Engaging patients and putting their needs and concerns first is essential for creating collaborative relationships that work to advance research and development of new pharmaceutical agents and disease management strategies.

Improving patients' lives through medical advances involves a deep understanding of their medical conditions, experiences, needs and priorities. Implementing this "patient centricity" for clinical trials in the biopharmaceutical industry requires a consistent and coordinated approach to ensure patients have an optimal experience.[1] Ora Recruiting is guided by the principle of patient centricity and is committed to providing a coordinated, seamless, respectful, and sensitive approach to patient engagement in the drug development process. By adhering to the concept of patient centricity, patients' participation is meaningful, ultimately leading to enhanced outcomes and more effective research that provides robust and actionable results for the pharmaceutical industry.[1]

RECRUITING

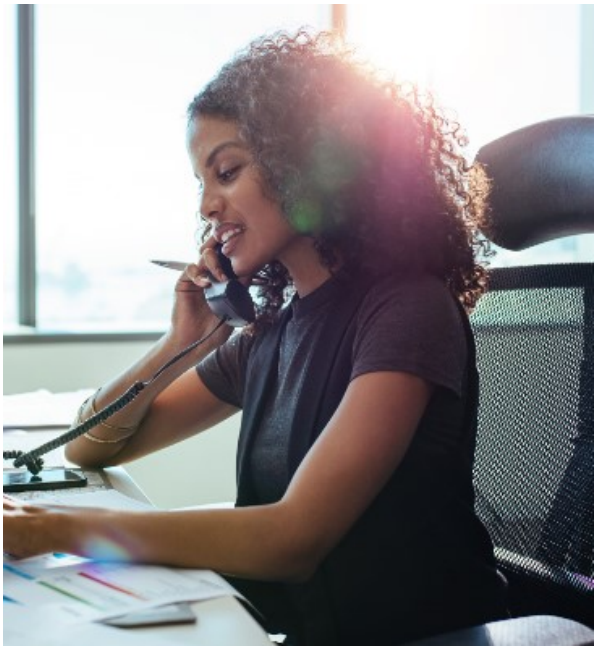
Ora Recruiting is dedicated to ophthalmic clinical research and strives to provide patients with unlimited support and information, so they are confidently able to decide whether to participate in a study. Our recruiting specialists walk potential subjects through the enrollment process, discuss expectations, and clearly describe all of the benefits that come from study participation.

Within Ora's recruiting database, interested patients are categorized by therapeutic area and geographic location. This database houses information on thousands of potential participants across a variety of therapeutic areas and allows us to target specific candidates for studies that they would be more likely to qualify for. By starting every study with a list of interested individuals, Ora's recruiting team is able to quickly reach out and expedite the recruitment and enrollment process.

UPFRONT SCREENING

At Ora Recruiting, our primary focus is creating the best experience for every patient. We have a team of recruiting specialists who utilize an upfront telephone screening process to review whether someone would be a good candidate prior to them even coming into the office. We do our best to be sensitive of people's time and try to avoid unnecessary steps for any patient, including needless trips to the clinic. Our goal is seamless clinical trial participation from the moment someone reaches out with potential interest to their final in-office appointment.

People of all ages, races and genders can volunteer to take part in a study as long as they meet the criteria for study participation. Every study is different, but they all have inclusion and exclusion criteria that outline exactly who is eligible to join. Some studies require patients with specific conditions while others require individuals with no pre-existing conditions. Our recruiting specialists, following strict HIPAA policies and procedures, utilize a screening protocol that is tailored to ensure patients are the right fit for each study. Potential participants are asked a series of questions about their lifestyle, general demographic information, as well as their health to look for things that may exclude them due to safety reasons. Once a patient has been screened and is determined to be qualified, he or she is eligible to move forward with the clinical trial. During the initial telephone screening process,



we look for candidates who are consistent in their answers, no matter what the outcome may be. The ease of a patient's ability to answer these questions over the phone helps our recruiting team determine if this person is a good fit for the study, and often translates to the type of patient they are in-office.

When participants have had a positive experience participating in that first trial, they are more likely to continue participating in other clinical research opportunities with Ora. Our focus on patient centricity makes our participants want to share their story with family, friends and on social media. This allows us to expand our patient database through word of mouth advertising.

MOTIVATIONS AND BENEFITS

There are many benefits to participating in clinical trials, and patients' motivations can widely vary depending on the drug indication or their condition. Based on conversations with previous participants, Ora has identified the five most common reasons why people decide to be part of a clinical research study.

1. Hope for relief. Many individuals seek out clinical trials after suffering with a condition or a disease for an extended amount of time, perhaps with pain or discomfort that is unresponsive to standard treatments. They often feel as though they have tried everything available and are frustrated with their options or lack thereof. In this case, clinical trials offer study participants the hope that they may find some relief for their symptoms and improve their quality of life. Many people are motivated by the opportunity to play a more active role in their health care.

2. Contribute to science. Many potential participants recognize that all prescription and over-the-counter drugs were first studied in the clinical trial process to gain FDA approval. By participating in a clinical trial, research candidates play a pivotal role in advancing science and perhaps, in experiencing breakthrough treatment options. Study participants are often excited about being part of a group effort to get a new drug approved, and find it rewarding to help numerous others with their same condition find relief.

3. Access to new treatments. When it comes to innovative and cutting-edge therapeutic options, clinical trial participants are among the few individuals who can gain access to certain experimental therapies. This is especially valuable and motivating for individuals who suffer from conditions that lack viable treatment options, or for those who have not found success with the current standard of care.

4. Join a community. Sometimes living with a disease or condition can be lonely and patients feel isolated from anyone who understands what they are going through. When people choose to participate in a clinical trial, they are instantly connected with other individuals who are experiencing many of the same things. They are comforted by being surrounded with a community who can relate to them and share the common experience of participating in medical research.

5. Compensation. Of course, time is valuable, and participants are compensated for their time and effort involved in study participation. Ora reviews the terms of payment with each study participant as part of the Informed Consent process, and all compensation is IRB approved.

Ora wants participants to have total confidence in their decision to join a study. We support them every step of the way, always putting their safety and well-being at the forefront.

The benefits of participation for patients

https://www.myeyestudy.com/why-join-a-study/

WHY BE A TRIAL SITE?

Ora has developed a central recruiting team that serves as the connecting thread between doctors and patients at each of our OraNet™ locations. We take the burden of screening and scheduling study participants off investigators and their office staff—this is a big advantage of working with the Ora team. We not only phone screen all participants ensuring that more qualified patients are chosen, we also "match them up," saving everyone time and creating efficiencies at every stage.

In general, there are two major advantages for clinical trial sites: improving patients' access to care and adding a revenue stream for the practice. Through trials, eye care providers can offer an alternative to standard treatments. Patients who have not found success with available treatment options may be interested in research to explore new ways to treat their condition. Other times, patients do not have insurance coverage and their only option to receive care is through a clinical trial. This situation is more common when it comes to the posterior segment—i.e. retinal diseases and glaucoma. Physicians can give all patients access to new treatment options, including those who are underserved and underprivileged.

Participating as a clinical trial site also provides a revenue stream. For larger practices, it offers a way to expand their general practice as well as their research population. Contracts vary based on study type, but generally speaking a site will either be compensated per patient enrolled or per assessment completed by investigators and their staff. Depending on the type of trial, a “per task” payment could be as much as $3,000 a visit. This amount multiplied by several visits and numerous patients can quickly add up to a lucrative revenue stream.

WHAT MAKES A SUCCESSFUL SITE?

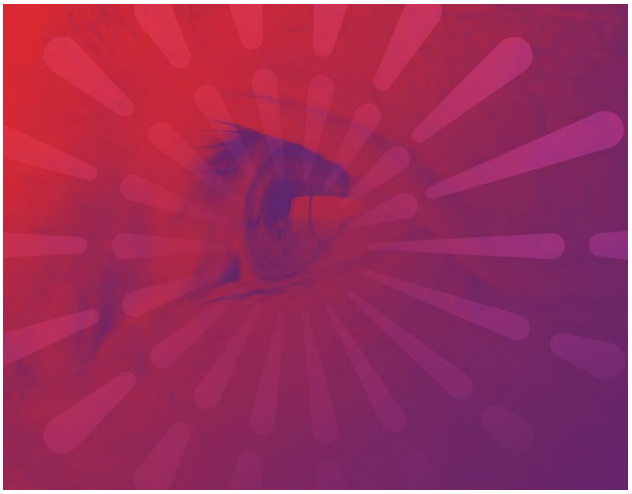
When evaluating which sites to choose for a clinical research study, Ora takes a few factors into account. Previous research experience, total patient population, the number of patients seen monthly, and the number of patients fitting a specific protocol, all give light to a site’s ability to successfully complete a trial and meet enrollment targets. Due to Ora's patent-centric

model and our block recruitment approach, practices that are willing to give Ora access to their patient database often see the most success. By combing through records and really understanding the number of patients available to a site, we can streamline the patient recruitment process. Our recruiting targets are usually higher than traditional enrolling studies, so each site needs to understand the volume of patients that are required to optimize success.

In order to protect patient privacy, Ora creates a business associate agreement with each site to safely access the practice's patient database. We may need to do this physically in person with paper charts, or we can access EMR information remotely. Privacy is covered under the umbrella agreement that contracts Ora to recruit and enroll patients for a site. Our specially trained team members go through this process using strict HIPPA policies and procedures.

Another way that research sites find success in building their research population is through patient referrals. High performing sites have clinical trial investigators who are dedicated, proactive and engaged, and this creates strong bonds and trust with study participants that in turn leads to patient referrals. Even if an investigator is not their personal doctor, having a friendly face as a resource throughout the study process often eases potential hesitations. Investigators are the key to making the experience a positive one for participants, with trust that they have the patients' best interest at heart.

One thing that may adversely affect a site's ability to participate in a trial is conducting too many concurrently. If a practice is running too many trials, it may be a red flag that they cannot adequately give all active studies the attention they need. Although we bring in team members and staff to assist with visits and study-related tasks, the investigator is ultimately responsible for all data produced by his or her site. Participating in too many trials leaves more room for error and risk, which Ora aims to minimize. From the investigator to the study coordinator, lab tech, etc., all members of the study team need to do their part to make a trial run smoothly. Successful sites are ones that are truly invested in patient care, and Ora provides resources to ensure that this is possible. We provide online tools, face-to-face trainings, remote staff trainings, marketing materials and any other support a site feels will contribute to their success.



CONCLUSION

At Ora, we have a sound process that helps us identify doctors and patients who are involved in research for the right reasons. We take a patient-centric approach, spending time up-front to screen potential participants and determine their eligibility in order to streamline the process and eliminate unnecessary onsite visits. What sets Ora apart lies in the support we offer both participants and sites, being able to block-recruit patients and ensure they have an excellent overall experience when participating in a clinical trial. This cultivates an environment where patients are more likely to participate in future trials, making the recruiting process even more efficient.

Ora understands and is deeply committed to the importance of putting patients at the center of the collaborative relationships that underpin successful ophthalmic research and drug development. Always putting the patient first ensures a respectful and compassionate approach to clinical research that we are proud of and achieves the best experience and outcomes for participants.

1. Yeoman G, Furlong P, Seres M, et al. Defining patient centricity with patients for patients and caregivers: a collaborative endeavour. BMJ Innov. 2017;3(2):76-83.

Clinical Trial Block Enrollment

The conventional "rolling" enrollment strategy can draw out the enrollment process for several months or years, delaying pivotal study timelines. For certain studies, Ora recommends using our block enrollment method. By identifying certain locations within OraNet™, our established ophthalmic site network, and scheduling all patients to come in for their visits together, enrollment expectations are higher than typical research studies.

Block enrollment allows us to meet aggressive study timelines, such as running an allergic conjunctivitis or dry eye disease study within one season. This process also minimizes variability and gives insight on forecasting and when enrollment numbers will be met – before your ophthalmic study even starts.

- *Enroll more patients per site*
- *Reduce the number of sites*
- *Reduce variability of data and accelerate timelines*

Integrated Research Operations

Ora's on-site staff supports the block enrollment process. Our skilled clinical team works closely with site staff to execute all study assessments and accurately and efficiently conduct study visits. This additional support helps facilitate the enrollment process, ultimately expediting your study's journey to the finish line.