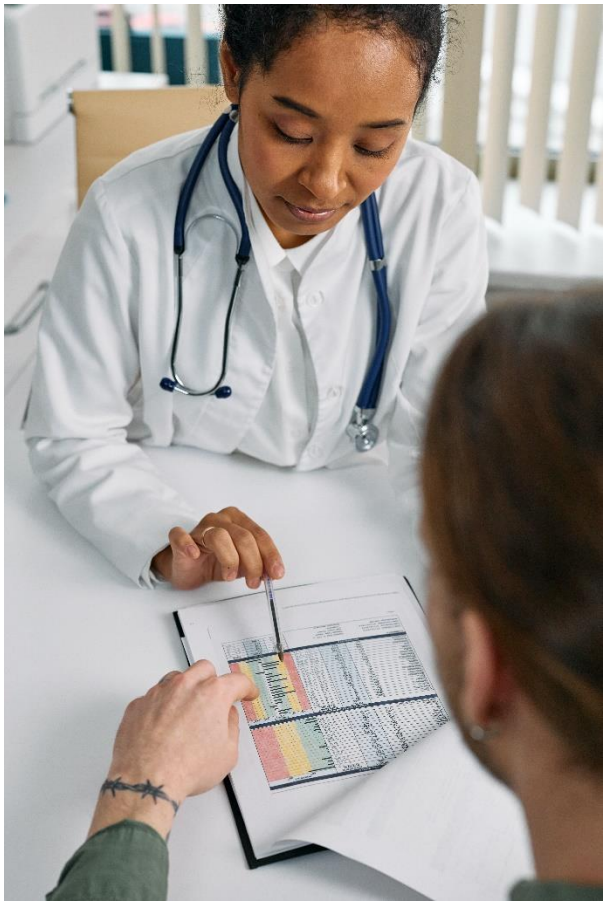
How to enhance your clinical trials in 2022

Overcome the post COVID-19 challenges in patient enrollment, by partnering with third-party providers



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https://clariness.com/contact-us/

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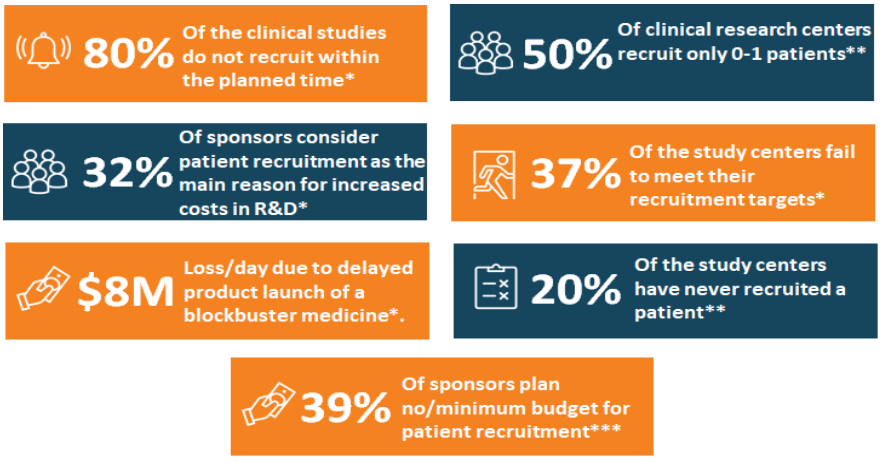
Introduction

Advances in the development of new medications and therapies have moved at a phenomenal pace over the past decades, arguably largely due to the standardization of Randomized Clinical Trials, digitalization and technological advances. The greatest test of this new model thus far was the COVID-19 pandemic. Yet, this only accelerated clinical research as the unprecedented development and approval of a variety of new diagnostic tools, treatment methods and vaccines shows.

The quick development of new vaccines and treatments has brought clinical research to the center of the public stage, with the latest developments being covered on a day-to-day basis in the media. More fundamentally, the largescale vaccine trials have brought more people then ever into contact with clinical research. Where in **2016-2017 fewer as 30.000 people participated** in clinical trials, in **2020-2021 this were some 300.000 people**.

Hence, clinical research' handling of the COVID-19 pandemic was not just an unprecedented achievement of clinical researchers and trial sponsors and organizers, but rather **the incredible level of public support and willingness to participate** in clinical trials was decisive.

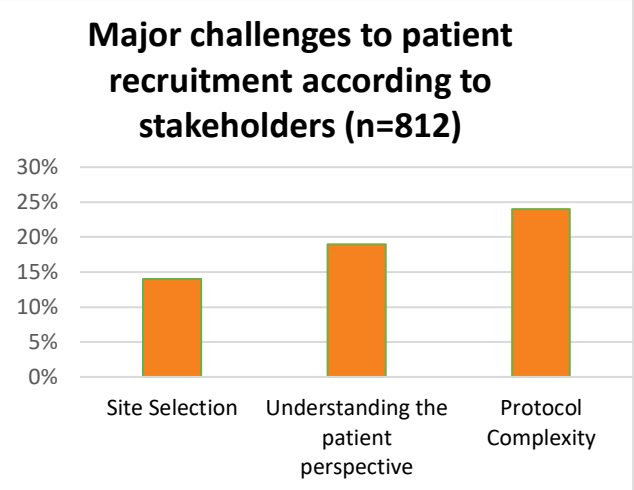
After all, a lack of participants was before the COVID-19 crisis the biggest challenge for clinical trials and according to most stakeholders, will remain the biggest challenge in 2022 and ahead. This whitepaper examines these challenges and looks at how sponsors can enhance their clinical trials and patient recruitment by partnering with third-party experts as Clariness.



1. The challenges of patient enrollment

Since late 2021, there have been increasing calls from clinical industry leaders, pharmaceutical journalists, and even regulatory leaders such as the FDA, to act in order to improve participation rates in clinical trials. The often-heard argument is that the COVID-19 pandemic has only enlarged the challenge of patient recruitment, as patients increasingly voice higher demands for participation in clinical trials.

Patient recruitment is seen as the biggest barrier to clinical trials, and there are many reasons for this as highlighted by the results of our 2019 survey conducted with 812 sponsors, Contract Research Organizations and research sites, and recent studies on the success rate of clinical trials.



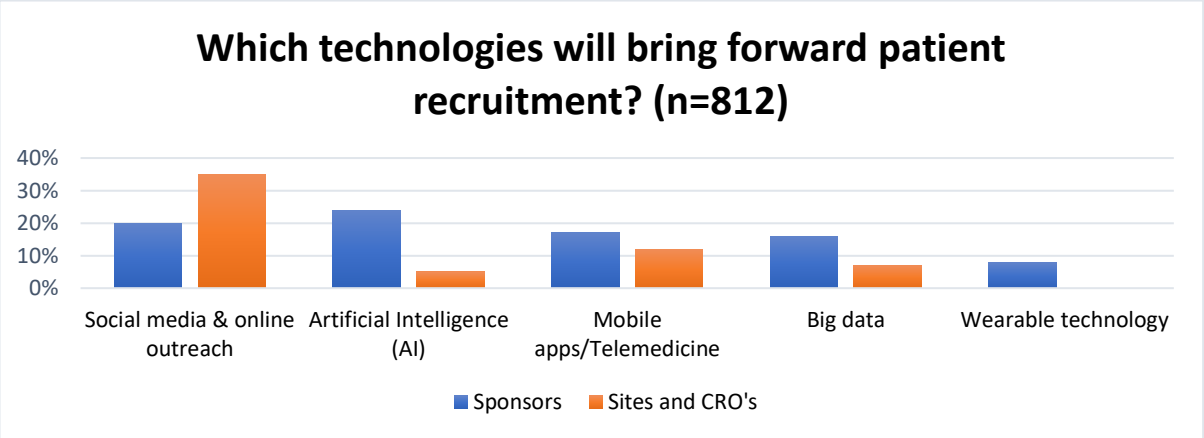
Clariness 2021-survey results of recruitment challenges for sponsors, CRO's and Sites

The biggest challenge related to patient recruitment, reported by almost a quarter of respondents, was regarded as protocol complexity, which makes it increasingly hard to find qualified patients. A lack of understanding of the patient perspective, was a close second.

Where in 2019 issues such as diversity, representation and patient-centricity were already increasingly becoming important topics, since 2022, they have become essential. As both the U.S. regulatory authorities and European Medicine Agency have released guidelines and requirements for diversity, this gives additional challenges to patient recruitment.

What will bring forward patient recruitment in 2022?

When sponsors or sites think of technology applied in clinical trials, the most common association are Decentralized Clinical Trials. Indeed, as a Forbes article recently notes wearables and mobile monitoring especially are increasingly important areas of investments for sponsors. **Yet, whereas patient recruitment is the area where clinical trials most often fail, it is also the area where technology is still not optimally used**.



As the results of our survey highlight, social media and online outreach are most commonly identified as the technological areas that could make a difference in the enrollment phase. It is also the area where sponsors most often look for a third-party provider.

Yet, **most third-party providers of patient recruitment still use social media and digital outreach in a rather traditional way**. That is to say, merely as a form of advertisement, that is not adjusted based on the local and global patient population of the respective therapeutic area that doesn't make use of big data underlining the outreach and performance, screening and contact tools.

Based on 17+ years of experience, at Clariness we know that it is crucial to optimize a outreach campaign based patient surveys and data-driven outreach that is constantly refined based on digital pre-screener and referral performance metrics. For detailed information, read our whitepaper on atopic dermatitis patient recruitment.

Solutions for common study enrollment challenges

The chart below shows the patient recruitment challenges most frequently cited by sponsors in our 2021 survey (n=812), as well as a detailed look at the problem and potential solutions.

THE CHALLENGE	THE ISSUE	THE SOLUTION
Protocol complexity	• Can make it hard for physicians to see whether their patients are eligible • Can exclude large percentages of the population through inclusion and exclusion criteria • Can confuse patients or put them off wanting to commit	• Use patient and physician input, through panels, surveys, and interviews, combined with knowledge and experience, to develop simpler protocols that still deliver, and that generate data that is closer to real-world experience
Site selection	• Around a third of initiated sites never enroll a single patient, and half enroll only one or two	• Select sites based on experience and knowledge of investigators and staff • Invest in staff resources, such as chart review and pre-screening
Understanding the patient perspective	• Patient centricity is becoming increasingly important, both for recruitment and for gaining approval from regulatory bodies	• Understand the patient's voice to help define the target population • Spend time with patients and understand what would make them join, and stay in, a clinical trial • Use the patient voice in materials
Lack of recruitment planning	• Many trials do not plan any budget for recruitment, and a large proportion only budget up to $0.5 million	• Plan the recruitment budget early on, and ensure that it is enough to cover the needs of the study • A well-planned and carefully budgeted study will save money and improve the chances of approval in the long term
Competition in clinical trials	• Increasing numbers and sizes of clinical trials, especially in the rarer diseases, mean that there is competition for sites, site staff, and patients	• Ensure that patients and physicians feel empowered, and that the studies meet the needs of the patients; this will improve the attractiveness of trials • Good use of technology will improve visibility and accessibility

3. Enhancing your study with third-party providers

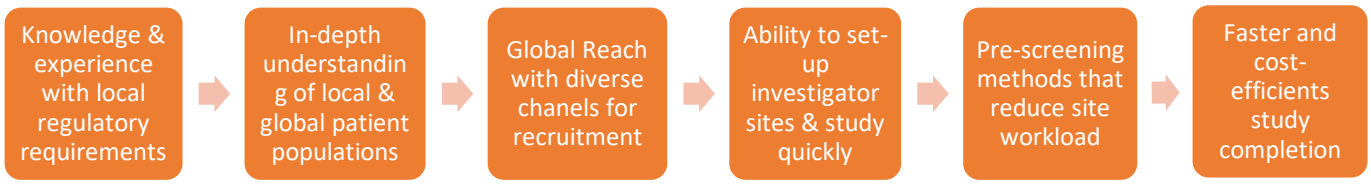
Traditionally, organizers of clinical trials heavily relied on doctor offices and internally organized recruitment campaigns to enroll participants for clinical trials. The perceived advantages are that doctor offices have established contacts with patients and that in house recruitment is a cheaper option with shorter feedback loops. Yet, there are some obvious drawbacks that make this model insufficient:

- **Medical office recruitment –** Depends completely on pro-active action of doctors and reaches only a limited, not representative, group of patients. Not able to scale quickly and not suitable for global studies.
- **Internal patient recruitment –** Lack of expertise and experience often result in slower and ultimately more expensive patient recruitment campaigns. The budget for a well conducted third-party patient recruitment campaign is a fraction of the potential cost of clinical trial delays.

Possibilities of third-party providers

By overseeing the practicalities of site set up, site capabilities, and recruitment campaigns, third-party providers can facilitate a smooth relationship between sites and sponsors. The time, effort and challenges associated with site preparation can cause tension within the site-sponsor relationship, but third-party providers can remove this pressure and ensure all parties are working towards the same trial goals.

An ideal third-party recruitment campaign would have the following advantages that speed-up the clinical trial process:



3.1 Three ways third-party provider can improve patient recruitment and retention

1. Site feasibility assessments to ensure the right site, for the right patient, and the right study:

Site feasibility assessments are a critical first step in developing a rigorous study plan that can prevent delays. Based on experience and a data-driven approach, a third-party provider helps sponsors to refine their study protocols and enhance retention:

- Is the study protocol viable for a patient recruitment campaign in this location?
- Is the investigation site suitable and able to cater to the protocol design?

2. Driving results by improving patient engagement, motivation, and support:

- Keep patients motivated, helping prevent the costly delays of dropout and having to revisit recruitment
- Enhance compliance to trial regimens and patient satisfaction, which is essential to maintaining the quality and integrity of trial data
- Offer patient education, ongoing support material, appointment reminder tools, and study branding to strengthen relationships with patients and keep them motivated for the duration of the trial

3. Experience in working with patient organizations and healthcare providers

By collaborating with healthcare providers and investigation sites, third-party providers can accelerate the enrollment of a study.

- Healthcare providers can play a particularly important role in patient retention, as they can recommend patients for enrollment as well as provide medical support and reassurance throughout the trial

4. Selecting a third-party provider

In recent years, the amount of startup companies offering patient recruitment services has exploded. A common issue with these providers is that they have too little experience with overcoming the above-mentioned challenges for recruitment and thereby fail to deliver a quality and premium service. More so, unfamiliarity with the

strict local regulations for marketing and an inability to filter on patients likely to qualify, can easily result in extra workload and frustration for both patients and sites. Furthermore, they often have to partner with more established recruitment vendors to reach international audiences, meaning they often act as a middle man and increase the cost of going directly to a more established provider.

Considering the challenges of modern clinical trials, we have therefore identified three critical capabilities a patient recruitment provider should possess, that also form the core of Clariness' approach to patient recruitment campaigns over the past 17 years.

1. Patient understanding & patient-friendly creatives

A **qualitative patient understanding** through patient and investigator surveys and a data-driven approach, third-parties can proactively select patients and sites that likely to qualify or cater to the study criteria, and are crucial for any campaign's success.

This combined with patient-friendly study recruitment and study materials that explain the study and clinical trials deliver a smooth experience for patients. At Clariness, we believe a true patient-centric approach to clinical trials not just requires these elements, but can also lead to a cost-effective and quicker recruitment phase, with more satisfied patients who are more likely to stay in the study.

2. Data-driven digital outreach capabilities

The best study plans incorporate a **creative patient-centric recruitment campaign** that utilizes technology platforms, builds relationships, and involves patients from the outset. This formula is constituted by outreach and marketing strategies designed to increase patient awareness and interest, along with for example **patient-friendly screeners** to facilitate a quality-based referral process.

At Clariness, we have 17+ years of experience with leveraging over 40+ digital channels that together with a data-driven approach and qualitative understanding of the patient population ensure a high quality of referrals.

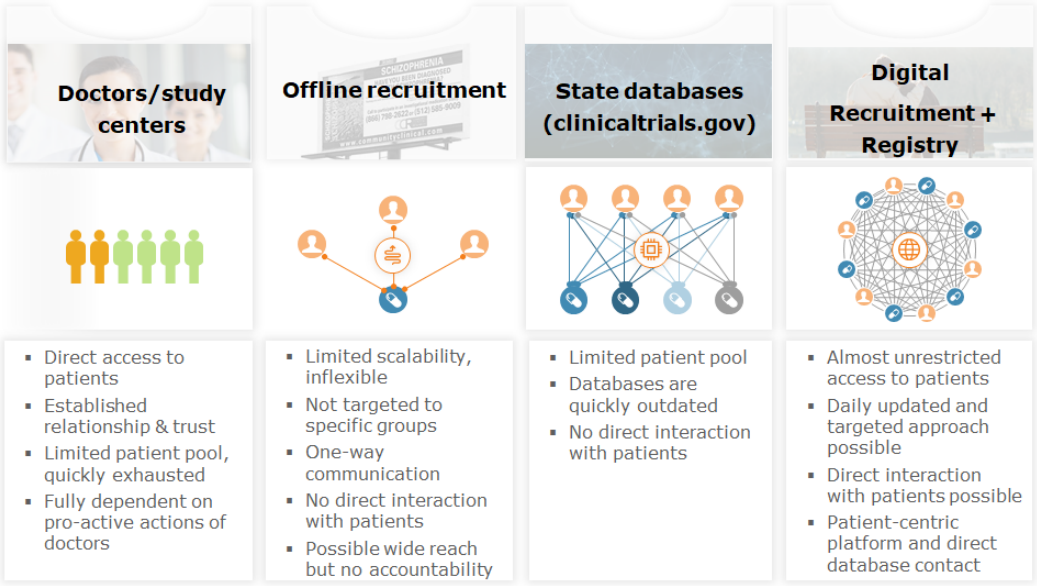
3. Site support

It's essential for third-party providers to conduct a **comprehensive feasibility and optimization study of each site**, not only in terms of the ability to conduct the trial but also to recruit and retain patients and compliance with local regulations. At Clariness we onboard sites quickly through easy-to-use resources include patient pre-screening tools,

site tracking and readiness tools, and support kits for patient engagement. This Investigator Service furthermore ensures that patient data is stored safely and anonymously, following the strict European data protection regulations.

5. A closer look: enhancing patient recruitment

Traditionally, most third-party providers of patient recruitment have relied heavily on offline recruitment through marketing in newspapers, public transport, or street posters whereas organizers relied heavily on doctors and study center recruitment. If the effectiveness of these forms of recruitment was already increasingly questioned before the pandemic, they can be said to be outdated since March 2020.



In 2021, people worldwide on average spend 2 hours and 25 minutes online. Studies have shown that these numbers are even higher for people with health problems with online medical searches for example increasing both before and after doctor visits. In fact, Google (Dr. Google, as some researchers have called it) has become the primary way patients search for answers to their medical questions and has undeniably assumed a major role alongside medical professionals.

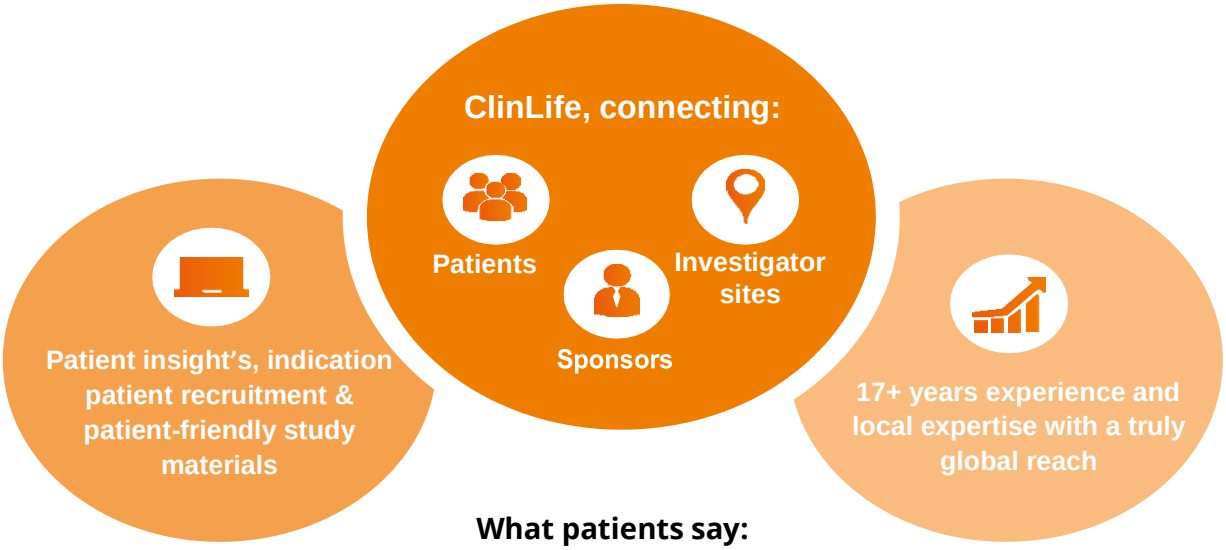
While it is recognized increasingly that the direct online outreach to patients is a great opportunity for patient recruitment, as noted earlier many third-party providers are unable to overcome the challenges of patient recruitment. This is even more true for

international recruitment, where campaigns require a combination of expertise and data-driven methods that can quickly adapt on the go.

Clariness' approach to patient recruitment

Central in Clariness' patient recruitment approach is a data-driven approach to patient insights, patient-friendly study materials and our ClinLife clinical trial database. Created in direct collaboration with patients and constantly being improved by patient feedback and analysis of performance data, ClinLife is a **neutral patient-centric database of clinical trials**. This patient-centric platform is contrasted by, for example, recruitment by individual sponsors or governmental platforms such as Clinicaltrials.gov or the German DRKS Deutsches Register Klinischer Studien, that suffer from outdated design and difficult-to-navigate web pages, with incomprehensible lay-unfriendly content. With ClinLife, organizers of clinical trials are flexible to do patient recruitment following their needs.

Clariness' core capabilities



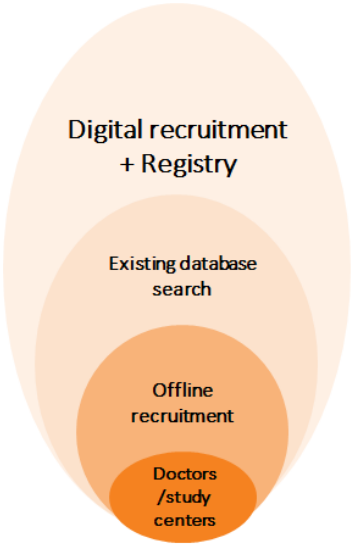
What patients say:

"I usually never click on ads, but this ad for a clinical trial really appealed to me, so I applied right away. It turned out that the research site was only 2 km away, so the personal targeting was optimal."

Clariness' Patient's Voice Conference Participation

What about cost?

Traditionally third-party providers are perceived as very costly methods of recruitment, but as mentioned, compared to clinical trial delays which can cost sponsors between $600K and $8M per day, the cost associated is often a fraction of these costs, typically a fraction of one day's lost sales.



More so, third-party providers as Clariness that take a patient-centric approach to patient recruitment through lay information, a neutral platform and easily navigable pre-screening improve patient satisfaction and trust. This is crucial, as patients who for example are excluded from one study yet are not disappointed by the recruitment process, could potentially participate in another study in the future.

Clariness for example works on the basis of a flexible and protocol-based pricing model, giving options as covering risk shared, performance based and subscription-based model. **The subscription model of the ClinLife study databank** for example is a predictable and constant cost in the budget, providing a steady stream of referrals based on indication-based marketing. The advantage is that this does not require additional EC approval and can start almost immediately, as no study specific information is shown in the outreach and rather, patients are forwarded to a patient-friendly indication page and screener that helps the find suitable studies for their condition and in their proximity.

It can be complemented by **Clariness' project-based recruitment**, that utilizes all the capabilities of Clariness from data-driven outreach methods based on study-specific criteria. This is suited for studies with very specific inclusion and exclusion criteria, or those towards the end a recruitment phase.

What sponsors say:

"The combination of recruitment via Clariness' online ClinLife platform and pre-screening has proved to be a very valuable tool for effectively monitoring, directing, and controlling patient referrals to investigator sites. The high quality of patients referred has resulted in many randomizations and a major reduction in screening efforts at the sites."

Clinical Research Study Leader, headquartered in Switzerland

Recap: Enhancing your studies through a third-party provider

To summarize, the potential benefits of partnering with a third-party provider come down to:

1. **Experience with patient recruitment for a specific therapeutic area**. If the selected third-party provider has a throughout understanding of the patient population and data-driven technology to support outreach and screening, it can boost the enrollment phase with high quality referrals.
2. **Faster timelines.** Some third-party providers as Clariness offer indication-based recruitment through a neutral patient-friendly database. This means that fully GDPR compliant recruitment can commence even before EC approval through non-study specific outreach and a patient database.
3. **Local expertise with a global reach.** Third-party providers often have experience with multinational recruitment and can therefore quickly scale their approach.
4. **Flexible solutions and pricing models.** Third-party providers often offer flexible and protocol-based pricing model, giving options as covering risk shared, performance based and subscription-based models.

Want to speak with one of our experts about your clinical trial recruitment?

CONTACT US