The processes that Ora, Inc. has developed and adhered to for decades have enabled the company to quickly adjust to challenges posed by the pandemic. Our professional protocols ensure that clinical trials continue to run safely and efficiently, no matter what curveballs the current environment may throw.

Ora's foundational concepts are based on our vast experience as a full-service ophthalmic CRO, and allow sponsors to quickly achieve their enrollment goals, hit desired milestones in a timely fashion and ensure protocol adherence for the highest quality data capture. During this challenging time of COVID-19, Ora's highly professional, standardized approach has been crucial for allowing clinical trials to continue moving forward. With the utmost attention to all recommended safety protocols, reinforcing peace of mind for patients, staff and physicians at each site, Ora has never stopped delivering desired results for our clients.

BLOCK ENROLLMENT AND HIGHLY TRAINED CRCs: MEETING GOALS WITH EXCEPTIONAL QUALITY

A major advantage that Ora has over other CROs is our block enrollment approach. This helps make enrolling patients run more smoothly in the current environment. With block enrollment, our team can maximize the number of patients over a short period of time, accelerating screening and condensing the enrollment timeline. At the same time, our standard operating procedures have been modified to ensure safety and hygiene protocols related to risk mitigation are in place at all times, as discussed later.

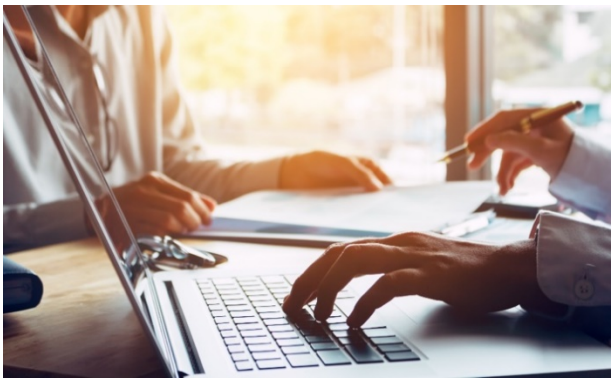
Ora's clinical research coordinators (CRCs) are highly trained in research across multiple therapeutic areas in ophthalmology. These professionals are experienced in all relevant disease states, and are intimately familiar with the entire process, from asking questions of participants to managing and standardizing the endpoint. With our team of CRCs, Ora ensures consistency and quality throughout the

trial. A workforce of CRCs is assigned to a given site, seeing multiple patients over just a few days. It would be challenging for a physician's office to execute this on their own with a single study coordinator who is tasked with helping to conduct the study, complete the necessary paperwork and meet all protocol requirements for the visit.

Even more unique to Ora, our CRCs ensure maintained quality and consistency. The same team who enrolled the patients initially will assist the investigator with subsequent trial visits at the site, continually providing oversight and standardizing protocol procedures. The questionnaires are asked the same way each time and the protocols are followed to the letter. This quality and consistency in process translates to clean and superior data, allowing a better study outcome for the sponsor which ultimately gives the study drug the best chance of success.

HOW THESE PROCESSES APPLY DURING COVID-19

As COVID-19 became more of a challenge, many practices had to slow down or stop altogether. Those involved in trials, however, prioritized clinical research and the Ora team supported our network sites with the continuation of trials in a controlled and successful manner. In fact, Ora's block enrollment and CRC support are tailor-made for the unprecedented pandemic situation because we are set up to partner with the site staff to meet recruitment goals and project timelines while helping to ensure the safety of staff and patients.



Safety Measures

In association with the site, Ora's CRC teams quickly modified our processes to prioritize safety and still maximize enrollment during these challenging times. Our standard operating procedures now incorporate safety protocols that include screening patients with a COVID-19 symptom questionnaire before they come to the clinic and upon arrival. Patients have a temperature check, and their CO2 is also measured. Social distancing is practiced in the clinic, patients are separated in the waiting rooms, and all patients and staff wear masks and additional PPE.

To keep visits streamlined and to avoid unnecessary contact, patients now move between a designated medical history area to the doctor's admission area, allowing for extensive sterilization between patients. Additionally, Ora has adjusted patient flow for studies. For example, if the CRCs need to schedule fewer patients per day to allow for

proper social distancing, we build in more days to accommodate that safety provision.

In short, Ora's staff are offering maximized oversight and helping to enact standardized protocols to ensure the safety of all participants, site staff, and physicians. These safety protocols, in turn, make patients feel at ease as they witness Ora's commitment to following federal, state, and local guidelines. The sites appreciate our methods for controlling patient flow with all standard procedures and safety precautions in place, as well as ensuring the use of PPE like masks, gowns, gloves, and glasses in some situations. Whatever is necessary, Ora's team has it covered.

Outreach and Monitoring the Virus

Ora did a lot of outreach ahead of time, not only prescreening participants but also walking them through protocols in the clinic to instill a level of confidence. The overwhelming majority of patients continued with enrollment.

Ora has also remained acutely aware of the impact of the virus throughout the country. We can be nimble and modify our study operations based on increased prevalence of COVID in particular regions of the country. Ora maintains regular contact with sites, holding roundtables to stay sensitive to any issues or areas of concern. In addition, we further regionalized our CRC support staff to reduce travel and let the teams stay in one place longer before moving to the next site. We have been able to pivot on this aspect for the added safety and comfort of our staff and the site.

For sites that were active in research studies, without Ora's support and professionalism in adhering to procedures that would help combat COVID concerns, many would have been forced to shut down their research in addition to their private clinics. (See testimonial about Ora's support from trial investigator Dr. David Evans, https://tinyurl.com/y4c33zo8?)

AT-HOME AND VIRTUAL ADVANCEMENTS

To advance in terms of virtual offerings – something that has become more critical in the COVID era – Ora has developed the EyeCup™ Smartphone device. This proprietary tool consists of a one-size-fits-all specialty molded cup which attaches to the smartphone and allows photographs of the eye to be taken by the patient at home. Photos are submitted to a web-based platform through automatic uploads along with diaries. This is representative of a real-world experience for participating patients, and not only increases the quality of the study endpoint, but also minimizes in-person visits which is especially important as we face safety challenges during the pandemic. It is always beneficial when part of the study can be done at home, and leveraging that technology for additional flexibility is especially beneficial now.

Ora has been accelerating the implementation of technology and processes to adapt to the need for telemedicine through a variety of tests, including an at-home visual acuity test performed through a smartphone or computer. Making participation in trials convenient for patients while at the same time gathering real-time data is another key part of what Ora can offer our clients.

Monitoring Oversight

As travel became increasingly challenging and Investigative sites were limiting access to CRCs, it was necessary to implement alternative strategies to ensure monitoring oversight without relying exclusively on on-site visits and source document verification. Fortunately, Ora was well positioned with regionally based CRAs as well as standard operating procedures that were already flexible enough to accommodate remote and alternative monitoring strategies. Despite support from regulatory agencies for risk-based monitoring dating back to 2013, most sponsors had a relatively slow adoption rate to implementing remote and risk-based monitoring. In light of the circumstances, almost all of Ora's sponsors welcomed recommendations on how to ensure ongoing patient safety and oversight during this time, and more than 80% of Ora's studies shifted to remote monitoring. These new methodologies are here to stay, and our clients are becoming increasingly receptive to risk-based monitoring. As we stay vigilant for another wave of COVID-19 cases, we remain nimble, having built-in flexibility for all of our monitoring plans.

Snapshot of Success

Ora is currently running 35 trials around the world. Based on our standard operations and the additional processes described herein, we have achieved successful start-up, maintained timelines, reached major milestones, and achieved database locks even during this challenging environment. The professional protocols we have developed and been adhering to for more than 20 years have allowed us to nimbly pivot to incorporating stringent hygiene and safety measures that observe all federal, state, and local regulations.

CONCLUSION

Ora's unique operations model of CRCs, standardized procedures and endpoints, and virtual offerings have been applicable to the COVID-19 environment and have allowed us to navigate clinical trials during an exceedingly difficult time. Our processes ensure we can adapt to whatever challenges come our way, all the while adhering to safety protocols and implementing the highest quality methodology that ensures all parties involved are comfortable and confident in the outcomes. Ora has built trust by working closely with a network of sites for almost a quarter of a century. We have a hands-on relationship with our partners and a true shoulder-to-shoulder approach with our investigators. Ora's agile and flexible nature has allowed important research to continue so that, ultimately, patients can have access to improved and novel treatments.