

Report

# A **Guide** to Patient Engagement and Recruitment Solutions



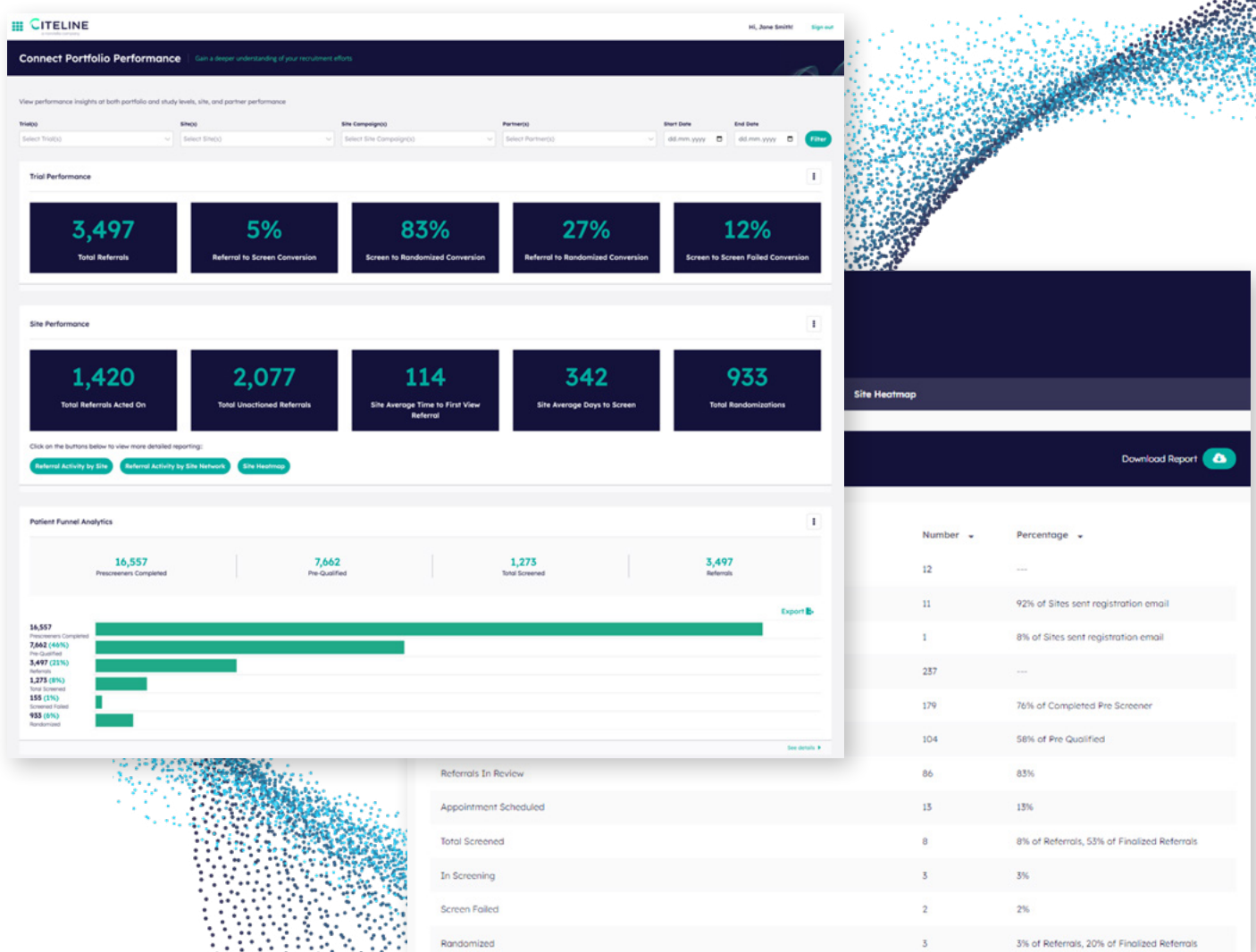
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# About the Guide

Clinical trials have grown in complexity over the past decades, making it exceedingly difficult to recruit patients to participate. An estimated 86% of clinical trials do not meet their initial patient enrollment target and timeline, and close to one-third of all Phase III trials fail because of enrollment problems.<sup>1</sup> Delays caused by under-enrollment can result in lost revenue of as much as \$8 million a day for drug developers.<sup>2</sup>

This guide touches on some of the most common challenges faced in clinical trial patient recruitment and provides tips on how to best address them through the use of a patient engagement and recruitment solution.



## Market challenges

As much as clinical trials have changed over the years, one thing remains constant: the battle to recruit participants. Sponsors and sites face many challenges in patient recruitment, but some of the more critical are...

### Lack of patient awareness of trial opportunities

The good news is patient awareness of clinical trial opportunities appears to have improved. According to the Center for Information and Study on Clinical Research Participation (CISCRP), 57% of respondents to its [2023 Perceptions & Insights Study](#) who have never participated in a clinical trial remember having seen or heard about a clinical research study that was seeking volunteers in the past six months.<sup>3</sup>

Still, that leaves 43% who do not recall seeing or hearing of any ongoing studies. This strongly indicates sponsors and sites are not reaching all potential trial candidates with their current recruitment efforts.

### Limited recruitment pools

When it comes to patient recruitment, site investigators often start with their own database to source and prescreen potential clinical trial candidates. This can be limiting in terms of size, recruitment area, therapeutic focus, and whether the data records in question are up to date.

According to CISCRP's Perception & Insights study, 46% of respondents who have never participated in a clinical trial prefer to hear about these trials online, and 48% of those respondents prefer to hear about them through social media.<sup>3</sup> Yet when going beyond their own databases, sites tend to use more traditional advertising methods for recruitment, which may not reach all available patients. Sites sometimes avoid advertising on social media and search engines because of a lack of expertise and experience with the regulations involved.

Competition is another limiting factor. A site recruiting for a study may be competing for the same patients with sites running similar studies in the same region. This is especially true for rare diseases, which have an inherently limited patient population.

### Inability to reach diverse patient populations

In recent years, especially in light of the US Food and Drug Administration (FDA) guidance mandating Diversity Action Plans for certain clinical trials, sponsors have increased efforts to seek out hard-to-reach patient populations. However, there is much room for progress.

According to the FDA's Center for Drug Evaluation and Research (CDER), white patients comprised more than 50% of the trial population enrolled for all but three of the 55 novel therapies approved in 2023.<sup>4</sup> That means 95% of approved drugs for the year had a majority white trial patient population.

Diversity covers a wide range of demographics, including racial and ethnic minority, gender, LGBTQIA+, age, and disability. Overly restrictive inclusion/exclusion criteria could summarily preclude individuals in underrepresented groups from participating in clinical trials. Failure to include diverse patients in a clinical trial can affect the quality of the study and lessen the validity of its results.<sup>1</sup>

### Site burden

Sites frequently face numerous challenges in patient recruitment and enrollment. For instance, it can be tough for sites to find candidates who fit all the criteria in a complex clinical trial protocol.

Given they are often managing multiple studies at once, sites may have inadequate staffing and operational inefficiencies that prevent them from closely tracking and reporting recruitment efforts. The use of multiple software platforms and formats can also make it hard to monitor recruitment activities.

## Missed patient follow-up

A potential trial candidate can drop off the radar at multiple points along the recruitment journey. The patient may not receive a phone call or email, or may be unable to visit the site for a screening. Overburdened sites may lack the staff or resources to follow up at every point on the continuum and thus miss an enrollment opportunity.

## Lack of visibility into recruitment efforts

Once sponsors hand over patient recruitment efforts to a site or third-party recruiter, they may be left out of the loop on how those efforts are progressing. Some sites may offer reports or tools through which sponsors can monitor their recruitment work, but they often only provide snapshots and do not dig as deeply as sponsors would like in terms of visibility.

## Inability to track performance or measure ROI

It is a gargantuan task to monitor clinical trial recruitment performance or ROI beyond the resulting number of patients enrolled. There is often no central source to track the different methods used in engaging and recruiting patients to see which are most effective and cost efficient. And without such a tool, it can be too much to ask an already overburdened site to closely monitor all these moving pieces.



## Ask these questions before engaging a patient engagement and recruitment solution:

- Does the site have access to enough patients to meet enrollment goals?
- Is the site able to reach diverse patient populations?
- Is a structure in place for educating, engaging, and prescreening potential participants?
- Is the site able to keep track of patients once they have expressed interest in the trial?
- Are you able to monitor the site's recruitment efforts as they take place?
- Are you getting enough information from the site to determine ROI on recruitment?

## Benefits of a Patient Engagement and Recruitment Solution

With the right patient engagement and recruitment solution, you can amplify and optimize trial recruitment across all studies to hit enrollment goals faster and gain a deeper understanding of trial performance. A patient engagement and recruitment solution can help you develop patient recruitment processes that...

### Save time and money while enhancing operational efficiency

Patient recruitment is time-consuming and expensive. More than \$1 billion is spent on recruitment, and the activity accounts for roughly 30% of development timelines.<sup>5</sup>

A multichannel patient engagement and recruitment solution can help shorten those timelines and cut those costs by providing one platform to broaden the scope of your recruitment efforts and allow you to track all channels and partners in the same place.

### Meet enrollment goals quicker

For a majority of clinical trials, difficulties in recruiting participants often lead to delays that can range from one to six months.<sup>5</sup> As noted earlier, these delays can run up trial costs and increase the likelihood of a trial's failure.

Find a solution that employs a vast network of partners to reach a wider and more diverse pool of trial candidates, along with infrastructure that engages these patients, educates them about your trial, and helps guide them through the enrollment process. This enables you to reach your enrollment goals with speed and precision.

### Set up sites and investigators for success

When a patient engagement and recruitment solution is put in place, sites and investigators no longer have to employ a scattershot approach to patient recruitment. Through one platform, they can easily access a wide range of patients through a network of partners, reach out and prescreen these patients via a dedicated web portal, and even employ resources such as call centers and referral management to ensure all potential candidates make it through to enrollment.

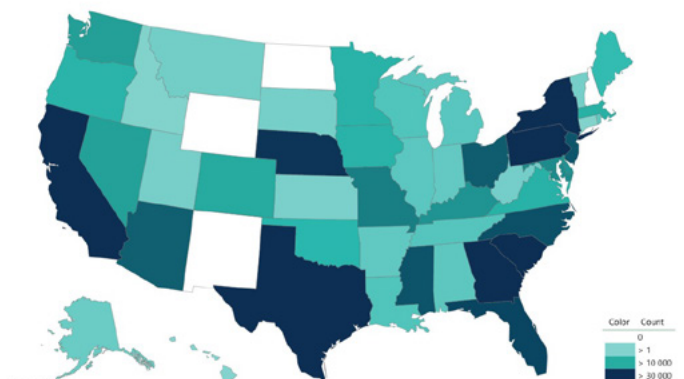
### Improve patient experience

According to CISCRP, 91% of respondents to its 2023 Perceptions & Insights Study who have never participated in a clinical trial are at least somewhat willing to do so.<sup>3</sup> However, patients who do want to participate in clinical trials can have a tough time locating the right trial for them. Even if they do, they may not know the next steps to take to get involved.

Employing an end-to-end solution — one that includes a patient-friendly clinical trials website — can make it simpler for these patients to discover, learn about, be engaged with, and enroll in your trial. It can give patients valuable information about the trial and guide them through the screening process so they can easily determine their eligibility. That way, when it comes time to enroll, the patient feels supported in making a well-informed decision.

### Increase enrollment diversity

Working with one source for patient recruitment can be limiting in terms of patient diversity. Having a solution with access to a network of recruitment partners makes it easier to find partners employing dedicated diversity, equity, and inclusion (DE&I) tactics and a broad enough demographic reach to contact a wide variety of candidates.



# Patient Engagement and Recruitment Solution features to look for

Not all patient engagement and recruitment solution offerings are built alike. Make sure you select a patient engagement and recruitment solution that provides all the features and functionality you need to run your trial recruitment from beginning to end. Some must-have features include...

## Large recruitment partner collective

A quality patient engagement and recruitment solution has a broad network of recruitment partners that can be tapped to help reach an expanded pool of patient candidates. This network can include patient recruitment companies, healthcare organizations, and patient advocacy groups. These partners should be pre-vetted and preferably already have contracts in place for smooth partnership entry.

## Competitive intelligence and real-world data (RWD) tools

An agile solution provides plenty of competitive intelligence and RWD tools that can be used to tweak recruitment strategy as needed. For instance, it should have the ability to pair lab data with medical claims information and electronic health records (EHR) data as well as intelligence on existing clinical trials.

## Dashboard, metrics, and reporting capabilities

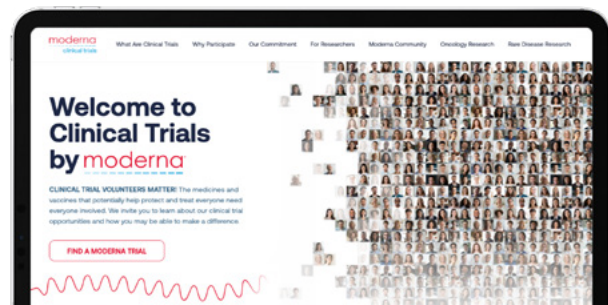
With a patient engagement and recruitment solution, you should be able to manage an entire recruitment campaign through one dashboard. Its metrics and reporting capabilities should reflect the overall performance of your recruitment efforts as well as allow for customized reports that focus on specific areas of concern. Also, make sure the solution offers the ability to track all campaign and site performance in real time.

## Strong technology foundation

A technically sound solution employs advanced algorithms to swiftly identify patient matches that meet all aspects of the study protocol. Plus, it should prevent drop-off and improve conversion rates with streamlined, site-centric technology that provides a seamless patient-to-site journey.

## Customized landing page for study recruitment

Your solution should provide a frictionless enrollment journey via a customized, IRB-approved landing page with built-in prescreening capabilities and real-time, compliant, direct-to-site handoff. This landing page can be either brand- or disease-focused and should inform, educate, and engage potential clinical trial participants. These candidates can then fill out a prescreening form that automatically sends their information to a site closest to their location.



## Dedicated website for patient and caregiver education

To help patients and caregivers make informed decisions about clinical trial participation, your solution should include a web-based educational component. It also should include information on clinical research across disease areas so potential participants can determine if relevant studies exist for them. According to a 2023 CISCRP survey, 67% of respondents who heard about a clinical research study did so online. Of those, 25% preferred to learn about studies from a pharmaceutical company's website.<sup>3</sup>

# A Guide to Patient Engagement and Recruitment Solutions

## Community portal for patient communications

Patients can feel alone in their clinical trial journey. Having a patient engagement and recruitment solution-backed portal through which they can receive compliant information about your trial can help them feel supported and reinforce their decision to participate.

The portal's platform should be HIPAA/GDPR-compliant, and the portal should allow the patient to choose which information and communications they receive.

## Connection with HCPs

According to CISCRP's 2023 Perceptions & Insights study, 58% of respondents who have never participated in a clinical trial would prefer to hear about a trial from their doctor.<sup>3</sup> Given that, it is important for a patient engagement and recruitment solution to employ RWD to locate healthcare providers (HCPs) with known patient pools for expanded enrollment outreach for your clinical trial. A solution with an opted-in HCP network can expand the swath of your enrollment efforts.

## Performance transparency across multiple recruitment partners

A reliable solution enables you to monitor recruitment efforts across multiple partners without having to keep track of separate systems and datasets. You can quickly get a deep look into exactly which partner's recruitment channels are working and which may need some fine tuning.

## Ability to track site-specific campaigns

Another feature to look for is the ability to break down recruitment campaign tracking efforts by site. That way, if a particular site needs additional support, you can offer it in a timely manner.

## Flexibility through customizable options

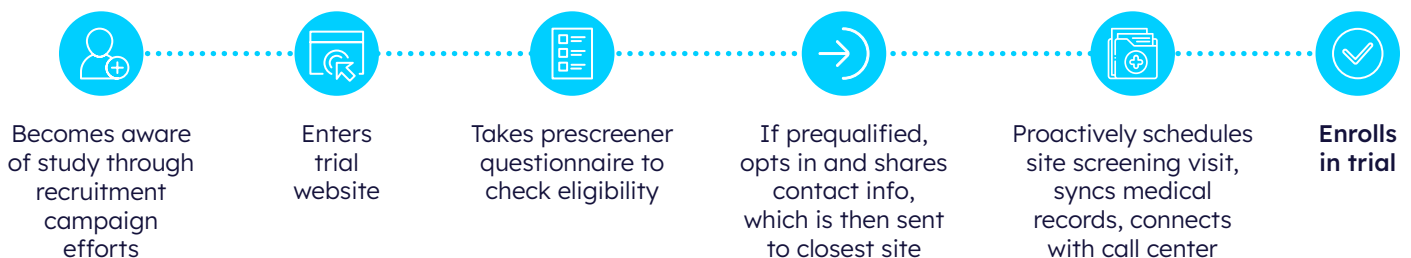
A mark of a good patient engagement and recruitment solution is whether it can pivot to fit your specific needs. Your solution should make the following available either as part of the offering or as add-on services:

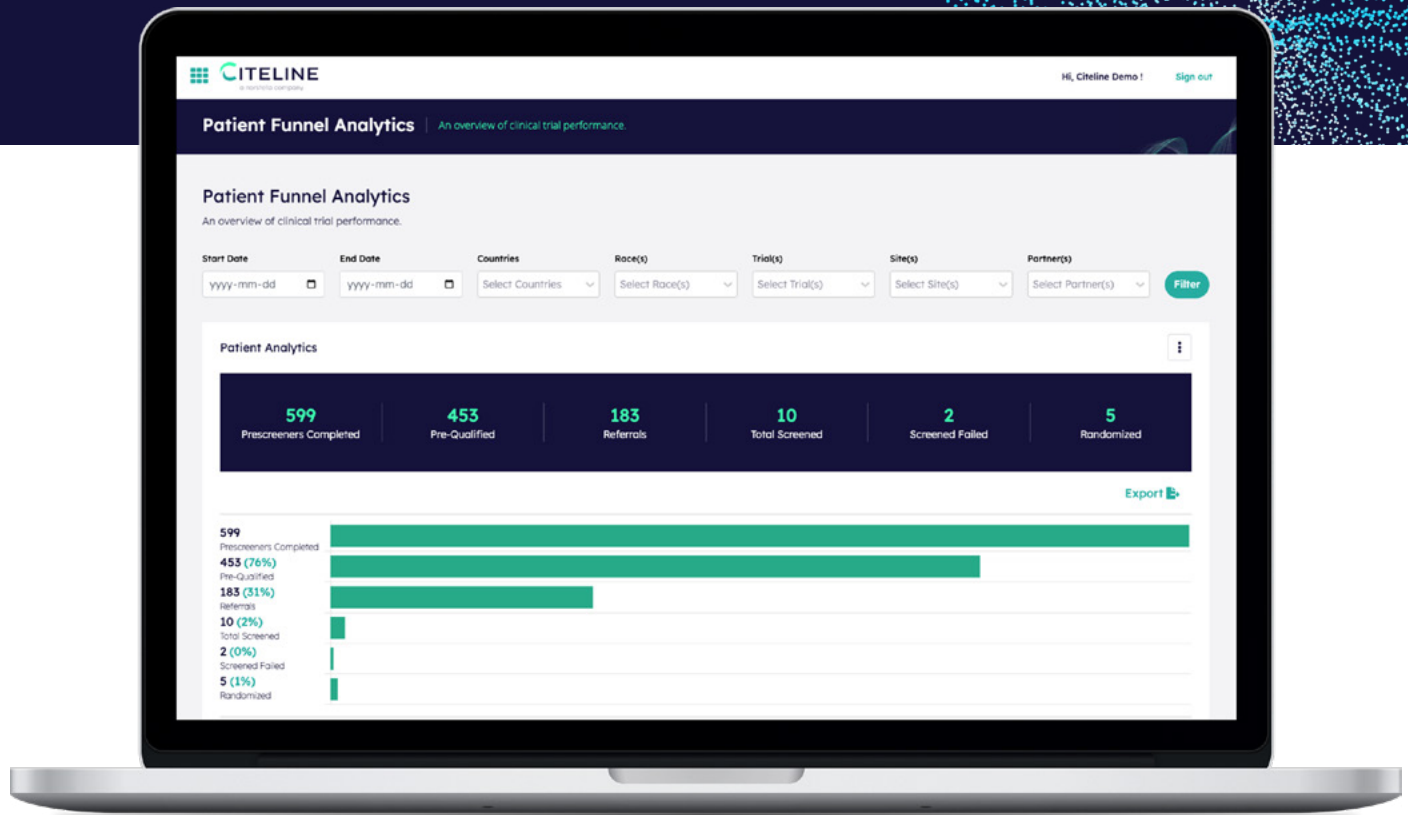
- **Call center capabilities** to enable patient and site follow-up
- **Referral management** so no prospective participant falls through the cracks
- **Medical records sync** to take the burden off both site and patient
- **Dedicated project manager** for the duration of the study
- **Appointment scheduler** to support patients in their enrollment journey
- **IRB-compliant support materials** such as email and call center scripts

## Expert support

A decent patient engagement and recruitment solution is bolstered by a team of experts who can answer questions and offer targeted guidance in whatever areas are needed.

## Patient's patient engagement and recruitment solution-enabled journey





# How the ideal Patient Engagement and Recruitment Solution can transform your recruitment campaign

A well-constructed patient engagement and recruitment solution facilitates dialogue, awareness, community, trust, and participation around clinical research by allowing you to....

## Inform strategy

With the right solution, you can try new strategies at speed with minimal risk and metrics reporting at every step.

## Drive patient engagement

The accessible educational content and robust engagement strategies provided by a patient engagement and recruitment solution will allow you to build a bridge to potential clinical trial participants globally.

## Recruit eligible patients

The bottom line for any patient engagement and recruitment solution is identifying the patients who are the precise fit for your study. The right solution can swiftly locate patient matches, prevent drop-off, and improve conversion rates.

## Track diversity metrics

The right solution enables you to track diversity, equity, and inclusion metrics across all studies. It also provides access to enough potential partners to drive study awareness and participation among diverse patient populations.

## Analyze performance

With a patient engagement and recruitment solution, you can centrally track and analyze campaign, prescreening, and site performance via multiple partners in a single platform. It enables you to monitor site activity and manage and optimize campaigns as needed. You also gain visibility on omnichannel performance to proactively address risk.

## Citeline Connect: your start-to-finish solution

Citeline Connect — built with patient/sponsor input and technology that has delivered the gold standard in clinical trial data for over 20 years — is underpinned by a central management platform. It boasts the functionality to create a branded, patient-centric experience that optimizes transparency, trial searchability, ongoing engagement, and enrollment, all of which supports a successful trial.

Employing several modules that combine for a truly scalable solution, Citeline Connect streamlines your clinical trial recruitment efforts from beginning to end.

### Citeline Connect Marketplace

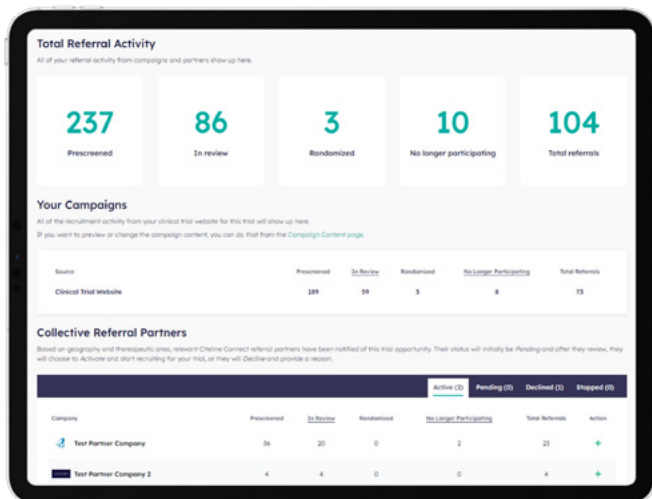
With 130+ pre-vetted, precontracted partners and a pay-for-performance model, Citeline Connect Marketplace helps you reach untapped patient populations and foster engagement across various channels.

### Citeline PatientMatch

Citeline PatientMatch pinpoints relevant patients for a clinical trial through a targeted approach with a customized algorithm and provides custom-timed alerts to enable greater site efficiency and optimization.

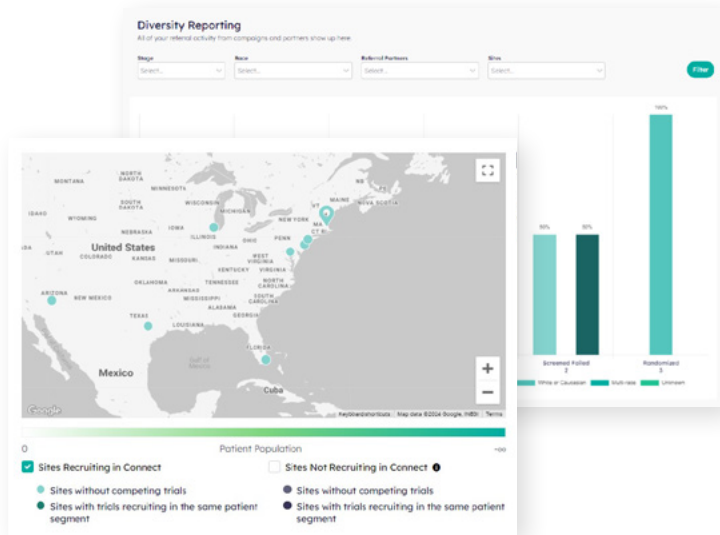
### Trial Portfolio Websites

Developed with patient input and based on a globally compliant data analytics platform, Trial Portfolio Websites reflect your commitment to transparency while helping patients better understand how clinical trials work and how to get involved.



### HCP Awareness

With HCP Awareness campaigns, we harness the power of RWD and a global network of 1.7 million healthcare providers to identify the ideal physician audience for your trial. Our team of clinical research managers collaborates closely with you to design and execute an effective outreach strategy, helping you build awareness of your clinical trial.




### Community

The Community enables sponsors to create a base of prospective participants for future trials. Sponsors can keep patients informed and engaged by sending custom messages to targeted groups, fostering trust with patients and caregivers. Survey your community to identify unmet needs and use these insights to design patient-inclusive clinical trials.

# Backed by experts

With decades of experience in all aspects of clinical trial education and enrollment, Citeline's patient engagement and recruitment experts come together to accelerate your research timelines. Through Citeline Connect, these experts offer targeted support to enhance planning, awareness, and execution of clinical trial recruitment strategies.



**Citeline Connect**, the end-to-end solution designed to drive consistent, successful clinical trial engagement and recruitment.

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## References:

<sup>1</sup> Kasahara A, Mitchell J, Mackey TK, et al. (2024) Digital technologies used in clinical trial recruitment and enrollment including application to trial diversity and inclusion: A systematic review. *Digital Health*, 10, 1-18. Available from <https://journals.sagepub.com/doi/full/10.1177/20552076241242390#bibr1-20552076241242390> [Accessed July 10, 2024]

<sup>2</sup> Brøgger-Mikkelsen M, Ali Z, Zibert JR, et al. (2020) Online Patient Recruitment in Clinical Trials: Systematic Review and Meta-Analysis. *Journal of Medical Internet Research*, 22(11), e22179. Available from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7673977/> [Accessed July 8, 2024]

<sup>3</sup> The Center for Information and Study on Clinical Research Participation, 2023 Perceptions & Insights Study. Available from <https://www.ciscrp.org/services/research-services/perceptions-and-insights-study/> [Accessed July 18, 2024]

<sup>4</sup> Center for Drug Evaluation and Research, Drug Trials Snapshot Summary Report 2023. Available from <https://www.fda.gov/media/178602/download?attachment> [Accessed July 15, 2024]

<sup>5</sup> Chaudhari N, Ravi R, Gogtay NJ, et al. (2020) Recruitment and retention of the participants in clinical trials: Challenges and solutions. *Perspectives in Clinical Research*, 11(2), 64-69. Available from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7342338/> [Accessed July 12, 2024]



# CITELINE

CLINICAL

Citeline, a [Norstella](#) company, powers a full suite of complementary business intelligence offerings to meet the evolving needs of life science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial, and regulatory-related decisions and create real-world opportunities for growth.

Citeline's global teams of analysts, journalists and consultants keep their fingers on the pulse of the pharmaceutical, biomedical, and medtech industries, covering them all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts, and more. For more information on one of the world's most trusted health science partners, visit [Citeline](#) and follow on [LinkedIn](#) and [X](#).