can be dire before study teams realize there’s a problem.

Every stage of the journey should have target metrics for conversions (how many patients moved forward out of all possible participants?) and transit time (how long did a patient stay in a particular stage of the journey?).

If you break the patient journey into specific segments, recruitment vendors should be able to tell a coherent narrative. For example, going from “qualified referrals” to “pre-screened” (a status achieved after completing a secondary phone interview) to “study visit one scheduled/attended” and ultimately “consented and screen-failed/randomized” helps you identify any problem areas in the recruitment process.

If your provider can’t track this, or won’t share it with you, you’re taking an unnecessary risk.

Qualification

Can you describe your screening process?

Almost all digital providers will produce an online questionnaire and use form logic to qualify or disqualify patients based on their responses. Asking sites to follow up with every single form response is too heavy a burden in most cases. Not all sites have specific staff dedicated to recruitment, and those who do never have staff dedicated to recruitment for a specific study. Deploying a committed resource to ensure timely follow-up during screening has a transformative impact on success rate.

It's also critical that your recruitment provider have some insight into what is happening at the site level so they can amend the screening process if needed. There's no sense in continuing to refer patients who could easily be screened out with one or two additional questions.

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