CRO LEADERSHIP AWARDS 2021

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Life Science Leader
CLINICAL LEADER

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JUNE 2021

Digital Technologies Will Continue To Drive Patient Outcomes

p. 6

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The Future Of Clinical Research Is Bright

ED MISETA Chief Editor, *Clinical Leader*

This is an exciting time to be involved in clinical trials. I feel like I have been saying that for the more than eight years that I have been writing about clinical research, and every year seems to bring new technologies and new opportunities. But I also feel the statement is more applicable today than ever before.

The first exciting development is the emergence of decentralized trials. For years, I have heard companies and industry leaders talk about patient-centricity and our ability to ease the burden of trials by taking studies to the patients. Unfortunately, little progress seemed to have been made.

Of course, 2020 changed all that. Suddenly, every sponsor company was scrambling to implement any technology that would allow patients to continue their trial participation from the comfort of their homes. Digital devices, remote monitoring, home nursing visits, and other virtual technologies were in high demand. In April, one technology vendor told me he'd had two consecutive months of record business proposals.

We don't yet know if these changes are here to stay, but if many in the industry have their way, there will be no returning to patient visits at brick-and-mortar clinical sites. One executive told me that, in the future, decentralized trials will simply be known as clinical trials.

It's interesting and informative to learn about the challenges companies face when implementing new technologies, and one of the articles in this supplement features Robbie McCarthy, GM, U.S. for Advicenne, discussing his first foray into the decentralized trial arena. He shares his insights on improving trial protocols, the vendor selection process, and avoiding common pitfalls.

Another change that is about to rock the world of clinical research is the adoption of AI and machine learning in drug development. There are currently a myriad of inefficiencies that plague clinical trials, many of which revolve around study start-up, including patient/site/country selection and the always-difficult and time-consuming recruitment process.

AI and machine learning are expected to eliminate the challenges around those chores and ultimately reduce trial costs and timelines. Still, many questions remain. How do you implement these solutions? Whom should you call? What data do you need? How do you gather the data? And what questions do you need to ask? Many sponsors will need help implementing these solutions, and solution vendors are available to assist them.

That brings us to the purpose of this CRO Supplement. Vendor selection can be a difficult process for clinical executives. There are many companies and solutions to evaluate. Your CRO can provide you with solutions you need, or help connect you with the companies that can. But selecting the right CRO is, in itself, a difficult and time-consuming process. The purpose of this guide is to assist you with that difficult decision.

Industry Standard Research has done the difficult work of surveying drug sponsors to determine which CROs they have worked with, and how they rate those partners. CROs are evaluated in five categories: quality, reliability, expertise, capabilities, and compatibility. We hope you see this supplement as a handy reference guide that you can keep nearby and refer to when it comes time to select an outsourcing partner.

There has never been a more exciting time to be involved in clinical research, and we look forward to joining you on this journey.

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DIGITAL TECHNOLOGIES WILL CONTINUE TO DRIVE PATIENT OUTCOMES

ED MISETA Chief Editor, *Clinical Leader* @EdClinical

Looking back on 2020, Christoph Koenen, EVP and chief medical officer at Otsuka Pharmaceutical Companies (U.S.) notes there was an explosion in the advancement of digital technologies in clinical trials. While other companies scrambled to implement technology tools to deal with the pandemic, he notes that Otsuka was an early adopter of tools such as eCRF and eConsent.

"Traditionally, Otsuka always has had a great interest in using digital technologies in our clinical trials," he says. "These technologies were standards in our trials – they were not optional. Virtual visits for patients and virtual monitoring have been backup solutions in our trials for years. I feel that early adoption gave us an advantage in 2020 over other companies that were not early adopters."

Going All In

Looking forward to 2021 and beyond, Otsuka hopes to continuously build on the technologies it has in place while engaging with new and emerging digital solutions. The implementation of new technologies will often require partnerships. When it comes to digital technologies, Koenen notes that there is only so much Otsuka can do on its own.

"We know there's a lot more we are capable of doing in partnership with companies that are focused on the development and utilization of technology solutions. For us, the main thing that has changed over the last 12 months is our willingness and ability to go all in when it comes to using digital technologies."

> **"Owning a smartphone should not be a prerequisite for participation in a clinical trial."**
>
> **CHRISTOPH KOENEN**
> **EVP And Chief Medical Officer**
> **Otsuka Pharmaceutical Companies (U.S.)**

In the past, Otsuka had virtual monitoring and virtual visits in place to prove they worked and could be used if needed. The technologies were available, and staff knew how to use them. What changed over the past 12 months is that the use of those technologies was no longer optional. Virtual interactions had to be used to ensure the safety of patients and the success of clinical trials. Virtual contact with some patients also became mandatory when some sites were physically closed. Therefore, the work performed prior to the pandemic had Otsuka well in front of the curve.

What Is The Risk?

At one time, companies considered the adoption of new technologies to be a risk. Koenen notes that Otsuka always performed risk assessments prior to implementation as a standard business practice. This was done to determine if the risk of adopting a new technology was greater than the risk of not doing it. He states that his company always viewed the long-term risk of not adopting digital technologies as being greater than the risk of adopting them.

"As part of the risk reduction process, Otsuka will build redundancies into its clinical trial process," says Koenen. "Although a trial might require some face-to-face visits, virtual visits would be included as a backup plan. COVID changed that model by making virtual visits mandatory to protect the health of patients. When that happened, discussions about the risks of those models suddenly seemed to go away."

For companies now using digital technologies, Koenen believes the adoption risk has dropped considerably. This is due to companies becoming more comfortable and experienced with using the technologies, as well as guidance released by regulators. In fact, Koenen now hears the risk argument coming up far less frequently.

Overcome The Digital Divide

A bigger concern for many drug developers right now has to do with patient diversity. Koenen believes the industry has an obligation to do something about that issue. When it comes to recruitment, he wants clinical trial populations to closely resemble the populations that will be served by the treatments. The benefits of using digital technologies are obvious. The problem is the digital divide that exists and was clearly exposed by student remote learning that took place in 2020. There are families that simply do not have access to the same technologies that exist in other households.

"As sponsor companies for clinical studies, we have to help overcome that divide," says Koenen. "It is not that difficult to do. For example, owning a smartphone is great. But owning a smartphone should not be a prerequisite for participation in a clinical trial. If a smartphone is required to participate in a trial, and a patient wants to use their own, that's great. We will let them do so. But if they don't have one, then sponsors will need to provide them with a device."

That device can be a smartphone or another piece of technology that caters more toward use in a clinical trial. For example, one solution Otsuka is investigating right now is placement of a digital device in a home that will allow for interactions with a healthcare provider. That device could also perform other tasks such as collecting EKG data or dispensing a pill.

"These devices will be specifically designed for use in a clinical trial," adds Koenen. "It may not have any other use outside of that trial. As sponsor companies, we need to discover solutions that will allow us to overcome that digital divide. We must be as accommodating as possible to the trial participants."

Lessons Learned In 2020

Koenen believes there were many lessons learned from managing trials during the COVID pandemic. One thing that stands out to him was the speed at which pharma companies drove change and innovation in their clinical trials. He hopes that spirit of innovation will continue in the industry once the pandemic has passed.

When thinking about what the industry could have done better, Koenen points to soliciting feedback from patients. In March, when the pandemic came crashing down, many trials were brought to a halt. In retrospect, he thinks there could have been more flexibility.

"Some companies were certainly more flexible than others, but I feel too many trials that patients depend on were completely shut down," he says. "For some trials, that action made sense. It may also have made sense to halt the recruitment for some trials. But I also believe there was an opportunity for us to talk to our patient populations and get their input on whether or not to continue to run the ongoing trials, especially in cases where virtual or digital technologies were at our disposal. If this situation were to occur again, I believe there will be a much more seamless transition from brick-and-mortar visits to virtual interactions."

"I personally feel the industry will keep a lot of these innovations made in the past year," continues Koenen. "I believe we will not be going back to how trials were conducted in the past. I think there will be a push by some in the industry to revert back to pre-pandemic trials. That will happen anytime you implement changes so quickly, and there will always be reasons to do that. However, I think the industry, the scientific community, and regulators will hold each other accountable to make sure that doesn't happen. The benefit to patients is too important to ever go back. I feel there is a consensus to not let that happen." L

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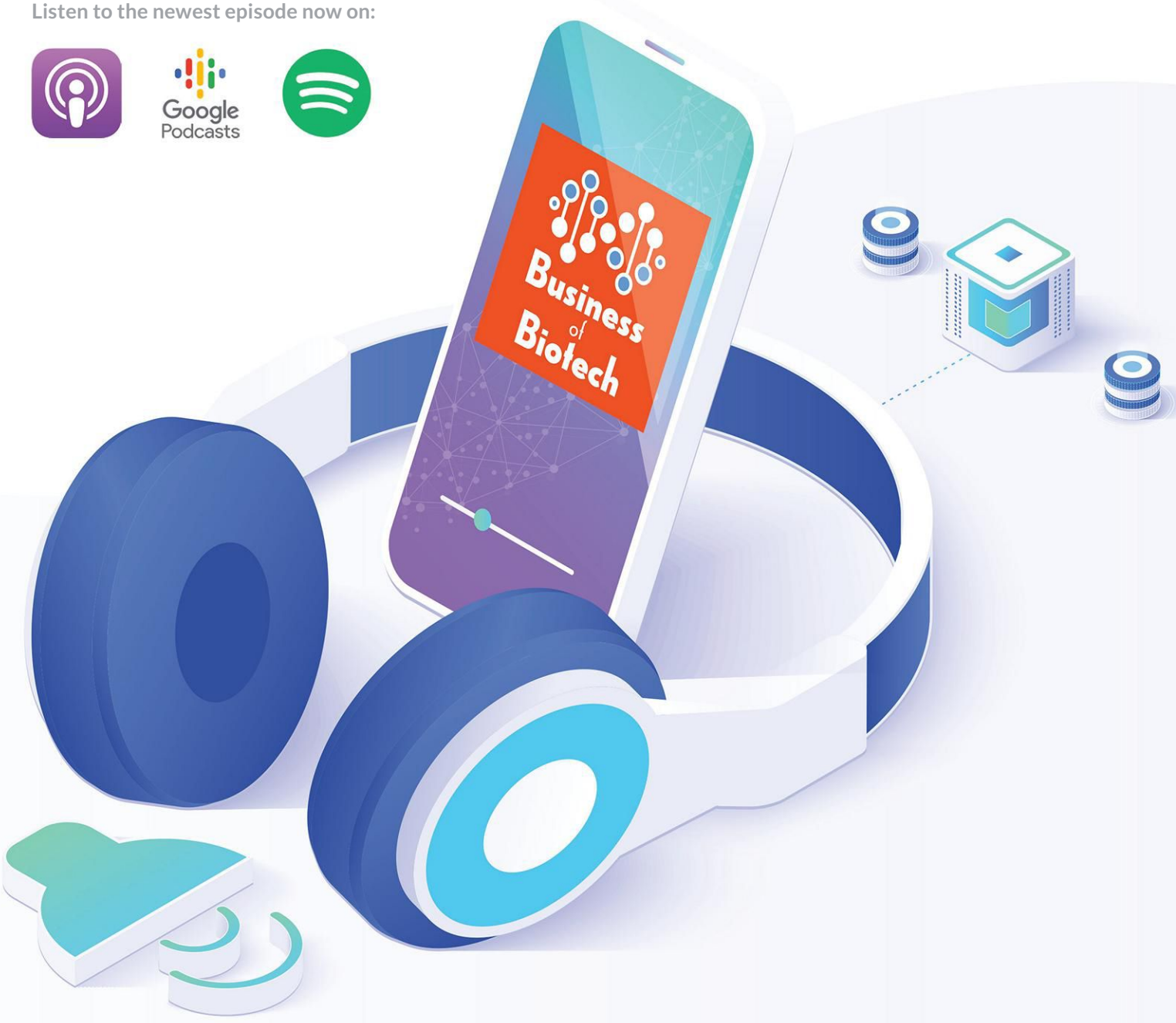

A Drug Developer's First Experience **With Decentralized Trials**

ED MISETA Chief Editor, *Clinical Leader* @EdClinical

When the FDA released new guidance for companies in May, it seemed every drug developer was scrambling to convert its clinical trials to a decentralized approach. Advicenne was no exception.

The France-based company has spent a decade developing treatments for rare kidney diseases. Its lead asset, ADV7103, received a positive opinion from the Committee for Medicinal Products (CHMP) recommending approval for the asset as a treatment for distal renal tubular acidosis (dRTA) in the European Union. Trials for the asset are underway in Europe, the U.S., and Canada.

The U.S. Phase 3 study is called ARENA2. It began recruiting patients in August 2019, and was active for more than a year when it was put on hold in 2020. The main reason for the hold was difficulties the company faced with patient recruitment.

"The population of patients with this disease is very small in the U.S.," says Robbie McCarthy, general manager, U.S. for Advicenne. "The initial study design required a randomized trial where patients would receive the active drug or a placebo. The original design also required patients to go through a six-day withdrawal period in a hospital setting. That was already a tough request for patients, and when COVID hit, it became impossible to execute. There was simply no capacity in the hospitals. It also was not in the best interest of patient safety to put them in hospitals with COVID-positive patients. We put the study on hold and used that time to reexamine the study protocol."

IMPROVING A TRIAL PROTOCOL

In reexamining the protocol, McCarthy hoped to do two things. First, Advicenne wanted to determine how it might increase its access to patients with dRTA anywhere in the country. The standard "brick-and-mortar" approach is difficult in rare disease studies since even a major site in a large city might only see one or two patients. Advicenne needed 32 patients for its study, and to reach that number, it would have to recruit around 50 patients, requiring 30-50 sites in the classic study model.

Second, McCarthy hoped to determine how patients could participate in the trial without a mandatory hospital stay. That led to him seeking out CROs and technology service providers that offered a decentralized approach to trials.

"We saw this move toward decentralized trials as a learning experience," states McCarthy. "When we started on this journey, I'm not sure we knew what we were asking for or what was possible. However, we initiated a very rigorous RFP process, which allowed us to hear from several providers. That allowed us to learn about and compare the different approaches and models."

McCarthy spoke to nine technology vendors and CROs. He learned about their capabilities and how they would execute a decentralized trial in a rare disease population in the face of COVID. He was a bit surprised by what he learned.

"I found some vendors did not have the needed capabilities at all," he says. "They simply suggested we take a traditional approach. Some were selling us a virtual study approach, but when we drilled down into the technology, the capabilities were not there. There was simply an app-based digital platform that allowed participants to enter patient-reported outcome data from home. There might be some home nursing or perhaps an ePRO solution. But what we saw from many vendors was still essentially a site-based model with a technology platform that enabled patients to conduct some activities without going to a site."

A TOOL TO FACILITATE VIRTUAL TRIALS

The company Advicenne was most impressed with was Science 37. McCarthy felt the company had a

"When patients have to travel to a site, they feel involved in the research, and special, because the focus is on them. That motivates them, and there is an obligation that comes with it. You can lose that when all engagements take place in a patient's home,"

ROBBIE MCCARTHY
General Manager, U.S.
Advicenne

well-established platform, and he liked the fact that Advicenne could use it to run a hybrid clinical model.

"Some of our sites are university hospitals where doctors have expertise in this rare condition," states McCarthy. "Those sites are also supplemented with neighborhood physicians who may be situated in the middle of nowhere and have access to one patient. They are not familiar with the disease, conducting research, or running a clinical trial. We require the ability to set up those clinics as a sub-investigator to the master site and allow the patient to participate remotely."

In that model, physicians are trained to be sub-investigators. Blood draws previously conducted in clinics would be performed by nurses in patients' homes. Patients could record outcomes they experienced and there would be telemedicine calls with the doctor. McCarthy notes that all work and appointments can be scheduled using the Science 37 platform.

WHO HAS THE CAPABILITY?

What surprised McCarthy the most were his discussions with CROs. They sold the idea of conducting decentralized trials, but when he dug deeper into their experience, he found they had a technology platform, but it was not an integrated solution; all the components were separate, such as the home nurse service, the telemedicine platform, and the app platform for patients.

Another issue McCarthy encountered revolved around home nursing services. Several of the vendors were contracting with third-party service providers. In 2020, he found that the prices charged by those service providers had increased substantially due to the increase in demand. Also, many of the providers did not have enough nurses on staff to meet the surging demand. Decentralized trials can be difficult to conduct without in-home visits by qualified medical personnel.

The offering that most resonated with McCarthy was a partnership between NC-based service provider PharPoint Research and Science 37. McCarthy describes PharPoint as a boutique CRO, but one that had knowledge of rare diseases and decentralized trials, and Science 37 as an integrated virtual study platform, combining econsent, ePRO, and telemedicine. The latter also offered a shared platform for both investigation teams and subjects, complemented by directly employed home health nurses who are trained on the platform.

One takeaway from the whole experience was the need to be careful when reviewing RFPs for a virtual study. McCarthy recommends making sure you're not sold on using a virtual platform for existing sites. There is a per-patient cost for a site-based patient model and a different per-patient cost for the decentralized model. "We have a mix of the two. So, if our trial goes from a 60-40 mix to a 70-30 mix, that changes our costs, and the contract we sign must reflect that. We went through multiple iterations to determine exactly what that mix should be."

A NEW APPROACH IN RARE DISEASE STUDIES

McCarthy believes this was the first time the Science 37 model would be applied to patients in a rare disease trial, and he knew there would be challenges — one of which was getting the sites comfortable using the new platform. "Most sites are using numerous platforms, so we spend a lot of time training the site staff until they feel familiar with the new process."

During his research into decentralized trials, he learned that one of the top risks of this model involves losing patients who are not adequately engaged with the trial. "When patients have to travel to a site, they feel involved in the research, and special, because the focus is on them. That motivates them, and there is an obligation that comes with it. You can lose that when all engagements take place in a patient's home."

Taking the 32 patients through a Phase 3 trial results in a very substantial per-subject cost. For Advicenne to retain these highly valuable patients, they all need to feel they're getting the same amount of attention and care they would have received in a clinic.

That's why the company developed a unique role to support patients through their study journeys. The Patient Navigation Specialists, or Patient Navigators, work like study social workers, providing direct contact and support for the patients and caregivers. Part of that support includes educating patients on what it means to participate in a study, the steps they need to go through, and a timeline of events that will involve them. Most importantly, they are there to answer questions and provide psychosocial support to the participating children and families.

"What we learn from this study can help us apply the model to future studies and hopefully help address the ongoing challenge of recruitment and retention in rare disease studies," concludes McCarthy.

The 3-Step Approach To Unlock **The Power Of Historical Trial Data**

LIZ ROBERTS
JULES DESMOND
AARON MANN

Historical data from the control arms of clinical trials hold tremendous value for researchers. Clues can be extracted from the data that aid researchers in discovery, analysis, and the design and execution of future trials, influencing the success and speed of research. Yet, too often, that data is underutilized once a trial is closed — often trapped inside corporate walls with limited reuse, even internally.

While the biopharmaceutical industry has made significant strides in the sharing and use of external trial data to help bring medications to patients faster, many organizations can find it difficult to make sharing and using this data routine. Sharing data externally and using shared data within an organization often require new operating practices, resources, and behaviors.

The global COVID-19 pandemic helped to catalyze change. In parallel with a global collaborative effort to enable the rapid rollout of multiple COVID-19 vaccines and therapeutics from discovery to distribution, the industry also spearheaded new data-sharing efforts with renewed vigor.

How do we build on this momentum to continue and accelerate the use of historical trial data to transform R&D in the future? We use the following three-pronged approach.

1 REINFORCE THE VALUE OF DATA SHARING

One of the biggest pain points for clinical trials is getting enough people to enroll and stay enrolled. A lack of awareness, understanding, and access to clinical trials persists in the general public. The added uncertainty of being randomized to the control or the investigational arm is often perceived as a barrier to enrollment. Once enrolled, an individual's participation in a trial can become burdensome or difficult to fit into their lifestyle. Finding ways to supplement new control arms with data from historical controls can help to reduce the number of participants needed in future trials, speed trial design and execution, better understand diseases, and improve overall patient experience. This helps advance research more efficiently.

TransCelerate Biopharma's Historical Trial Data (HTD) Sharing Initiative was established to benefit patients and sponsors alike by maximizing the value of clinical data collected in the control arms of clinical trials by enabling the sharing of patient-level data from completed studies among biopharma companies while also safeguarding patient privacy. Today, participating member companies share data through DataCelerate, a secure and fully validated platform developed to support a variety of data sharing initiatives.

Biostatisticians and researchers can gain access to high-quality historical data from the platform. Its voluntary adoption among TransCelerate member companies has steadily grown, and the database becomes more valuable each time members upload new data.

As the pandemic took hold last year, the value of such data sharing specifically for COVID-19 became abundantly clear. A new COVID-19-specific module was created on DataCelerate, allowing both members and, for the first time, eligible non-member biopharmaceutical companies and government research agencies to participate — provided they are engaging in COVID-19 research and meet defined participation criteria. Additionally, the scope of data sharing was expanded to include both investigational product and control arms from trials relevant to COVID-19. In all instances, the

> *"Ultimately, the hope is for it to become routine behavior that companies opt to share historical trial data, and that data are then used to help design, execute, and analyze new clinical studies."*

data are pseudonymized or anonymized prior to sharing to protect patient privacy.

These developments are exciting, and they demonstrate that companies are further embracing a collaborative spirit of sharing. In a matter of weeks, we were able to facilitate a shift from concept to executed data sharing agreements. This COVID-19 module also has started to see this data populate. And progress is continuing, as the HTD Initiative strengthens collaboration with regulators on using historical trial data in regulatory submissions. The team also continues to engage the research community to establish best practices to encourage more widespread use.

However, while the need for historical data sharing and utilization is gaining traction, internal roadblocks may still hinder progress. Understanding the value external trial data can bring to an organization is a key to both taking full advantage of an important data source and to reducing internal data sharing process and resource hurdles.

2 IMPROVE DATA UTILITY

Translating data sharing from a conceptual idea that a company supports to its practical execution can be challenging. There needs to be buy-in for additional resources, and there must be an awareness of the short-term versus long-term value of the control arm data that are collected during clinical research. It's important to understand that the value of the database grows exponentially over time as more data is shared to the database.

Another key focal point is protecting participant privacy while still providing high-quality, functional data sets. Privacy protections and data quality standards exist to ensure both. Both the HTD and COVID-19 data-sharing initiatives have physical, digital, and legal safeguards implemented to protect data sharing, including execution of key legal agreements relating to data sharing and data processing, as well as sharing via a secure platform. Therefore, historical control data can be protected, while still enabling users to benefit from high levels of data utility.

The structure, governance, and requirements of quality data are all key to maximizing its utility and are ongoing priorities for TransCelerate's HTD Initiative.

3 TAKE THE LONG VIEW

Equally important is a mindset shift for sponsors to become comfortable sharing their data throughout the ecosystem. Of course, change doesn't happen overnight, and companies must take a long-term view about the value of data-sharing efforts and their role in the data-sharing ecosystem. It will take time to ingrain new organizational behaviors and change mindsets to make sharing and utilizing historical trial data the norm. And as companies populate databases, such as DataCelerate, with more clinical trial data across different disease states, the value to users will continue to grow.

The COVID-19 pandemic may be the fuel that was needed to ignite stronger action around data sharing, as companies aren't just talking about working together to solve global problems — they're also making more tangible contributions. As data sharing picks up more steam, companies will be able to incorporate data-sharing activities across other disease areas, bringing innovative medicines to patients faster.

But in regard to the exciting advancements that lie ahead, speed isn't the only focus. We also have a responsibility and obligation to respect patients' time and contributions by maximizing the use of data collected during a clinical trial and, if possible, by reducing the number of patients needed to participate in the control arms of clinical trials. By maximizing the use of data collected from patients, we can move everyone closer to solutions that treat debilitating and life-threatening diseases, while reducing the future demands required of patients in research.

Ultimately, the hope is for it to become routine behavior that companies opt to share historical trial data, and that data are then used to help design, execute, and analyze new clinical studies. The more we can ease and encourage the secure upload of clinical trial information, the more powerful the tool will become, and the greater the benefits to patients. L

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How CRO-Sponsor Partnerships **Spurred Innovation In 2020**

DENISE CALAPRICE, PH.D.

For decades, operational progress within the clinical research industry has been profoundly shaped by the relationships between sponsor companies and their CRO partners. Among other advances, these relationships have contributed to sponsors' abilities to globalize clinical trial operations, expand therapeutically, manage risk effectively, and optimize processes, impacts that have been studied for nearly 20 years in the annual Avoca Industry Survey. While much of the world observed, the clinical research industry in 2020 speedily adapted its practices to accomplish remarkable feats of rapid and high-quality vaccine and therapeutic development. What close observers had witnessed over the years prior, in contrast, was that the ability to innovate in this manner varied widely across companies, and on balance, had not been a source of industry pride. To study this transition, the Avoca Industry Survey in 2020 focused on practices related to clinical research innovation, and in this article, we draw from the data to explore the role played by CRO-sponsor relationships.

WHO PARTICIPATED IN THE SURVEY?

The 2020 Avoca Industry Survey was designed to study how the events of 2020 accelerated operational and study design innovations within clinical development, as well as how respondents perceived clinical trial quality and efficiency to have been impacted, how management practices were adapted, and whether respondents anticipated a return to pre-innovation approaches, or an acceleration of innovation, post COVID-19. Invitations to participate were sent to contacts in Avoca's database late in the year, and an open invitation to participate also was posted on the Avoca website and on LinkedIn.

The respondents included 145 representing sponsor companies and 84 representing providers. Approximately half represented clinical development/operations; slightly over 1/4 represented quality assurance; and the remainder represented a wide spectrum of management and functional roles. Thirty-one percent of respondents represented companies that sponsored or conducted more than 50 clinical trials during 2020, and 25% represented companies that sponsored/conducted fewer than 5. Most respondents worked for companies headquartered in the U.S., but approximately one-fifth represented companies headquartered in Western Europe or Japan.

PERCEPTIONS OF INNOVATION-RELATED PRACTICES

When asked to rate their agreement to positively phrased statements about their organizations' innovation-related practices in each of clinical development operations (CDO) and clinical study design (CSD), respondents' mean ratings on a scale of 1 (strongly disagree) to 5 (strongly agree) ranged from the low to mid-3s, and were uniformly higher for CDO-related than for CSD-related innovations (Figure 1). On average, provider respondents rated every statement higher than did sponsors, generally by approximately 0.3 units. Across both classes of companies and both the CDO and CSD areas, the most positive average ratings highlighted organizations' recognition and adoption of innovations likely to become successful, whereas organizations' willingness to accept occasional failures and to allocate and educate resources effectively scored more poorly.

ROLE OF CRO RELATIONSHIPS IN INTRODUCING INNOVATIONS

For the statement, "My organization has been introduced to new innovations through its relationships with CROs," the mean agreement rating was 3.3 for innovations related to CDO, and 3.0 for innovations related to CSD. Interestingly, in each case, there were statistically significant relationships between ratings for this statement and corresponding ratings for the statements in Figure 1: the more that an organization had been introduced to new innovations through its relationships with CROs, the more positively its staff felt about their company's recognition and adoption of innovations that appeared likely to be successful (CDO: F=9.6, p=.002; CSD: F=10.1, p=0.002), effective evaluation of the use of innovations in terms of both data impacts and ROI (CDO: F=12.2, p=0.0006; CSD: F=12.4, p=0.0006), education of teams in proper selection, evaluation, and deployment of innovations (CDO: F=2.9, p=0.09; CSD: F=6.8, p=0.01), investment of an appropriate number of resources into identifying and deploying innovations (CDO: F=7.4, p=0.007; CSD: F=11.9, p=0.0007),

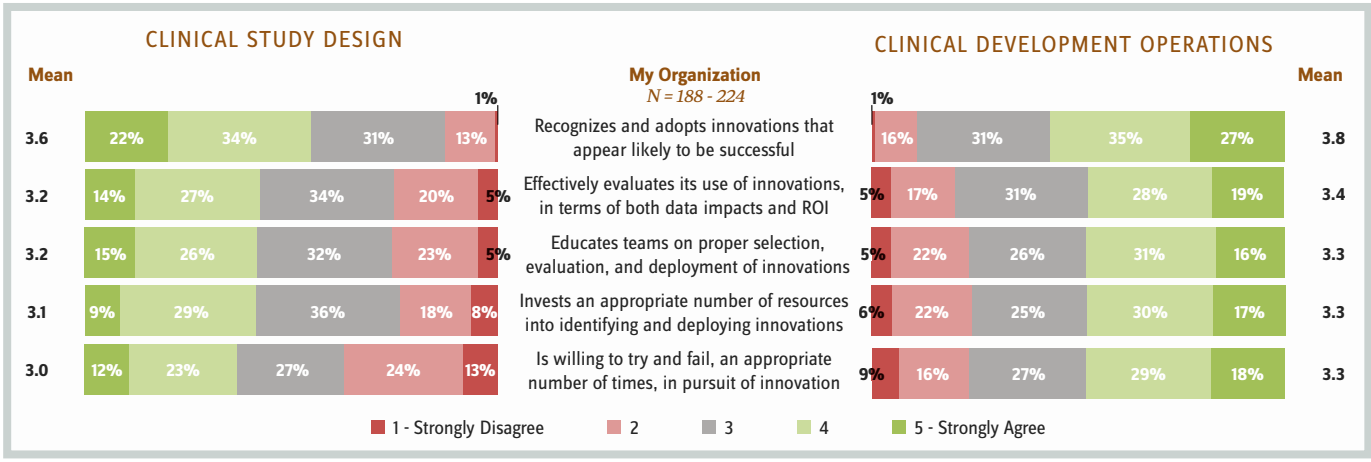


Figure 1. *Perceptions Of Companies' Innovation-Related Practices*

and willingness to try and fail an appropriate number of times in pursuit of innovation (CDO: F=5.0, p=0.027; CSD: F=16.1, p<0.0001). Thus, it appears that when innovations are adopted through these relationships, the relatively positive performance of CROs with respect to these aspects may be transmissible to their customers.

INNOVATION ADOPTION BY TYPE

For each of 35 specific innovations, respondents were asked whether their companies had adopted the innovation prior to the COVID-19 pandemic, because of COVID-19, during COVID-19, but not because of COVID-19, or not at all. Some innovations were commonplace, particularly those in the CDO category: few respondents had not already adopted (or made plans to adopt) remote source data review (3%), remote source data verification (5%), risk-based monitoring tools (7%), electronic patient diaries (7%), e-consent technologies (8%), study visits by telemedicine (6%), and/or home healthcare providers (8%). In contrast, large fractions had no plan to adopt completely site-less trials (49%), synthetic control arms (53%), or use of AI to detect possible unreported AEs (58%). Respondents that provided ratings of 4 or 5 to the statement, "My organization has been introduced to new innovations through its relationships with CROs," compared to those that provided lower ratings, were more likely to have adopted nearly all listed innovations prior to COVID-19, and were less likely to have no plans for their adoption at the time of the survey.

CORPORATE INNOVATION-READINESS IN CLINICAL RESEARCH

A similar pattern was seen for survey items relating to corporate innovation-readiness. For these items, comfort levels (on a rating scale from 1= "extremely concerned" to 5= "extremely comfortable") varied widely. Nearly half of respondents were comfortable about keeping their own skills and perspectives up to date, but only one-third were comfortable about this for their companies' workforces on the whole. At least one-third were uncomfortable with their companies' procedures for evaluating whether and when to deploy innovations in clinical development and for managing clinical trial quality in the context of innovation use. Even more were uncomfortable with their companies' approaches to assessing the ROI of innovations (38%), and with clinical trial workers' understanding of the quality implications of changes being made (40%), with again, more uncomfortable than comfortable in each case. In most areas, ratings among respondents from sponsor companies, especially those outside of the "Top 20," were again slightly lower than ratings among respondents from providers.

The pharmaceutical industry has relied on sponsor-CRO relationships to enhance clinical trial performance in a multitude of ways, and the adoption of clinical trial innovations appears to be no exception. In the 2020 Avoca Industry Survey, respondents from provider companies were generally more positive about their companies' innovation-related attitudes, practices, and workforce readiness than were those from sponsors, and sponsor respondents whose companies were introduced to potential innovations largely by their CRO partners were generally more positive about these things — and had experienced higher actual rates of innovation adoption — than those whose companies were not. Not surprisingly, then, areas in which sponsors have traditionally been more reluctant to fully engage CRO partners (i.e., those related to clinical study design as opposed to clinical development operations) were characterized by lower rates of, and poorer performance in, innovation adoption. Clinical research executives may be well-advised to acknowledge the potential role of providers in the adoption of clinical research innovation, and to embrace this dynamic fully through enhanced transparency about potential opportunities. L

DENISE CALAPRICE, PH.D., is senior consultant at the Avoca Group.

Message To CROs: Keep That Pandemic Tool Belt Handy

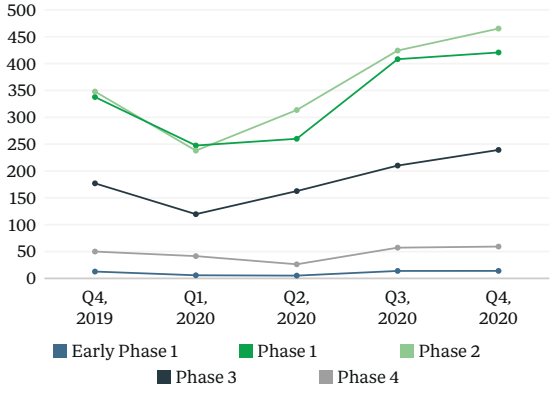
SHERRY HUBBARD-BEDNASZ

Over the past year, the pharma industry has been in overdrive. The best of the best around the world – biochemists, scientists, doctors, researchers, and the like – came together to develop a COVID-19 vaccine in record time.

Several vaccines have been approved for emergency authorization; manufacturing, distribution, and inoculation efforts are happening at rates never seen before. Despite the countless obstacles and dangers, the pharma industry managed to remain steadfast and put one foot in front of the other to get to where we are today – hopefully with COVID-19 in the rear-view mirror.

Let's take a closer look at the numbers. We at ISR like to keep an eye on some specific core industry metrics. The line graph below puts the past year in perspective – the bottoming out of Q1 2020 to the explosive ramp-up between Q2 and Q3. Between Q1 and Q4, the number of industry-sponsored submissions for Phase 1 studies rose from 246 to 420. That's a 70% increase. The number of submissions for Phase 2 and Phase 3 studies doubled: Phase 2 rose from 237 to 464; Phase 3 rose from 119 to 238. For an industry not known for its speed, this snapshot proves otherwise.

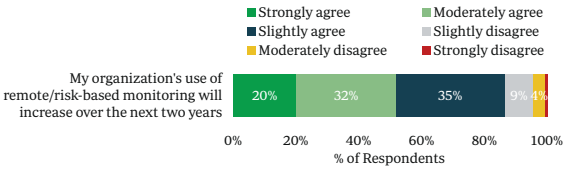
Actively Recruiting Industry-Sponsored Clinical Trial Submissions



Sponsors can't churn out the work alone. We know many companies turn to CROs for the heavy lifting of their clinical development programs. Finding the service provider best suited to meet trial needs and ensuring that provider can meet performance expectations constitutes the onerous and time-intensive decision-making process that companies take on if they need to outsource any or all components of their clinical trials. Every year, we survey hundreds of clinical development outsourcers to share their perspectives and experiences regarding Phase 1 and Phase 2/3 outsourcing activities and provider usage.

Add in the complexities of conducting trials during COVID-19 and you've got sponsors looking for providers who can pivot to nontraditional methods and solutions. One element we explore per our annual CRO benchmarking survey is outsourcers' future expectations for their clinical development programs. How much deviation from the traditional clinical trial infrastructure do sponsors anticipate? And while we are hoping COVID-19 is in the rear-view mirror, this does not suggest that sponsors want these new tools to fade into the sunset with it.

Something still very much on the radar is remote/risk-based monitoring. Trials traditionally assess site performance via on-site monitoring, and they rely heavily on source data verification. Risk-based monitoring reduces the volume and frequency of source data verification, and is designed to focus on high-risk sites — those that flag with potential issues requiring verification. We asked 272 outsourcers their levels of agreement with the statement below. More than four in five respondents (87%) agreed that their organizations' use of this type of monitoring will increase over the next two years. Sponsors want to have this at the ready in the future, regardless of a pandemic bearing down or not.



One respondent gave this complimentary reason for their overall satisfaction rating regarding the recent use of a Phase 1 provider: "Regulatory expertise, risk-based monitoring expertise, great clinical operational support, data management and biostats, and offering hybrid approach in terms of virtual trials, especially during COVID-19. Global knowledge of Phase 1 units and SME database."

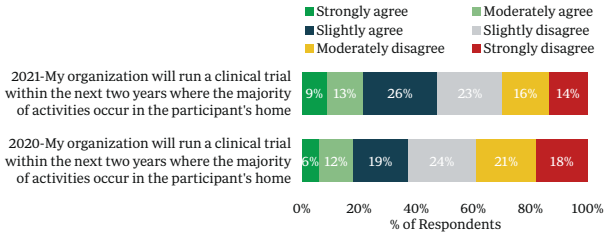
Conversely, others were not as fortunate with their Phase 1 provider experiences. One respondent shared: "Although the performance was quite good, they were not able to quickly adapt to COVID-19, and we had to move the trial." And this respondent noted a change in performance: "The site has historically executed well, with quality project management. The site is experiencing turnover (likely due to COVID-19), which is understandable; however, scheduling of bed space has been problematic of late."

In another ISR study looking at the use of EDC systems, we asked respondents what improvements they would like to see made to today's systems. One suggestion was the addition of or enhanced remote monitoring capabilities to accommodate decentralized trials during the pandemic. Indeed, sponsors want the right tools for this new breed of trials.

We also learned whether virtual clinical trials and home-based trials will be a consideration for outsourcers two years from now. The interest in these types of decentralized or hybrid trials continues to hold. We speculate the effects of the pandemic on human interaction will not be short-lived. Undoubtedly, the terms "contactless" and "social distance" will linger in our lexicons for a while. And that's OK. The cautious restoration of "normalcy" will be a marathon, not a sprint.

The charts below compare findings between the past two benchmarking studies (2021 n=272, 2020 n=329). This year, 58% of respondents slightly to strongly agreed with the statement that virtual clinical trials will be a major component of their organizations' clinical portfolios within two years. This is an uptick of 10 percentage points since 2020.

Likewise, 48% of respondents slightly to strongly agreed with the statement that their organizations will run a trial within two years where the majority of activities occur in the participant's home — an uptick of 11 percentage points since 2020.



These findings tell us that companies expect to break as needed from their traditional blueprints to pursue new ways of managing their clinical development programs. If they were not delayed or pulled due to the pandemic, clinical trials needed to go on during the past year. Patients and volunteers still needed to be recruited. Data still needed to be collected. Results still needed to be delivered. Phase 1 outsourcers gave more commentary on the effects of the pandemic on their trials and provider experiences compared to Phase 2/3 outsourcers. Perhaps this has to do with the timing of data collection (November-December 2020). Even so, CROs were presented quite a challenge this year — keeping all things and humans connected, even when it seemed impossible.

SHERRY HUBBARD-BEDNASZ is market research director at Industry Standard Research.

Survey Methodology: Industry Standard Research is a full-service market research provider to the pharma and pharma services industries. ISR's CRO Quality Benchmarking research is conducted annually via an online survey. For the 2021 CRO Awards data, more than 60 service providers were evaluated on over 20 different performance metrics. Research participants were recruited from biopharmaceutical and medical device companies of all sizes and are screened for decision-making influence and authority when it comes to working with CROs. ***Respondents only evaluate companies with which they have worked on an outsourced project within the past 18 months.*** This level of qualification ensures that quality ratings come from actual involvement with a business, and that companies identified as leaders are backed by experiential data.

For more information, please visit www.ISRreports.com.

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Sandra Dejewski
Sr. Director, Global Contracts & Legal Services

Patricia Riggs
HR Manager

Dawn Niccum
Senior Director, Quality Assurance & Compliance

Where the best and brightest can flourish

Lori Buckenmyer
Head of Clinical Operations and Project Management

Nina Anderson,
Senior Manager, Clinical Operations

List Of Winners
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Company Profiles
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CRO LEADERSHIP AWARDS 2021

Clinical Leader's and *Life Science Leader's* readership of pharmaceutical and biopharmaceutical executives have told us about their struggles in efficiently vetting potential CRO partners. In response to this input, the CRO Leadership Awards were developed.

Based on research from Industry Standard Research's Contract Research Organization Quality Benchmarking annual online survey, nearly 60 contract research organizations were evaluated on more than 20 different performance metrics. Research participants were recruited from biopharmaceutical companies of all sizes and were screened for decision-making influence and authority when it comes to working with contract research organizations. Respondents only evaluated companies with which they have worked on an outsourced project in the past 18 months. This level of qualification ensures that quality ratings come from actual involvement with a business and that companies identified as leaders are backed by experiential data. CROs have an opportunity to win these awards in up to three groups of outsourcing respondents — Big Pharma, Small Pharma, and Overall (combined Big and Small Pharma).

We also recognize those companies that scored 1.5 standard deviation or more above the weighted average in each of the core categories. You will see these companies noted as the *Champions.*

WHAT ARE THE AWARDS?

ISR's survey participants were asked to provide an expectation rating for each CRO they have worked with in the past 18 months. Points were then totaled for a combined score for each attribute, and a composite score for each core category was determined. Winning CROs were identified when comparing their overall scores vs. the competitive set.

To learn more about ISR's industry reports and customized research, or to be included in future CRO Leadership Awards annual surveys, visit isrreports.com or contact ISR at (919) 301-0106.

PRESENTED BY:

CLINICAL LEADER

Life Science Leader

RESEARCH CONDUCTED BY:

ISR reports

Smarter questions ∴ Smarter answers

CRO LEADERSHIP AWARDS 2021 CAPABILITIES

- Access to patient populations
- Access to "unique" tests, machines, equipment
- Biostatistics
- Central lab
- Data management
- Investigator recruitment
- Monitoring
- Patient/volunteer recruitment (Phase 1)
- Patient recruitment (Phase 2/3)
- Speed of site start-up
- Technology for real-time access to data

CAPABILITIES

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Innovaderm
CTI Clinical Trial & Consulting
Ora
PSI CRO
Celerion
Quotient Sciences
Worldwide Clinical Trials
Eurofins Scientific, S.E.
Frontage Laboratories, Inc.
Parexel
Bioclinica
IQVIA

BIG PHARMA

Eurofins Scientific, S.E.
Worldwide Clinical Trials
Celerion
Frontage Laboratories, Inc.
ICON plc
Parexel

SMALL PHARMA

Celerion
PSI CRO
Ora
Worldwide Clinical Trials
Quotient Sciences
QPS LLC
Bioclinica
Medpace
Covance by Labcorp
IQVIA
PPD
Duke Clinical Research Institute
Eurofins Scientific, S.E.
Parexel
PRA Health Sciences

The terms "Small Pharma" and "Big Pharma" pertain to the outsourcing respondents, not the winners. "Overall" is a combination of Big and Small Pharma.
To be recognized as a Champion, company must have scored 1.5 standard deviation or more above the weighted average in the particular category respondent group.

CRO LEADERSHIP AWARDS2021 COMPATIBILITY

- Easy to work with
- Responsiveness
- Timely project communications

COMPATIBILITY

CHAMPIONS

OVERALL

CTI Clinical Trial & Consulting

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Quotient Sciences
PSI CRO
Celerion
Innovaderm
Frontage Laboratories, Inc.
QPS LLC
Worldwide Clinical Trials
Medpace
Eurofins Scientific, S.E.
ICON plc
Duke Clinical Research Institute
SGS Health Science
Syneos Health

BIG PHARMA

Celerion
Frontage Laboratories, Inc.
SGS Health Science
ICON plc
Eurofins Scientific, S.E.
Syneos Health
Worldwide Clinical Trials

SMALL PHARMA

PSI CRO
Quotient Sciences
Celerion
Worldwide Clinical Trials
QPS LLC
Frontage Laboratories, Inc.
Duke Clinical Research Institute
Medpace
Bioclinica
Novotech
PPD

The terms "Small Pharma" and "Big Pharma" pertain to the outsourcing respondents, not the winners. "Overall" is a combination of Big and Small Pharma.
To be recognized as a Champion, company must have scored 1.5 standard deviation or more above the weighted average in the particular category respondent group.

CRO LEADERSHIP AWARDS2021 EXPERTISE

- Local market/regulatory knowledge
- Operational excellence
- Scientific knowledge of the Phase 1 unit's lead investigator
- Study design expertise
- Therapeutic expertise

EXPERTISE

CHAMPIONS

OVERALL

PSI CRO

Quotient Sciences

SMALL PHARMA

PSI CRO

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Innovaderm

CTI Clinical Trial & Consulting

Ora

Celerion

Duke Clinical Research Institute

Worldwide Clinical Trials

Eurofins Scientific, S.E.

Frontage Laboratories, Inc.

Parexel

QPS LLC

Medpace

BIG PHARMA

Eurofins Scientific, S.E.

Celerion

Frontage Laboratories, Inc.

ICON plc

Parexel

Worldwide Clinical Trials

SMALL PHARMA

Quotient Sciences

Ora

Celerion

Medpace

Worldwide Clinical Trials

Duke Clinical Research Institute

Frontage Laboratories, Inc.

QPS LLC

Bioclinica

Eurofins Scientific, S.E.

Syneos Health

IQVIA

Covance by Labcorp

CRO LEADERSHIP AWARDS 2021 QUALITY

- Data quality
- Project manager quality

QUALITY

CHAMPIONS

OVERALL

Quotient Sciences

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

PSI CRO
CTI Clinical Trial & Consulting
Celerion
Innovaderm
Worldwide Clinical Trials
Duke Clinical Research Institute
Frontage Laboratories, Inc.
ICON plc
Parexel
Eurofins Scientific, S.E.

BIG PHARMA

Celerion
Eurofins Scientific, S.E.
ICON plc
Worldwide Clinical Trials
Parexel
SGS Health Science

SMALL PHARMA

Quotient Sciences
PSI CRO
Celerion
Frontage Laboratories, Inc.
QPS LLC
Duke Clinical Research Institute
Medpace
Worldwide Clinical Trials
PRA Health Sciences

The terms "Small Pharma" and "Big Pharma" pertain to the outsourcing respondents, not the winners. "Overall" is a combination of Big and Small Pharma.
To be recognized as a Champion, company must have scored 1.5 standard deviation or more above the weighted average in the particular category respondent group.

CRO LEADERSHIP AWARDS 2021 RELIABILITY

- Meeting overall project timelines
- Operational excellence
- Staff turnover

RELIABILITY

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

PSI CRO
CTI Clinical Trial & Consulting
Quotient Sciences
Innovaderm
Celerion
Ora
Frontage Laboratories, Inc.
Worldwide Clinical Trials
SGS Health Science
Duke Clinical Research Institute
QPS LLC
Eurofins Scientific, S.E.
Medpace
Parexel
PRA Health Sciences

BIG PHARMA

Celerion
Eurofins Scientific, S.E.
SGS Health Science
Frontage Laboratories, Inc.
ICON plc
Parexel

SMALL PHARMA

PSI CRO
Quotient Sciences
Celerion
Worldwide Clinical Trials
Medpace
Ora
QPS LLC
Duke Clinical Research Institute
Bioclinica
PRA Health Sciences
Frontage Laboratories, Inc.

CRO LEADERSHIP AWARDS

INDIVIDUAL ATTRIBUTE AWARDS

The Individual Attribute Awards were developed as a result of many conversations we have had with the readers of *Clinical Leader* and *Life Science Leader*. These conversations uncovered common attributes that sponsor companies identified as being imperative when choosing a supplier and deciding to continue doing business with a supplier.

They were often referred to as the ever-important "intangibles" a supplier brings to the table. Outside of the cover metrics of capabilities, compatibility, expertise, quality, and reliability, these attributes were what our readers identified as being most important, and, as such, we felt it was important to share the data with other sponsor companies.

DATA QUALITY

TOP PERFORMERS

Quotient Sciences
Celerion
PSI CRO
CTI Clinical Trial & Consulting
Innovaderm

EXCEEDED CUSTOMER EXPECTATIONS

Worldwide Clinical Trials
Frontage Laboratories, Inc.
Eurofins Scientific, S.E.
Duke Clinical Research Institute
ICON plc
Parexel

MEETING PROJECT TIMELINES

TOP PERFORMERS

Quotient Sciences
PSI CRO
CTI Clinical Trial & Consulting
Celerion
Innovaderm
Ora

EXCEEDED CUSTOMER EXPECTATIONS

Worldwide Clinical Trials
SGS Health Science
Frontage Laboratories, Inc.
PRA Health Sciences
Bioclinica
QPS LLC
Medpace
Eurofins Scientific, S.E.
Parexel
ICON plc

OPERATIONAL EXCELLENCE

TOP PERFORMERS

CTI Clinical Trial & Consulting
Quotient Sciences
PSI CRO
Celerion
Innovaderm

EXCEEDED CUSTOMER EXPECTATIONS

Worldwide Clinical Trials
Duke Clinical Research Institute
Ora
Frontage Laboratories, Inc.
Parexel
Eurofins Scientific, S.E.

CRO LEADERSHIP AWARDS

INDIVIDUAL ATTRIBUTE AWARDS

RESPONSIVENESS

TOP PERFORMERS

CTI Clinical Trial & Consulting

Quotient Sciences

PSI CRO

Celerion

Innovaderm

QPS LLC

Frontage Laboratories, Inc.

EXCEEDED CUSTOMER EXPECTATIONS

Worldwide Clinical Trials

Ora

Medpace

Syneos Health

Eurofins Scientific, S.E.

TECHNOLOGY FOR ACCESS TO DATA

TOP PERFORMERS

CTI Clinical Trial & Consulting

Ora

EXCEEDED CUSTOMER EXPECTATIONS

Celerion

IQVIA

PSI CRO

Worldwide Clinical Trials

Parexel

ICON plc

PPD

CATEGORIES WON:

Bioclinica

Princeton, NJ
bioclinica.com

Phone: (877) 632-9432
Contact: Eric Forsthoffer
Email: eric.forsthoffer@bioclinica.com

KEY LOCATIONS: Princeton, NJ, USA; Newark, CA, USA; Munich, Germany; London, UK; Shanghai, China; Tokyo, Japan; Mysore, India

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)

Drug Substance Production: Primary Process Development

Formulated Drug Production: Dosage Form Development

MAIN SERVICE AREAS:
Full-Service Clinical

SERVICES & CAPABILITIES: Bioclinica provides medical science and technology expertise to the life sciences industry, including solutions in Medical Imaging, Cardiac Safety, Clinical Adjudication, Clinical Trial Software, and Safety and Pharmacovigilance.

THERAPEUTIC AREAS: Oncology, Neuroscience, Musculoskeletal, Hepatology (NAFLD/NASH), Gastroenterology, Cardiovascular, Dermatology, Endocrinology, Infectious Disease, Inflammatory, Ophthalmology, Orthopedic, Pediatrics, Rare Disease, Urology, Women's Health, and more

INDIVIDUAL ATTRIBUTE AWARDS: Meeting Overall Project Timelines

CATEGORIES WON:

Celerion

Lincoln, NE
celerion.com

Phone: (402) 476-2811
Contact: Michelle Maklas-Baker
Email: michelle.maklasbaker@celerion.com

KEY LOCATIONS: Lincoln, NE, USA; Tempe, AZ, USA; West Conshohocken, PA, USA; Belfast, Northern Ireland; Zurich, Switzerland; Berlin, Germany; Vienna, Austria; Montreal, QC, Canada; Singapore; Seoul, South Korea

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2)

MAIN SERVICE AREAS:
Lab, Full-Service Clinical

SERVICES & CAPABILITIES: Celerion excels at Phase 1/2 clinical pharmacology ranging from PK/PD, FIH, SAD/MAD, DDI, QTc, BioE, and ADME studies to multisite patient studies with full services (i.e., project management, data management, monitoring, and bioanalytical).

THERAPEUTIC AREAS: Biosimilar Development, Vaccine Development, Immunotherapy, Infectious Disease, Respiratory Disease, Metabolic Disease, Renal Impairment, Hepatic Impairment, Cardiovascular, Oncology Studies

INDIVIDUAL ATTRIBUTE AWARDS: Data Quality, Meeting Overall Project Timelines, Operational Excellence, Responsiveness, Technology For Access To Data

CATEGORIES WON:

Covance by Labcorp

Durham, NC
covance.com

Phone: (888) 268-2623
Contact: Christopher Allman
Email: media@labcorp.com

KEY LOCATIONS: Indianapolis, IN, USA; Princeton, NJ, USA; Leeds, England, UK; Bangalore, India; Beijing, China

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, PreClinical, Clinical (Phase 1, Phase 2, Phase 3)

Formulated Drug Production: Dosage Form Development, Dosage Form Production, Logistics

MAIN SERVICE AREAS:
Lab, PreClinical, Full-Service Clinical

SERVICES & CAPABILITIES: Covance by Labcorp provides end-to-end drug development, medical device, and diagnostic solutions from early-stage research to clinical development and beyond. Customers include biopharmaceutical, medical device, and diagnostic companies.

THERAPEUTIC AREAS: Oncology, Immunology, Diabetes, NASH, Rare Disease and Orphan Drugs, Pediatrics, Dermatology, Endocrinology and Neurology

CATEGORIES WON:

CTI Clinical Trial & Consulting

Covington, KY
ctifacts.com

Phone: (513) 598-9290
Contact: Joe McCafferty
Email: jmccafferty@ctifacts.com

KEY LOCATIONS: Cincinnati, OH, USA; Covington, KY, USA; Raleigh, NC, USA; Ulm, Germany; São Paulo, Brazil; Dubai, UAE; Sydney, Australia

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Lab, Full-Service Clinical

SERVICES & CAPABILITIES: Trial Planning and Design, Medical Writing, Regulatory Strategy, Feasibility, Project Management, Clinical and Medical Monitoring, Safety, Biometrics, Phase I-IV Site Services, Full-Service Lab, Strategic Consulting, Evidence Generation, HTA Reporting and Negotiation

THERAPEUTIC AREAS: Rare/Orphan Diseases, Regenerative Medicine/Gene Therapy, Immunology, Immuno-Oncology, Transplantation, Nephrology, Hematology, Oncology, Neurology, Sleep Research, Infectious Diseases, Hepatology, Cardiopulmonary, Pediatrics/Neonate, Devices

INDIVIDUAL ATTRIBUTE AWARDS: Data Quality, Meeting Overall Project Timelines, Operational Excellence, Responsiveness, Technology For Access To Data

CATEGORIES WON:

Duke Clinical Research Institute

Durham, NC
dcri.org

Contact: Suzanne Pfeifer
Email: suzanne.pfeifer@duke.edu

KEY LOCATIONS: Durham, NC, USA

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Full-Service Clinical

SERVICES & CAPABILITIES: Clinical Events Classification, Imaging, Independent Data Monitoring Committee (IDMC), Site Monitoring and Site Management, Project Management, DCRI Faculty Oversight, Data Management, Statistics, Medical Writing, Site Contract Negotiations (DCRI Legal)

THERAPEUTIC AREAS: Cardiovascular, Gastroenterology, Infectious Diseases, Musculoskeletal, Nephrology, Neurosciences Medicine, Pediatrics, Respiratory Medicine

INDIVIDUAL ATTRIBUTE AWARDS: Data Quality, Operational Excellence

CATEGORIES WON:

Eurofins Scientific, S.E.

Bruxelles, Belgium
eurofins.com

USA Phone: (717) 656-2300
International Phone: +322-766-1620
Contact: Timothy Oostdyk, Ph.D.
Email: pharma@eurofins.com

KEY LOCATIONS: Australia, Belgium, Canada, China, Denmark, France, Germany, India, Ireland, Italy, Japan, Netherlands, Singapore, Spain, Sweden, Switzerland, UK, USA

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Bioanalytical, PreClinical, Clinical (Phase 1, Phase 2, Phase 3, Phase 4)

Drug Substance Production: Primary Process Development, Drug Substance Production

Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

MAIN SERVICE AREAS:
Lab, PreClinical, Full-Service Clinical

SERVICES & CAPABILITIES: From compound discovery and clinical research through manufacture and release of commercial product and post approval, Eurofins provides seamless, end-to-end solutions to help clients progress through the drug development cycle.

THERAPEUTIC AREAS: Eurofins supports all therapeutic areas within the biopharma industry and offers an integrated solution with the most comprehensive range of state-of-the-art analytical technologies with a global geographic reach.

INDIVIDUAL ATTRIBUTE AWARDS: Data Quality, Meeting Overall Project Timelines, Operational Excellence, Responsiveness

CATEGORIES WON:

Frontage Laboratories, Inc.

Exton, PA
frontagelab.com

Phone: (610) 232-0100
Contact: Azhar Kalim
Email: akalim@frontagelab.com

KEY LOCATIONS: Exton, PA, USA; Concord, OH, USA; Secaucus, NJ, USA; Shanghai, China; Suzhou, Jiangsu, China; North Wales, PA, USA; Vancouver, BC, Canada; South Brunswick Township, NJ, USA

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, PreClinical, Clinical (Phase 1, Phase 2)

Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

MAIN SERVICE AREAS:
Lab, PreClinical

SERVICES & CAPABILITIES: Laboratory and Clinical Services Supporting Drug Discovery and Development through DMPK, Safety and Toxicology, Bioanalytical, CMC, and Early-Stage Clinical

THERAPEUTIC AREAS: Frontage supports multiple therapeutic areas across various business areas and expanded expertise in pain management, oncology, endocrinology, and dermatology from small and large molecules.

INDIVIDUAL ATTRIBUTE AWARDS: Data Quality, Meeting Overall Project Timelines, Operational Excellence, Responsiveness

CATEGORIES WON:

ICON plc

Dublin, Ireland
iconplc.com

Phone: (215) 616-3000
Contact: David Green
Email: david.green@iconplc.com

KEY LOCATIONS: Dublin, Ireland; Philadelphia, PA, USA

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Lab, Full-Service Clinical

SERVICES & CAPABILITIES: ICON plc is a global provider of outsourced drug and device development and commercialization services to pharmaceutical, biotechnology, medical device, and government and public health organisations.

THERAPEUTIC AREAS: Cardiovascular, Cell and Gene Therapies, Central Nervous System, Endocrine and Metabolic Disorders, Infectious Diseases and Vaccines, Internal Medicine and Immunology, Medical Device, Oncology, Rare and Orphan Diseases, Transplant Immunology, Women's Health, Vaccines

INDIVIDUAL ATTRIBUTE AWARDS: Data Quality, Meeting Overall Project Timelines, Technology For Access To Data

CATEGORIES WON:

IQVIA

Durham, NC
iqvia.com

Phone: (866) 267-4479
Contact: Bob Thompsen
Email: robert.thompsen@iqvia.com

KEY LOCATIONS: USA and Canada; Latin America; Europe, Middle East and Africa; Asia

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Lab, Full-Service Clinical

SERVICES & CAPABILITIES: Biostatistics, Clinical Monitoring, Data Management, Life Cycle Safety, Medical Writing and Document Publishing, Patient Recruitment, Project Management, Regulatory Affairs, Q_2 Solutions (Lab), Technology Solutions

THERAPEUTIC AREAS: Biosimilars, Cardiovascular, Central Nervous System, Diabetes, Infectious Diseases and Vaccines, NASH, Nephrology, Oncology, Ophthalmology, Pediatrics, Rare Disease, Regenerative Medicine, Reproductive Health, Respiratory, Rheumatology

INDIVIDUAL ATTRIBUTE AWARDS: Technology For Access To Data

CATEGORIES WON:

Medpace

Cincinnati, OH
medpace.com

Phone: (513) 579-9911
Contact: Medpace Business Development
Email: info@medpace.com

KEY LOCATIONS: Cincinnati, OH, USA; Shanghai, China; Singapore; Tokyo, Japan; Leuven, Belgium; London, UK; München, Germany; Warsaw, Poland

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Full-Service Clinical

SERVICES & CAPABILITIES: We offer a full range of integrated services: Medical Affairs, Regulatory, Clinical Monitoring, Clinical Trial Management, Biometrics, Safety & Pharmacovigilance, Quality Assurance, and Technology.

THERAPEUTIC AREAS: Autoimmune Diseases, Cardiovascular, Endocrine and Metabolic, Hematology and Oncology, Infectious Diseases and Vaccines, NASH, Nephrology, Neurology and Psychiatry, Ophthalmology, Pediatrics, Rare Disease and Orphan Indications, Advanced Therapies

INDIVIDUAL ATTRIBUTE AWARDS: Meeting Overall Project Timelines, Responsiveness

CATEGORIES WON:

Novotech

Pyrmont, NSW, Australia
novotech-cro.com

Phone: (650) 798-5238
Contact: Barry Murphy
Email: barry.murphy@novotech-cro.com

KEY LOCATIONS: Australia; New Zealand; Greater China; South East Asia; South Korea; India

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Full-Service Clinical

SERVICES & CAPABILITIES: Feasibility Assessments, Ethics Committee and Regulatory Submissions, Data Management, Statistical Analysis, Medical Monitoring, Safety Services, Central Lab Services, Report Write-Up to ICH Requirements, Project and Vendor Management

THERAPEUTIC AREAS: Oncology, Infectious Diseases, Neurology and Psychiatry, Metabolic and Endocrinology, Respiratory and Allergy, Cardiovascular, Musculoskeletal, Dermatology, Gastroenterology, Pain Management, Blood Disorders, Ophthalmology, Inflammatory and Autoimmune, Urology

CATEGORIES WON:

Parexel

Durham, NC
parexel.com

Phone: (919) 544-3170
Contact: Christine Rogers
Email: christine.rogers@parexel.com

KEY LOCATIONS: North America; South America; Europe; Middle East; Africa; Asia

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Full-Service Clinical

SERVICES & CAPABILITIES: Parexel helps biopharmaceutical clients transform scientific discoveries into new treatments that improve patient health through the delivery of expert clinical development services, from clinical trials to regulatory and consulting to market access.

THERAPEUTIC AREAS: Parexel has deep therapeutic expertise across a wide range of acute, chronic, and rare diseases and treatment modalities, including oncology and hematology, cardiovascular and metabolic diseases, infectious diseases, vaccines, and cell and gene therapies.

INDIVIDUAL ATTRIBUTE AWARDS: Data Quality, Meeting Overall Project Timelines, Operational Excellence, Technology For Access To Data

CATEGORIES WON:

PPD

Wilmington, NC
ppd.com

Phone: (910) 251-0081
Contact: PPD Business Development
Email: ppdinfo@ppd.com

KEY LOCATIONS: Wilmington, NC, USA; Research Triangle Park, NC, USA; Middleton, WI, USA; Austin, TX, USA; UK; Europe; Middle East; Africa; China; Japan; Asia-Pacific; Latin America

DRUG LIFE CYCLE STAGES:
Research & Development: PreClinical, Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Lab, Full-Service Clinical

SERVICES & CAPABILITIES: Phase I-3b, Peri- and Post-Approval, GMP/Bioanalytical/Central/Vaccine Sciences Labs, Biomarkers, COVID-19, Digital/Decentralized Trials, Site/Patient Services, Clinical/Product Development, PPD® Biotech, FSP, Consulting

THERAPEUTIC AREAS: Cardiovascular, Cell/Gene Therapy, Vaccines, COVID-19, Critical Care, Dermatology, Endocrine/Metabolics, Gastrointestinal, Hematology/Oncology, Immunology, Infectious Diseases, Neuroscience, Pediatrics, Rare Diseases, Respiratory, Women's Health

INDIVIDUAL ATTRIBUTE AWARDS: Technology For Access To Data

CATEGORIES WON:

PRA Health Sciences

Raleigh, NC
prahs.com

Phone: (919) 786-8200
Contact: Danaka Williams
Email: williamsdanaka@prahs.com

KEY LOCATIONS: Raleigh, NC, USA; Blue Bell, PA, USA; Lenexa, KS, USA; Mannheim, Germany; Reading, UK; Swansea, Wales; Osaka, Japan; Charlottesville, VA, USA

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)

Drug Substance Production: Primary Process Development, Drug Substance Production

Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

MAIN SERVICE AREAS:
Full-Service Clinical

SERVICES & CAPABILITIES: PRA provides services for all phases of biopharmaceutical drug development. We have the depth of therapeutic expertise and operational diversity to offer high-quality, full-service support as well as embedded staffing solutions.

THERAPEUTIC AREAS: Over the last five years, PRA has supported 3,500+ clinical trials/consulting projects (1,600+ clinical) in 80+ countries in many therapeutic areas. The top therapeutic areas are neurology, oncology, hematology, immunology, and infectious diseases.

INDIVIDUAL ATTRIBUTE AWARDS: Meeting Overall Project Timelines

CATEGORIES WON:

PSI CRO

Research Triangle Park, NC
psi-cro.com

Contact: Brenda Reese
Email: Brenda.Reese@psi-cro.com

KEY LOCATIONS: Zug, Switzerland; Munich, Germany; Oxford, UK; Hong Kong; Sydney, Australia; St. Petersburg, Russia; Paris, France; Bangalore, India

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 2, Phase 3)

Drug Substance Production: Primary Process Development, Drug Substance Production

Formulated Drug Production: Dosage Form Development, Dosage Form Production, Logistics

MAIN SERVICE AREAS:
Full-Service Clinical

SERVICES & CAPABILITIES: Data Management, Clinical Operations, Medical Monitoring, Medical Writing, Feasibility, Site Identification, Study Start-Up, Marketing, Risk Management, and Quality Management

THERAPEUTIC AREAS: Inflammatory Bowel Diseases, Oncology, Hematology, Infectious Diseases, Multiple Sclerosis, Rare Diseases

INDIVIDUAL ATTRIBUTE AWARDS: Data Quality, Meeting Overall Project Timelines, Operational Excellence, Responsiveness, Technology For Access To Data

CATEGORIES WON:

QPS LLC

Newark, DE
qps.com

Phone: (512) 350-2827
Contact: Gabrielle Pastore
Email: gabrielle.pastore@qps.com

KEY LOCATIONS: Newark, DE, USA; Miami, FL, USA; Springfield, MO, USA; Groningen, The Netherlands; Graz, Austria; Taipei, Taiwan; Suzhou, China; Hyderabad, India

DRUG LIFE CYCLE STAGES:
Research & Development: PreClinical, Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Lab, PreClinical, Full-Service Clinical

SERVICES & CAPABILITIES: QPS is a global CRO, providing custom-built preclinical and clinical drug development services since 1995. Our service areas include Toxicology, DMPK, Neuropharmacology, Preclinical and Clinical Drug Development, and Clinical Research Services.

THERAPEUTIC AREAS: Alzheimer's and Parkinson's diseases, Cardiovascular, CNS, Dermal and Transdermal, Endocrinology, Gene Therapy, Hepatitis C, HIV, HPV, Neurosciences, Oncology, Rare Diseases, Respiratory, Vaccines (including COVID-19, Ebola, Zika...), Women's Health

INDIVIDUAL ATTRIBUTE AWARDS: Meeting Overall Project Timelines, Responsiveness

CATEGORIES WON:

Quotient Sciences

Nottingham, UK
quotientsciences.com

Phone: (800) 769-3518
Contact: Kieron Hall
Email: kieron.hall@quotientsciences.com

KEY LOCATIONS: Philadelphia, PA, USA; Miami, FL, USA; Nottingham, UK; Reading, UK; Alnwick, UK; Edinburgh, UK

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, PreClinical, Clinical (Phase 1, Phase 2, Phase 3)

Drug Substance Production: Primary Process Development, Drug Substance Production

Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

MAIN SERVICE AREAS:
Lab, PreClinical, Full-Service Clinical

SERVICES & CAPABILITIES: Drug Substance, Preclinical and Clinical Formulation Development, Clinical Trial Manufacturing, Commercial Manufacturing, Clinical Pharmacology, Data Sciences, Bioanalysis, Drug Development Consulting, Isotope Labeling, 14C ADME, Pediatrics, Inhalation

THERAPEUTIC AREAS: Orphan/Rare Disease, Pediatrics, Oncology, Neurology, Cardiology, Gastroenterology, Infectious Diseases, Psychiatry, Hematology, Dermatology, Immunology, Metabolism and Endocrinology, Respirology, Rheumatology, Urology, Women's Health, Substance Abuse

INDIVIDUAL ATTRIBUTE AWARDS: Data Quality, Meeting Overall Project Timelines, Operational Excellence, Responsiveness

CATEGORIES WON:

SGS Health Science

Mechelen, Antwerp, Belgium
sgs.com/cro

Contact: Clinical Research
Email: clinicalresearch@sgs.com

KEY LOCATIONS: Antwerp, Antwerp, Belgium; Mechelen, Antwerp, Belgium; Germantown, MD, USA; Glasgow, Dumbartonshire, UK; Saint-Benoit, Nouvelle-Aquitaine, France

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, PreClinical, Clinical (Phase 1, Phase 2, Phase 3)

Formulated Drug Production: Packaging, Logistics

MAIN SERVICE AREAS:
Lab, PreClinical, Full-Service Clinical

SERVICES & CAPABILITIES: Drug Development Consultancy, Clinical Pharmacology, Clinical Trial Management, Biometrics Services, Regulatory and Pharmacovigilance, Biosafety Services, Drug Development Laboratory Services

THERAPEUTIC AREAS: Infectious Diseases, Respiratory, Neurology/CNS, Dermatology, Renal and Urinary Disorders, Endocrinology, Genetic Disorders, and more

INDIVIDUAL ATTRIBUTE AWARDS: Meeting Overall Project Timelines

CATEGORIES WON:

Syneos Health

Morrisville, NC
syneoshealth.com

Phone: (919) 876-9300
Contact: Andy Silverman
Email: info@syneoshealth.com

KEY LOCATIONS: Princeton, NJ, USA; New York, NY, USA; Buenos Aires, Argentina; Quebec City, QC, Canada; London, UK; Shanghai, China; Tokyo, Japan

DRUG LIFE CYCLE STAGES:
Research & Development: PreClinical, Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Lab, Full-Service Clinical

SERVICES & CAPABILITIES: Full-Service, Biostatistics, Monitoring, Data Management, Drug Safety/Pharmacovigilance, Feasibility/Study Start-Up, Value and Access, Late-Stage, Medical/Scientific Affairs, Medical Writing, Patient Recruitment, Risk Management, Deployment Solutions

THERAPEUTIC AREAS: Therapeutic expertise in Biosimilars, Cardiovascular, CNS, Cell/Gene, Dermatology, Gastroenterology, Hematology, Infectious Disease, Immunology and Inflammation, Metabolic, Oncology, Ophthalmology, Pediatrics, Rare Disease, Respiratory, Women's Health

INDIVIDUAL ATTRIBUTE AWARDS:
Responsiveness

CATEGORIES WON:

Worldwide Clinical Trials

Research Triangle Park, NC
worldwide.com

Phone: (610) 632-8190
Contact: Sara Davis
Email: sara.davis@worldwide.com

KEY LOCATIONS: North America, South America, Europe, Russia, Asia

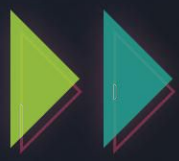
DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)

MAIN SERVICE AREAS:
Full-Service Clinical

SERVICES & CAPABILITIES: Worldwide Clinical Trials delivers full-service contract research services, extending from bioanalytical labs, early-phase I-2a, clinical-phase 2b-3, Phase 3b-4, through real-world evidence studies.

THERAPEUTIC AREAS: We help sponsors move from discovery into clinical development and commercialization across a range of therapeutic areas, including central nervous system, cardiovascular, metabolic, general medicine, oncology, and rare diseases.

INDIVIDUAL ATTRIBUTE AWARDS: Data Quality, Meeting Overall Project Timelines, Operational Excellence, Responsiveness, Technology For Access To Data



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CONNECT

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