

Concierge-Style Services Becoming a Staple In Clinical Trials

BY DEBORAH BORFITZ | OCTOBER 11, 2023





growing number of companies, many originally in the meetings and events management industry, have pivoted to providing concierge-style services to clinical trial participants, enabling study sponsors to recruit patients faster, retain more of them, and get their outcomes data sooner.

Among the small sphere of players are Clincierge, which launched as a brand in 2015, followed by Scout Clinical in 2016. Patient concierge services are also on the menu of meeting planning veteran the Scarritt Group and Colpitts Clinical, which is heavily focused on travel and expense management. In the U.K., the mdgroup is offering a suite of patient services that are all underpinned by a patient mobile app and support portal.

In 2018, the contract research organization (CRO) PPD—now a clinical research business division of Thermo Fisher Scientific—entered the fold when it teamed up with Acurian (one of its subsidiaries) to provide personalized support to patients. Today, Thermo Fisher Scientific offers "comprehensive and robust centralized and one-to-one patient support" across study phases, according to Lauren Herring, vice president of medical communications for the company's PPD clinical research business (Clinical Trial Contact Center).

Demand for white glove services is particularly high for rare disease studies but that's not where it stops, according to representatives from each of the companies. Big pharma has been slower to adopt the concierge mentality, despite the potentially high return on investment (ROI), but new regulatory guidelines designed to balance the socioeconomic playing field for trial participation have created some tailwinds that have been good for business, reports Scott Gray, CEO of Clincierge, a business division of Gray Consulting International.

'Bobbing and Weaving'

Clincierge was created in 2013 at the request of a

biotech customer that had approval to run a rare disease trial in 18 countries outside the U.S. but didn't know how to get the patients from where they lived to the nearest enrolling research site, says Gray. After about six months, the client moved all their U.S. patients to Clincierge because it was offering better service quality than the existing vendor, he adds. Clincierge today supports patients in 42 countries, about 60% of them in the US.

The company's focus from its founding in 1994 until the Clincierge brand was born in 2015 to make patient concierge services available more broadly was providing

Demand for white glove services is particularly high for rare disease studies but that's not where it stops, according to representatives from each of the companies.

the best experience possible for attendees of corporate events and sales rep meetings, mostly for pharmaceutical companies. "In running corporate events all around the globe, we were always bobbing and weaving to figure out the obstacles that constantly presented themselves," he points out. In the same way, Clincierge now endeavors to enhance the clinical trial experience in every conceivable way outside of the medical regimen spelled out in the study protocol.



Clincierge, like Scout Clinical and Thermo Fisher Scientific's PPD clinical research business, works internationally across multiple therapeutic areas and is quick to cite the shortsightedness of relying solely on technology as the solution rather than a means of support. A recruitment company that was presenting at a conference seven years ago pitched the idea of building websites, Gray recalls. "I quickly googled how much of the world's population has access to the internet and at that point it was only 55% of the global population," a big miss.

Retention rates get a boost from concierge services, says Gray, citing a statistic in the "mid to upper 90%" among the patients Clincierge supports on behalf of trial sponsors—easily 20 percentage points above industry norms.

The bottom line for Clincierge, says Gray, is to remove some of the barriers of clinical trial participation that are well known by industry—most notably, financial and logistical concerns and the lack of resources for supporting study enrollment and retention—with "a foundational mentality... of hospitality." To that end, sponsors will sometimes include funding in their research budgets for Clincierge to, as necessary, pay for hotels, ground transportation, and meals for participants.

During the pandemic, Clincierge went so far as to charter private medical aircraft to move critically ill or immunosuppressed patients to study sites so they could continue with their research regimen, he says. These

were "exceptional requests" in instances where patients only had a few more visits before completing the trial, so the sponsor authorized the additional investment to ensure their safety.

With Alzheimer's patients, attempts were made to move site personnel to the home of study participants and their caregivers, but the tactic proved to be neither popular nor enduring, says Gray. "Patients said they actually enjoyed the trip to the research site because for many of them it was one of the few social interactions that they had left in their lives."

Running the Numbers

If study sponsors are going to make the investment in patient support services, they first must recognize the ROI, says Gray. In terms of patient recruitment alone, the hemorrhaging of funds can be stopped.

One widely circulated report pegs the average cost of recruiting a single patient at \$6,500, which is money lost and then some if that patient drops out and the sponsor must reinvest in the activity, Gray elaborates. The timeline of the trial of course also extends. "If it's a 12-month trial and at six months someone has trial fatigue because they can no longer afford the airfare [or otherwise] do whatever is necessary to still attend the trial, they drop out and you have to reenroll, and that trial is now 18 months long."

Retention rates get a boost from concierge services, says Gray, citing a statistic in the "mid to upper 90%" among the patients Clincierge supports on behalf of trial sponsors—easily 20 percentage points above industry norms. And the savings extend beyond recruitment, since companies get their outcomes data sooner and more quickly submit their products to regulatory bodies for marketing approval.

In a practical sense, Clincierge suggests initial service offerings as sponsors are developing their study budgets, he says. The key considerations are potential limitations



of patient populations they are trying to recruit, including issues with cognition, vision, hearing, using technology, or simply living in a region where Wi-Fi and internet access aren't readily available.

Trial participants and their families receiving support from Clincierge are assigned a coordinator who functions as the logistics manager for the entire unit until their participation in the trial concludes. This effectively gives patients "an advocate who can raise up questions about the unique conditions in their life that may require exceptions," says Gray.

He offers as an example the relocation of families to other cities or countries to enable trial participation, a scenario that would involve renting a house or apartment, having food ready upon their arrival, and arranging delivery of a crib and diapers if the family unit includes an infant. The coordinator is familiar with "all the vendors in our ecosphere of providing services," he adds, drawing a distinction from the trial services of Uber Health where patients are unlikely to get the same, trusted driver visit to visit.

On the other end of the spectrum are participants who only need "non-concierge services": to be reimbursed the cost of transportation to their study visits and a few bottles of water, says Gray. Clincierge is currently putting the finishing touches on workflow technology that will enable those sorts of routine services to be handled via a user-friendly app.

There are many players on the payment side of the business, owing to its popularity with study sponsors. Greenphire recently published a <u>case study</u> highlighting how ClinCard participant reimbursement solution enabled the Moffitt Cancer Center to save 40 hours per week on tedious administrative tasks. In this case, the big win was the ability of clinical trial operators to run automated reports and associate charges with the right account, as well as for happy participants to be compensated with reloadable debit cards—all in real time—which can also help foster <u>feelings of connection</u> in decentralized clinical trials (DCTs).

'Empathetic Mindset'

Scout Clinical, part of the Meeting Protocol Worldwide brand family, is likewise on a mission to help patients enroll in clinical trials and stick with them. Its services fall into two main camps, patient reimbursement and high-touch logistical support, according to Executive Vice President of Operations John Fontenault. He joined the company in April, bringing with him more than three decades of experience in the drug development industry with a focus on technology solutions for clinical trial data capture.

The reimbursement services of Scout Clinical cover both expenses associated with trial participation and any per diem or stipends that participants are to be paid. This might be done one transaction at a time or in "bulk fashion" where stipends are being processed for payment once clinical data files are received, says Fontenault.

Now more than ever, it's critical to make the journey through a trial as easy as possible for participating patients and their family, says Fontenault.

Activities associated with the more white-glove type services vary significantly—and is where Scout Clinical is making a bigger impact "with the right kind of empathetic mindset," he adds. It can be "as simple as getting [participants] a taxi or Uber to their next site visit all the way through to a cross-border relocation to another country where they need visa support and long-term lodging and cultural assistance."

Now more than ever, it's critical to make the journey through a trial as easy as possible for participating patients and their family, says Fontenault. Studies have



grown increasingly more complex with numerous primary and secondary endpoints and extensive inclusion and exclusion criteria, making recruitment and retention two of the biggest holdups. When it comes to rare disease studies, in particular, patients are the ones driving demand for logistical support because participation often requires extensive travel for many months, he notes.

In addition to assisting customers meet their trial diversity needs, many customers have also begun strengthening their commitment to green initiatives and are looking to Scout Clinical to help them hit their sustainability targets, adds Fontenault.

Technology solutions enabling data capture for DCTs, which were necessary during the pandemic, have not endured at the level initially anticipated, he says. Scout Clinical leverages technology with sites and patients as a means of providing its suite of reimbursement and travel services for what is more typically a hybrid experience combining traditional and virtual trial elements.

Clients of Scout Clinical include study sponsors large and small as well as CROs of every size, among them a few top-five CROs, says Fontenault. Based on positive feedback from some of its larger customers, the company "takes pride in focusing on putting the patient and their care circle first with the motto of 'no request is too big or too small'," he adds. Scout employs patient navigators to guide individuals through every step of their trial journey, which often involves helping families find long-term lodging as well as schools for their children when relocating for study participation purposes.

Tailored Interactions

Thermo Fisher Scientific goes "beyond simply arranging for patient transportation and sending follow-ups by providing a personalized connection to encourage diary and questionnaire completion,

gather feedback on their experience, and create site and study connections, while empowering patients with information and breaking down barriers," says Lauren Herring. "We've found that patients appreciate a meaningful connection whenever and wherever they need it. Our 24/7/365 omnichannel approach makes this possible."

Particularly important during and since the pandemic, she reports, is ensuring accurate and timely collection of medical information and electronic patient-reported outcomes data to alleviate some of the workload on sponsors while keeping patients engaged. DCTs and hybrid trials, which have risen in popularity, also "inherently benefit from one-to-one support of concierge services."

Scout Clinical leverages technology with sites and patients as a means of providing its suite of reimbursement and travel services for what is more typically a hybrid experience combining traditional and virtual trial elements.

Concierge services, as Herring defines them, are available throughout the clinical trial journey. For individuals exploring the possibility of participation, Thermo Fisher Scientific first educates them about trials that may be a good fit to create a "meaningful connection," she says. Interactions are therefore tailored to the needs and situations of specific populations.



Patients who are pre-qualified for a study are all given a single point of contact for receiving trial information and getting connected to the closest enrolling site and are engaged on an ongoing basis until their first site visit, says Herring. Individuals who are interested in participating in a trial but don't qualify may later be contacted about other studies where they'd be a potential match, provided they've given their consent to the outreach.

The business of removing the barriers to retaining and supporting enrolled trial participants can be "long and complex," Herring says. One such obstacle could be the need for travel support. "A patient in a trial for a rare disease contacted her concierge expressing concern about her ability to travel to her appointments, since she and her husband shared a vehicle," she offers as an example. "The concierge solved the immediate need by scheduling a car service and escalated a recommendation for rental car services to the sponsor... [and ultimately] was able to obtain sponsor approval for a rental vehicle for the patient's travel to her study appointments and she remained in the trial."

Patient support extends to reporting and resolving adverse events. An example here is when a patient called his concierge to report he was experiencing severe nausea while on the treatment and intended to drop out of the trial. "The concierge expressed empathy for the participant's symptoms and then offered to transfer [him] to his clinical trial site," she says, where he had his treatment adjusted such that he opted to remain in the study.

Directly connecting patients with support makes them less likely to drop out, which also helps maintain trial diversity, says Herring, noting that her team is extensively trained on "customer service best practices, empathy, specific populations and cultural sensitivity," as well as training that is disease-state-specific. This has enabled meaningful connections and engagement with participants representing a "broad range of race, gender, sexual orientation, age and ethnicity, including minority groups that have been historically underserved in healthcare."

It behooves sponsors to pay attention to the experience of patients during a trial, she adds, since it influences their desire to participate again in the future, she adds. The Clinical Trial Contact Center offers solutions to help ensure "an exceptional experience at every critical touchpoint" and brings that to fruition by partnering with Thermo Fisher Scientific's clinical services team as well as trial sponsors.