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PARTNERS

Clinical Trial Site Networks

Market Research Report

September 12, 2024

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Vice President

4+ years of dedicated pharma services and healthcare investment banking, with experience leading transactions across nearly all clinical research services & technology subsectors

Leads clinical research services & technology coverage and provides transaction execution support across broader pharma services segments

BS, University of North Carolina at Charlotte

Sector Expertise

Clinical Research Site Networks

Patient Recruitment & Engagement

Clinical Technology & Data Analytics

Full-Service & Specialty CROs

Select Transaction Experience

- Clincierge has been acquired by greenphire, a portfolio company of THOMABRAVO
- BOURNE STRATEGIC CAPITAL has completed a growth investment in Eximia Clinical Research
- reverba, a portfolio company of 424 CAPITAL, has acquired Six Degrees Medical
- spencer health solutions has raised growth capital from RCT Research Corporation Technologies
- CTT Clinical Trials of Texas, 20 Years of Excellence; FLOURISH RESEARCH has been recapitalized by NMS | CAPITAL
- BCT Boston Clinical Trials; ALCANZA CLINICAL RESEARCH FOR ALL has been recapitalized by MARTIS CAPITAL
- ASCENT Development Services has been acquired by PHARMALEX, cencora
- **Project Yellowstone**: Global Clinical Trial Payments and Support Services Provider; BOURNE PARTNERS; *Sell-Side M&A Advisory*

Note: Includes transactions completed at a prior investment bank

FIVE (5) Key Take-Aways on Clinical Trial Site Networks

We view the rise of clinical trial site networks as one of the most attractive and dynamic trends in the pharma services space today through our transaction experience and frequent discussions with top executives of site networks and private equity investors. In our view, the creation of site networks should help address what is arguably the number one structural "pain point" in drug development today -- the life sciences industry's reliance on a fragmented universe of sub-scale standalone clinical trial sites.

1. **Site management organizations/SMOs (or site networks) exist to bring economies of scale** to an otherwise fragmented universe of standalone clinical trial sites. However, scale comes in different forms, and site networks need to take care in determining which specific dimension of scale they are trying to achieve. One strategy that came up in many of our conversations was the need to build scale in geographies with targeted demographics given the elevated focus by both sponsors and regulators on clinical trial enrollment diversity.

2. **Acquisitions are the preferred growth strategy** for many site networks that we spoke with. Acquiring an established clinical trial site tends to result in a faster path to financial success/breakeven, whereas starting a clinical trial site from scratch takes time and investment. However, some site networks have seen success with de novo expansion strategies since there are no integration issues as all sites can be purposedly built on a common technology stack, with consistent operating procedures, and common branding.

3. **We find that a hybrid strategy of dedicated and embedded sites helps to diversify a site network's operating profile.** Dedicated sites allow for the maximum control over operations, procedures, physical infrastructure, and growth initiatives since there are no competing day-to-day priorities that normally exist at a medical practice. However, embedded sites can take advantage of existing doctor-patient relationships, making it easier to recruit for therapeutically complex clinical trials in specialty disease areas.

4. **We are hearing more about "preferred provider arrangements" between sponsors and site networks** -- similar to that which we have seen evolve between sponsors and CROs over the past couple of decades. Also, we are seeing site networks expanding into areas traditionally reserved for CROs, e.g., protocol design, medical monitoring, and data management. In response, CROs have been acquiring their own site networks. ICON, for instance, plans to triple its captive Accellacare site network, and IQVIA has closed two sizable site acquisitions over the past 18 months.

5. The use of standalone independent clinical trial sites still has certain advantages. That said, **to be successful with standalone sites, sponsors and CROs need to seriously rethink their site relationships with a greater focus on collaboration and communication.** This sounds simple, but it would require significant culture change, which may be difficult to accomplish for many pharma companies and CROs.

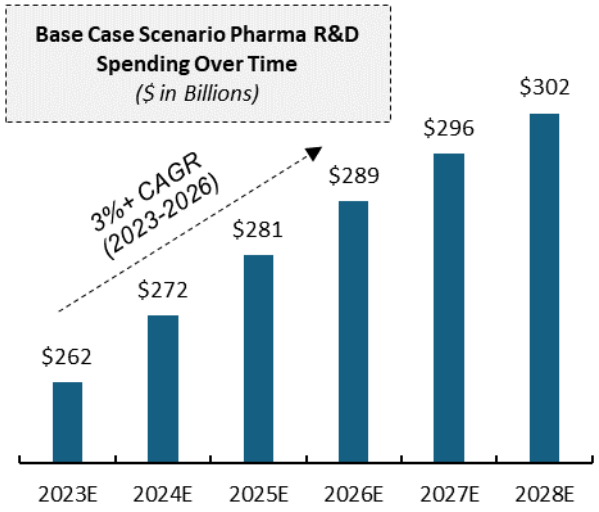
Key Macro Considerations for Clinical Trial Sites

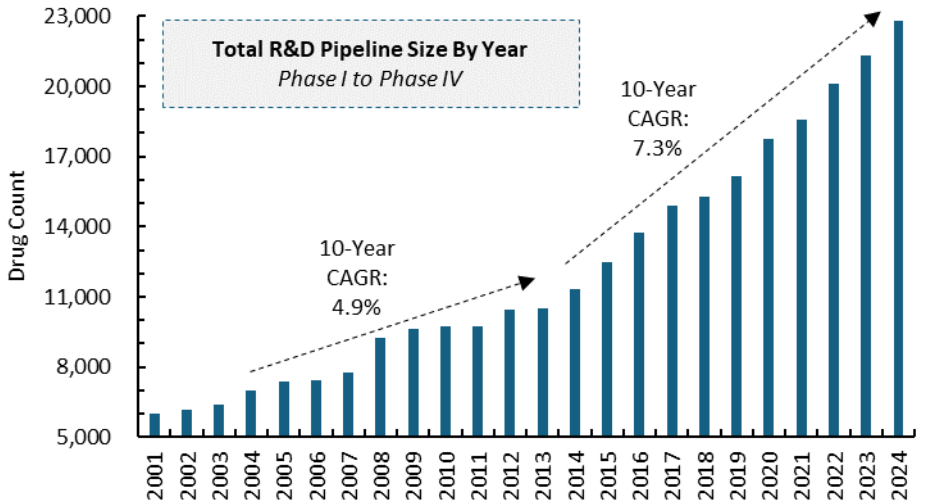
A Strong and Improving Life Sciences R&D Environment…

In our view, **worldwide clinical development spending is comfortably over $100B+ annually**, with growth trending in the ~low/mid-single digits. We estimate about a third of this clinical development spending represents payments to clinical trial sites -- and the United States, in turn, accounts for about a third of the research site market.

The life sciences funding environment continues to markedly improve with services and technology vendors broadly reporting high single digit growth in RFP activity. After a period of heavy focus on re-prioritizing R&D pipelines in 2022 and 2023, we see the pharma industry as much more stabilized and positioned to move forward with new clinical projects. Adding to this, many large pharma companies are facing significant patent expirations in the coming years, which should stimulate more R&D spending.

Moreover, **a number of large pharma companies have shifted their outsourcing strategies towards functional service provider (FSP) relationships.** This includes the use of dedicated site networks (or site management organizations/SMOs). Essentially, large pharma companies want to retain greater control over their product development strategies and their provider relationships.





Note: The pharma R&D spending (above left) includes both preclinical and clinical development spending.
Source: Fortrea, ICON, and Bourne Partners

… However, Access to Sites Remains a Key "Pain Point"

In our view, **a major structural "pain point" for the life sciences industry is its reliance on standalone independent site investigators.** Pharma companies depend on partnerships with independent sites to execute their clinical trials to advance new drugs and medications through regulatory approvals. However, many of these sites are independent medical practices with conflicting patient care priorities that distract them from clinical research projects.

The core of the challenge is that the pace of clinical research is *far* outpacing the growth in the number of investigators. The number of clinical trials (on clinicaltrials.gov) has increased by ~9% annually over the past five years, while the number of physicians (i.e., potential investigators) has remained unchanged. We see no indications that either of these trends will improve in the near/mid-term.

This "pain point" significantly worsened during the COVID-19 pandemic as many sites were forced to shut down due to social distancing concerns. This resulted in a bottleneck for clinical trials through much of 2020 and 2021. Then, coming out of the pandemic, the volume of clinical trials accelerated, but the availability of sites only partially rebounded. This has resulted in a chronic shortage of sites and greater interest in new ways to leverage site networks.

Exacerbating these shortages, is a large population of inexperienced clinical trial investigators due to the increasing specialization of research involving rare diseases and genetic conditions. Currently, about two-thirds of investigators only participate in one clinical trial. This results in many investigators having no/little chance to develop experience in the nuances and logistics of regulated clinical trials.

Tufts University

41%

Clinical trials fail to meet their planned enrollment

ADVARRA

67%

Increased burden in setup/training on sponsor technology

wcg™

3%

Physicians involved in clinical trials

KMR GROUP A WCG Company

30%

Sites fail to enroll a single patient

BAIN & COMPANY

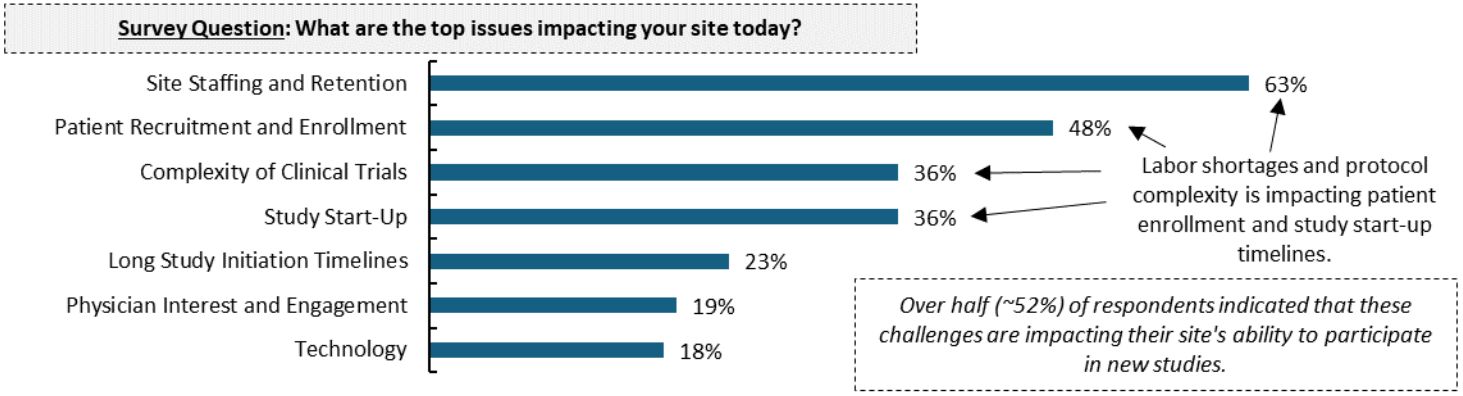
*Over half (**53%**) of investigator sites report lacking the bandwidth to run new clinical trials, up from **14%** pre-COVID -- and even up from **47%** at the peak of COVID-19 pandemic in mid-2020.*

Source: Bain & Company, the Tufts Center for the Study of Drug Development, Advarra, KMR Group, WCG Clinical, and Bourne Partners

An Increasingly Challenging Environment for Trial Sites

There are numerous surveys highlighting the various challenges faced by clinical trial investigator sites. In our view, **there are FOUR (4) common recurring themes** that we have come across in our research and literature review.

1. **Shortages and Retention of Staff.** In our opinion, the number one challenge in clinical research today is labor costs, particularly for nursing staff. Hospitals and physician offices are struggling to attract and retain sufficient labor to meet their patient and population health priorities. This is limiting their ability to allocate incremental labor resources to research activities.
2. **Study Complexity.** Clinical trial complexity is frequently mentioned as an increasing burden on clinical trial sites. Advances in molecular biology have resulted in more complex clinical trial designs that involve biomarkers for patient stratification, more safety and efficacy endpoints, and more technical sophistication with respect to therapy administration.
3. **Recruitment and Enrollment.** The life sciences industry's focus on precision medicine for genetic and rare diseases has made identifying and recruiting patients much more difficult for sponsors. This will likely only get more difficult with potential new regulation requiring greater racial and ethnic diversity in clinical trial enrollment.
4. **Technology Overload.** Life sciences companies have attempted to deploy new digital tools, software applications, and decentralized clinical trial (DCT) methodologies to improve patient access and engagement. However, this has significantly added burden on clinical trial sites who are now often juggling as many as 20 different software applications.



Note: The above data comes from a survey of 500+ clinical research sites in the United States.
Source: WCG Clinical: 2023 Clinical Research Site Challenges Survey Report

Shortages of Clinical Trial Site Investigators and Staff

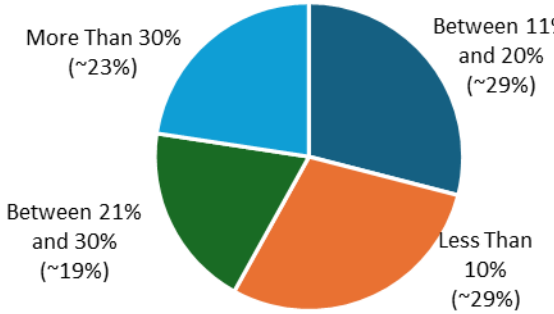
Staffing shortages (and turnover) consistently comes up as a top challenge (limiting factor) for clinical trial sites, according to our research. This is having a negative effect on the ability of independent sites to take-on new projects.

Recent survey data suggests that turnover rates for clinical trial site patient-facing staff has almost doubled from pre-COVID levels -- from a range of 10%-37% historically to a range of 35%-61% currently. This elevated attrition is being driven by various factors, but much of it, in our view, has to do with the burdens of study start-up procedures, administrative work, and training on new software applications. All of this contributes to employee frustration and burnout.

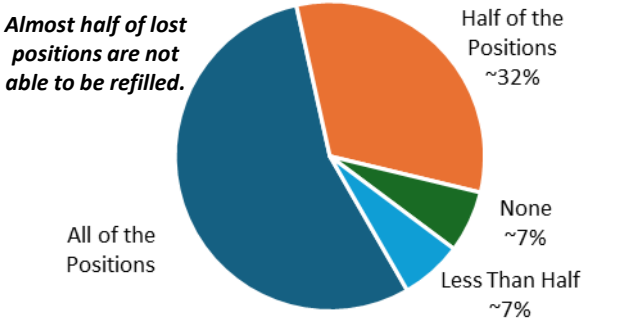
Moreover, **clinical trial sites are struggling to replace staff that is lost.** In 2022, there was a shortfall of almost one million applicants compared to the amount of posted clinical research positions, according to the *Association of Clinical Research Professionals*. Much of the clinical trial site staff attrition (~85%) has been to well-financed pharma companies and CROs who are able to "bid up" compensation with sign-on bonuses and flexible working options.

Chronic staffing shortages (and turnover) result in study delays, inconsistent performance, and higher costs. The cost of recruiting and training a new patient-facing staff member is generally six months of pay, and sites are increasingly having to replace departing research coordinators with individuals without experience. This elongates the onboarding and training process, which can take up to a year. Also, to mitigate attrition, many sites have had to bid up compensation and benefits as well as offer flexible work schedules.

Survey Question: How many staff members did you lose last year (% of workforce)?



Survey Question: What percent of positions left open by employee attrition has been refilled ?



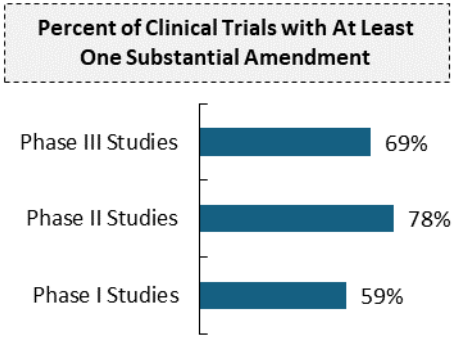
Source: Society for Clinical Research Sites (August 2023) and Bourne Partners

Increasing Study Complexity Pressuring Clinical Trial Sites

A major challenge for clinical trial sites that comes up over and over again is increasing study complexity. This reflects the industry's focus on genetic conditions and rare diseases, which involves more scientifically rigorous protocols.

Clinical trial complexity is rising both therapeutically and operationally. Study designs now often include multiple treatment arms, variable visit schedules, and personalized care. There has also been an increasing number of endpoints with an elevated focus on "quality of life" and other non-clinical data collection. Per the Tufts Center for the Study of Drug Development, data collected in an average Phase III study has tripled over the past decade.

In our view, **the increasing complexity of clinical trials is best empirically highlighted by a recent academic study in *Nature* (February 2024).** This academic study showed that, in fact, clinical trial complexity has increased over the past decade by 15%+ for Phase II and Phase III studies -- across every therapeutic area. The increase in complexity of Phase I studies was even more pronounced -- up 40% over the past decade.



Protocol Complexity Examples

- Multiple treatment arms
- Dynamic visit schedules and cycle expansion
- Variable dosing schedules
- Undefined or variable dose strength, escalation, reduction
- Single or double-blind design, especially with multiple therapy administration methods
- Adaptive randomization or re-randomization requirements
- Dynamic cohort design
- Multiple disease types (basket trial design)

Operational Complexity Examples

- Decentralized clinical trials
- Variable supply chain strategies
- Cold chains
- Direct-to-patient shipping
- Global geographies, especially if patients have options to visit multiple sites
- Long trial duration
- Personalized medicine

Source: Markey, Nigel, "Clinical trials are becoming more complex: a machine learning analysis of data from over 16,000 trials"; Nature.com (February 12, 2024) and the Tufts Center for the Study of Drug Development

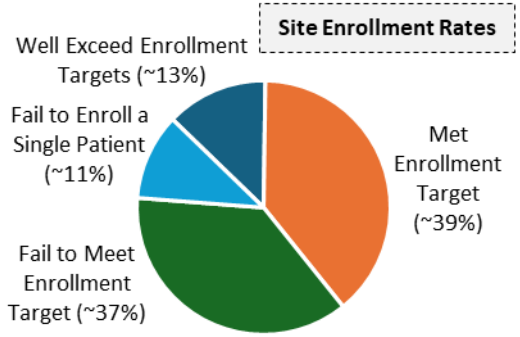
Challenges with Patient Recruitment and Enrollment

Today, **patient recruitment and enrollment can account for as much as a third of the total cost of a pivotal clinical trial, and we expect this cost to increase** in the coming years. In our view, the life sciences industry's current focus on precision medicine and rare diseases has made recruiting patients more and more difficult for sponsors, CROs, and sites.

Patient enrollment and engagement in clinical trials has broadly deteriorated since the COVID-19 pandemic, resulting in sponsors and CROs often having to contract with additional sites during the course of a clinical trial. In total, it is estimated that ~$2.0B is spent annually on clinical trial patient recruitment in the United States (and ~$6.0B is spent globally).

Clinical trial site location is critical to patient recruitment and retention because travel is, by far, the number one challenge for patient recruitment. Enrollment rates decline 10% for every 30 miles a patient is from the clinical trial site. This can be partially addressed with travel/concierge services, but this can add costs to a study. A second related barrier are a patient's out-of-pocket cost for participating -- e.g., mileage, taxi/cab fares, meals, tolls, parking, etc., particularly for lower income patients.

Direct-to-patient marketing campaigns work well for common/chronic diseases and conditions that can be self-diagnosed and reportable by patients (e.g., diabetes, depression, and weight management). However, **more sophisticated software-driven analytical approaches are often needed for acute conditions and rare diseases**. These diseases/conditions often require complex protocols (e.g., lab testing and biomarkers) and short/limited windows for treatment (e.g., oncology).



Phase II / III Trials	Randomization Rates 2019 *Pre-COVID*	Randomization Rates 2023 *Post-COVID*	Completion Rates 2019 *Pre-COVID*	Completion Rates 2023 *Post-COVID*
Cardiovascular / Metabolic	84%	66%	93%	61%
CNS / Neuroscience	25%	16%	74%	66%
Inflamatory Disease	75%	68%	81%	54%
Oncology	63%	56%	69%	22%

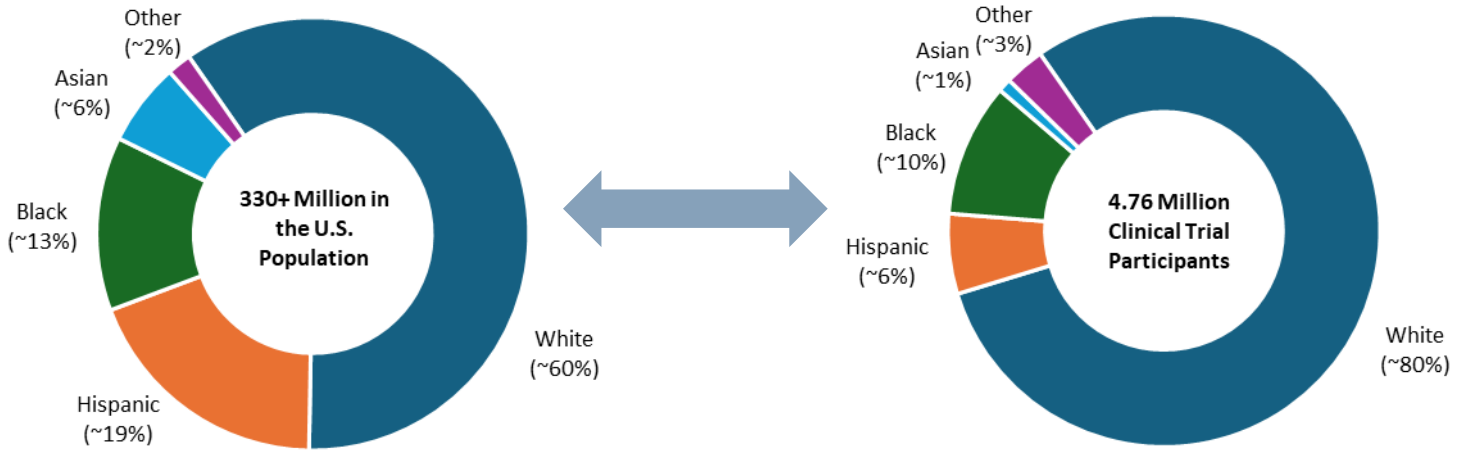
Source: The Tufts Center for the Study of Drug Development, Citeline, Oracle Health, and Bourne Partners

Pending Diversity Regulations May Add New Pressures

New potential regulations by the FDA on racial and ethnic diversity in clinical trials will likely put significant new pressure on the ability of sponsors and CROs to enroll patients. This will likely put a significant premium on clinical trial sites located in areas with diverse populations (i.e., a high proportion of Hispanic and/or black people).

In June 2024, the U.S. Food and Drug Administration (FDA) issued long-awaited draft guidance for racial and ethnic diversity in clinical trials. The goal of the FDA is to have participants in Phase III (and other pivotal) clinical trials be more representative of the patients who will be using the treatment being evaluated. The public has until September 26, 2024 to comment on the FDA guidance. Thereafter, the FDA will release final guidance making it mandatory for all trials.

Under the draft guidance, **sponsors and CROs are expected to publicly disclose recruitment goals for different racial groups, stratified by age and gender, and explain their rationale for doing so.** Some strategies to improve racial and ethnic diversity would include engagement with patient advocacy groups, offering transportation services to faraway patients, study designs supporting diversity, selecting clinical trial sites located in areas with diverse populations, and using decentralized clinical trial approaches.



Source: Avalere Health and Bourne Partners

Increasing Information Technology Overload

Biopharma companies have attempted to address the increasing therapeutic complexity of clinical trials by deploying digital and software applications. However, many of these digital tools and software applications have proven to be counterproductive, in our view, only adding to the complexity of clinical trials and the burden on the sites.

Today, **clinical trial site investigators need to manage dozens of overlapping digital tools and software applications.** Many of these tools and applications were designed for pharma sponsors and CROs and are subsequently pushed on to the sites. Specifically, a 2022 poll of clinical research sites found that 60% of sites are using 20+ overlapping software applications each with their own usernames and passwords and training requirements. Storing passwords in excel worksheets is not secure and navigating these various software applications is a challenge.

Adding to this, **the post-COVID rise of decentralized clinical trial (DCT) designs has led to even greater operational burdens.** DCTs greatly improve patient access, but this comes as a new burden for clinical trial sites. Sites are forced to juggle a range of digital patient engagement technologies (e.g., telemedicine, eConsent, etc.) and services (e.g., home nursing and phlebotomy). Sites often do not have the personnel to visit patients and collect data, so this creates a new need to coordinate with third-party services companies.

To access the full unblinded report, contact: research@bourne-partners.com

ADVARRA

*Two-thirds (**67%**) of sites indicate setup and training on sponsor technology are more burdensome versus five years ago.*

SCRS
Society for Clinical Research Sites
Our Voice | Our Community | Your Success

*Sites reported that they spent an average of **17.5** hours per month training for trials with remote technology. And 40% said they spent **5-15** hours training, which is time that could have been with patients.*

Source: Digital Data Institute at Harvard, Advarra, the Society for Clinical Research Sites, and Bourne Partners

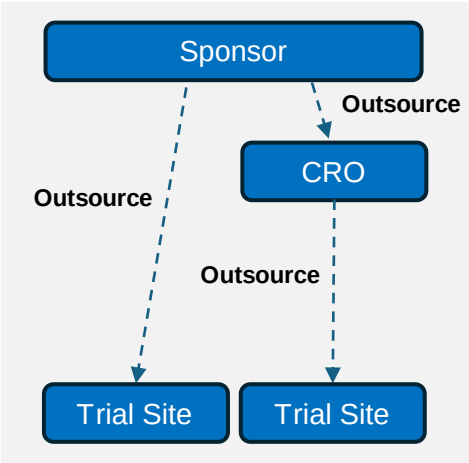
Rethinking Standalone Clinical Trial Sites

THREE (3) Strategies to Address Investigator Site Pressures

Looking ahead, **we see THREE (3) overlapping strategies that the life sciences industry can adopt to generate greater economies of scale from an increasingly limited pool of quality/experienced clinical trial sites.** In our view, the industry's reliance on standalone independent clinical trial sites -- *in its current form* -- is unsustainable.

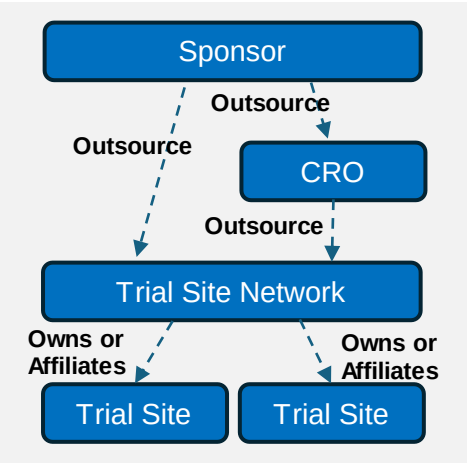
1. Improve Standalone Site Relationships

Pharma companies and CROs can rethink and modernize their relationships with standalone independent sites with a greater focus on collaboration and communication. This sounds simple, but it would require significant culture change, which may be difficult to accomplish for many pharma companies and CROs.



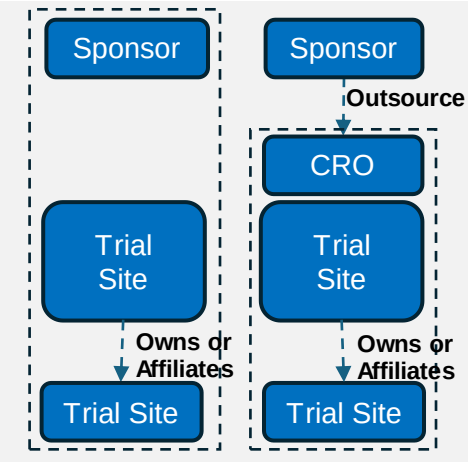
2. Develop Site Networks

Standalone clinical trial sites can merge and/or affiliate into larger site networks (site management organizations). This helps to better pool limited resources and generate economies of scale on labor and corporate costs. Also, site networks can leverage the use of information technology and standardize on best practices.



3. Vertically Integrate

Pharma companies and CROs can directly acquire and build their own captive network of clinical trial sites and employ quality investigators. This ensures site access for their clinical development programs, but it requires capital. It could also lead to channel conflicts with competing pharma companies and CROs.



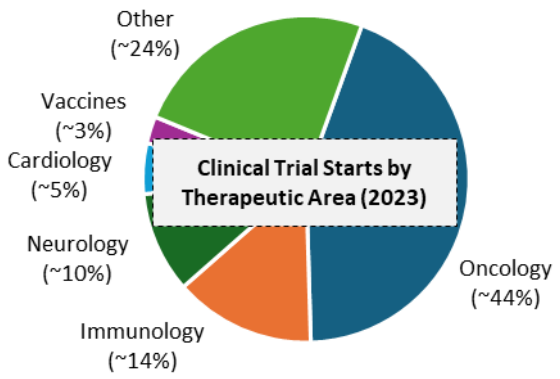
Source: Bourne Partners

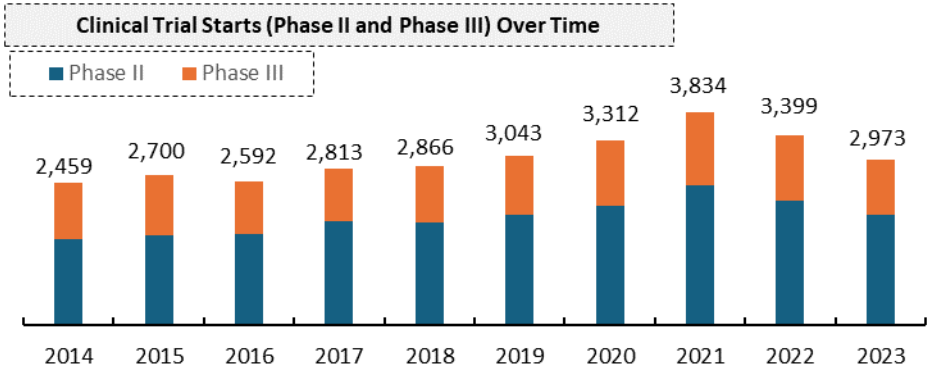
The Use of Standalone Independent Clinical Trial Sites

The use of standalone independent clinical trial sites does have certain advantages and use cases. Standalone independent sites are under tremendous pressure, but they will continue to have a role to play. However, sponsors and CROs need to seriously rethink and modernize their relationships with these standalone sites.

The advantage of working with standalone clinical trial sites is the flexibility it affords the site, the sponsor, and the CRO. Certain specialized sites may want to be able to work with multiple sponsors and CROs -- not be captive to a site network, a sponsor, or a CRO. In turn, sponsors and CROs want the flexibility to select and optimize their own sites across various therapeutic verticals. This is particularly the case for niche medical specializations, e.g., oncology and rare diseases, where there are a delimited number of key opinion leaders and relevant academic health systems. It would not make sense for these medical specialists to be captive to a site network, a single sponsor, or a single CRO. So, to some extent, the standalone site model will always be around, in our view.

That said, to be successful with standalone sites, **sponsors and CROs need to seriously rethink their approaches to site relationships** with a greater focus on creating positive experiences for investigators. The ability of a sponsor or a CRO to create positive site experiences is a critical competitive advantage since investigators who have a good experience tend to enroll more patients – sometimes twice as many as those who have a neutral or negative experience according to some we have spoken to. So, we think small investments here can payoff with faster clinical development times and extra months of IP-protected revenue for the sponsor.





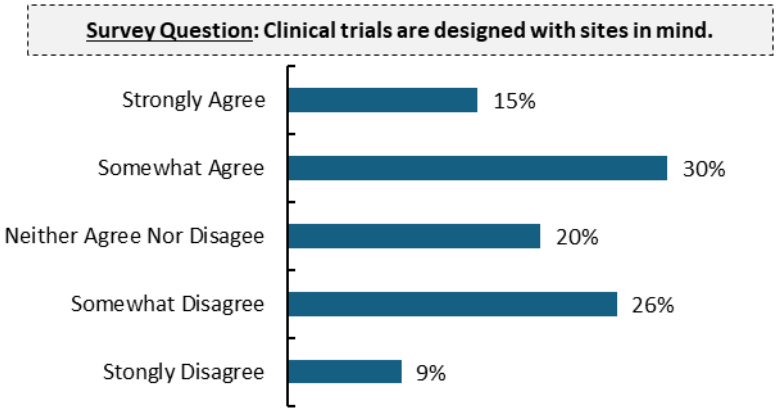
Source: IQVIA Institute, January 2024

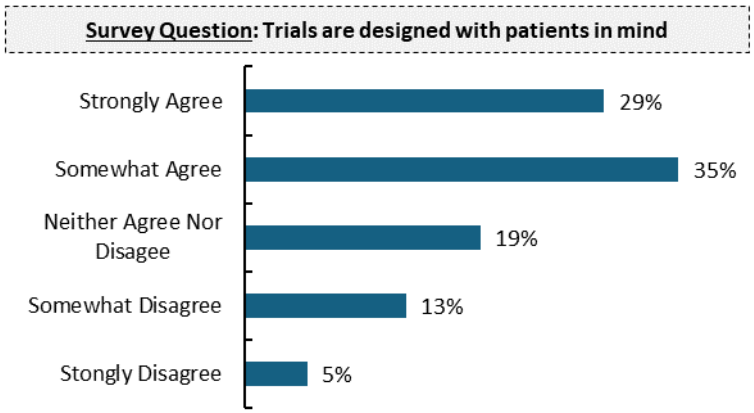
FIVE (5) "Fixes" to Site Relationships (Slide 1 of 2)

Based on our literature review and our conversations in the field, **we highlight FIVE (5) areas where sponsors and CROs can improve their relationships with standalone clinical trial sites.** The good news is that many of the frustrations that we hear from clinical trial sites with respect to sponsors and CROs are operational in nature -- meaning that they do not require significant financial investment. The bad news is that they will require a culture change and a different way of thinking, which can be difficult to implement in large organizations.

Fix #1: Collaborative Clinical Trial Design

Sponsors and CROs should consider clinical trial design with site investigators in mind. Sites have different models, staff resources, infrastructure, and clinical priorities. Many industry observers question whether some of the increased clinical trial complexity in recent years is necessary, e.g., measuring similar endpoints in different ways or having a large number of exploratory endpoints. So, the simplest thing sponsors and CROs can do to improve their relationships with sites is to regularly solicit feedback from sites and give sites a say in protocol design. This seems like a simple concept. However, the reality is that few sponsors and CROs do this.





Source: The 2023 Avoca State of the Industry Survey and Bourne Partners

FIVE (5) "Fixes" to Site Relationships (Slide 2 of 2)

Fix #2: Improved Communications

Investigator sites often report that there is not a single point of contact at the sponsor or CRO to triage study questions and issues. Adding to this is the high turnover of CRAs, which often results in investigator sites having to educate new CRAs. Also, sites commonly point out that existing "portal" technologies are difficult to navigate and often not updated. As normal course, sponsors and CROs should provide sites with an organization chart of their study teams and vendors along with contact information so everyone at a site knows who is responsible for what and how to reach them when needed.

Fix #3: Fragmented Technologies

Investigator sites very frequently express frustration with the wide range of software applications that are imposed upon them, many of which duplicate their existing software. The burden of managing multiple software systems increases as sites work on additional studies with different sponsors and CROs. Sponsors should try to accommodate existing software at their study sites when designing trials. Also, sponsors can do simple things like extend the timeframe for password expiries and include sites in user acceptance testing for new software. Finally, sponsors and CROs should offer 24×7 technical support for all systems as well as clear instructions.

Fix #4: Poorly Thought-Out Budgets

Investigator sites find it difficult to work from generic budgets that are not tailored to the needs of a specific trial. This results in a need for follow-up conversations to better explain to the sponsor what it takes for a site to conduct a study. Sponsors and CROs should ensure that budget negotiators are educated about the therapeutic area and the indication involved (rather than just working off of boilerplate templates).

Fix #5: Burdensome Study Start-Up Processes

The study start-up process often includes many time-consuming and superfluous tasks, such as pre-study qualification visits. Also, there are redundant information requests from different members of the same sponsor or CRO. To save time, sponsors and CROs can pre-populate redundant information on feasibility questionnaires and rethink the necessity of pre-study site qualification visits by using site performance databases that compile and showcase site data and experience.

Source: Bourne Partners

Site Network Strategies

Fragmented and Undeveloped Market for Site Networks

The total addressable market (TAM) for clinical trial site networks is significant. However, the site network marketplace is still very early in its development with the vast majority of sites being independent of any network, sponsor, or CRO.

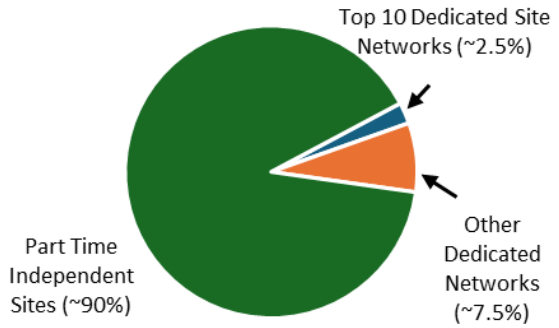
We estimate that spending on U.S. clinical trial sites is upwards of ~$10B annually, growing in the ~mid-single digits. However, the revenue opportunity for site networks is likely much larger than this given that many larger site networks have started to offer adjacent (add-on) services, such as protocol design assistance, medical monitoring, and data management -- similar to CROs.

There are upwards of 80,000+ clinical trial sites globally, including 25,000+ in the United States, by our assumptions. We believe that only a small minority (less than 10%) of these research sites are part of a broader site network with the rest consisting of part-time standalone investigators. This suggests only several thousand locations that are committed to a site network.

The clinical trial site network space itself is highly fragmented with the top ten dedicated site networks accounting for less than 600 total sites (i.e., less than ~25% share). Of note, three of the top four largest dedicated site networks are now owned and operated by global CROs, i.e., PPD, ICON, and IQVIA. The largest non-CRO site network accounts for only ~4% share.

Name of Site Network (SMO)	Primary Sponsor	Number of Trial Sites
Accelerated Enrollment Solutions	Thermo Fisher Scientific (PPD)	~170
Accellacare	ICON plc	~110
Velocity Clinical Research	GHO Capital	~105
Avacare Clinical Network	IQVIA Holdings	~60
Alcanza Clinical Research	Martis Capital	~32
Alliance for Multispecialty Research (AMR)	Curewell Capital	~32
Flourish Research	NMS Capital	~24
Evolution Research Group (ERG)	Linden Capital Partners	~20
CenExel Clinical Research	Webster Equity Partners	~18
Headlands Research	KKR	~18
Estimated Total Clinical Trial Sites (U.S.)		~25,000

Breakdown of Clinical Trial Sites
(~25,000 in the United States)



Source: Company filings and Bourne Partners

The Value Proposition of Clinical Trial Site Networks

Increasingly, **standalone independent clinical trial sites are consolidating into larger networks to bring "economies of scale" into clinical trials.** In our view, site networks should align their strategies around a specific dimension of economies of scale that they are trying to achieve. For instance, adding a new therapeutic capability might be desirable, but this needs to be done with consideration about how it brings scale (synergy) to the broader network.

There are a wide variety of different site networks. Some site networks directly own and manage a network of dedicated sites with a direct financial interest in the operations of the sites. Others are "brokers" who connect integrated networks of independent sites with sponsors and CROs. This latter group of site networks will often also "embed" clinical trial support and logistical services (e.g., training, tech support, etc.) to its site network on an exclusive or semi-exclusive basis.

In our opinion, **a site network should generally be able to outperform groups of standalone sites due to its exclusive focus on clinical trials.** For sites, a network brings "negotiating power" with pharma companies, CROs, technology vendors, and suppliers with respect to pricing and contracting. For sponsors (and CROs), site networks bring greater operational predictability due to the ability of the site network to standardize around best practices. Also, for both sites and sponsors, site networks facilitate better communication by offering a single point of contact for the sponsor and CRO.

Essentially, **the value proposition of a site network is its ability to bring "economies of scale"** in multiple dimensions across an otherwise fragmented universe of standalone trial sites.

1. *Financial Leverage.* A key source of economies scale is leveraging back-office expenses including the use of labor, e.g., nurses, pharmacists, and site coordinators, etc.
2. *Therapeutic Expertise.* Site networks can share principal investigators with unique expertise in emerging-modality therapeutics across a network of sites.
3. *Information Technology.* Site networks can standardize the use of information technology (e.g., CTMS and eReg) to gain process efficiencies. This includes reduced down-time for training and improved interoperability.
4. *Demographics.* Site networks can help scale recruitment with respect to specific geographies and demographics.
5. *Other.* Site networks can help reduce transaction costs by scaling marketing and contracting across a network.

Source: Bourne Partners

Two (2) Site Network Operating Models

In our view, **there are two general site network operating models: 1) dedicated sites and 2) embedded sites**. Each model has its advantages and disadvantages. Based on our conversations, we find that a hybrid approach with both dedicated and embedded sites gives a network the best of both models and helps to diversify a site network's financial profile.

1. Dedicated Sites

The dedicated site strategy involves a site network directly owning a clinical trial site and directly employing support staff. In many cases, this includes the principal investigators. In some cases, principal investigators are imported from area medical practices, and they work on a contract basis.

The obvious advantage of the dedicated site approach is the focus that it brings to clinical trials. Dedicated sites give the site network manager maximum control over operations, procedures, physical infrastructure, and growth initiatives since there are no competing day-to-day priorities that normally exist at a medical practice. Also, with sufficient volumes, dedicated sites should generate better economies of scale and operating margins, in our opinion.

The disadvantage of the dedicated site approach is that it is entirely dependent on referrals. Dedicated sites must constantly have pre-marketing outreach campaigns to develop and sustain relationships with local provider groups and ensure access to patients. Also, dedicated sites tend to be limited to consumer-oriented studies involving relatively healthy patient volunteers, e.g., vaccines, dermatology, weight management, and general medicine.

2. Embedded Sites

The embedded site strategy involves a site network partnering with an existing physician practice using the physical infrastructure and staff of the "host" physician practice. Under this strategy, the site network will embed research support staff and technology at the host physician practice. Interest in these partnerships tends to come from mature physician groups looking for new growth channels.

The advantage of the embedded site strategy is improved access to patients as it takes advantage of existing doctor-patient relationships, making it easier to recruit for therapeutically complex clinical trials in specialty disease areas. Access to EHR software systems is core to the embedded site model. This involves the site network having direct login credentials and regular patient cohort reports that help match patients to a prospective protocol.

The disadvantage of the embedded site strategy is the lack of control and focus caused by working within someone else's business/infrastructure. Clinical research must compete for time, attention, and resources against the other priorities of the host medical practice, including the demands of day-to-day priorities of patient care.

Source: Bourne Partners

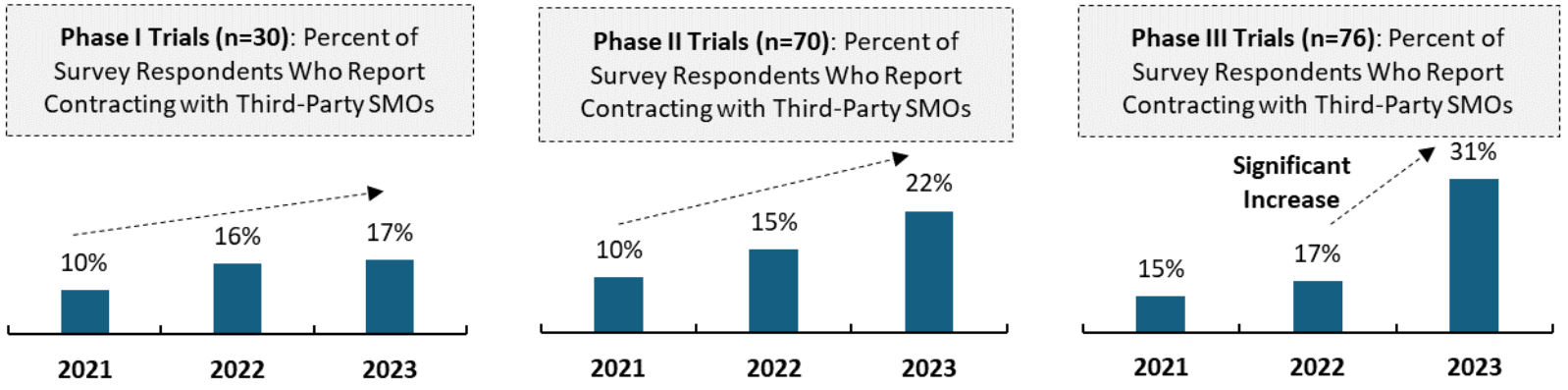
Increasing Demand for Site Networks

Demand for site networks (or SMOs) has been increasing over the past several years, particularly for larger and complex *Phase III* clinical trials. This demand is being driven by all of the industry trends that are pressuring standalone sites -- e.g., labor shortages, increasing study complexity, recruitment challenges, and technology overload.

Today, **30%+ of *Phase III* clinical trials include a site network (or a SMO)**, per recent survey data (below), and we expect that this will continue to increase in the coming years. This is consistent with our view that the value proposition for site networks is directly a function of the size and complexity of a given clinical trial. The use of site networks has also been increasing for smaller *Phase I* and *Phase II* clinical trials as well, although significantly less so.

That said, **most sponsors and CROs continue to contract with sites on a site-by-site basis.** This site-by-site approach to site selection and contracting reflects the fact that sponsors and CROs set up their site databases based on physician names, rather than sites.

Going forward, **the rise of site networks now gives sponsors and CROs a chance to consolidate their contracting** and we expect to see an increasing use of strategic partnerships (preferred provider arrangements) between sponsors and site networks -- similar to the strategic partnerships that we have seen develop between sponsors and CROs over the past couple of decades. Over time, this should reduce the need for sponsors and CROs to deal with the nuances of individual sites (when contracting on a site-by-site basis).



Source: L.E.K. Clinical and eClinical Pharma Services Survey (2023) and Bourne Partners

Site Network Growth Strategies and Observations

Site network growth strategies vary, but there seems to be a preference for acquisition-driven expansions, based on our conversations. In our view, consolidation of the site network space will likely follow the pattern of the CRO space with a handful of large site networks coupled with a number of smaller site networks with niche areas of focus and expertise.

Acquisition Driven Expansions. Acquisitions are the preferred growth strategy for many site networks that we spoke with. Acquiring an established clinical trial site tends to result in a faster path to financial success, particularly given the currently strong demand environment, whereas starting a clinical trial site from scratch takes considerable time and investment. Adding to this, sponsor preference for working with experienced investigators makes it even more difficult to build traction with new sites.

De Novo Expansions. The upside to de novo expansion strategies is that there are no integration issues since all clinical trial sites can be built on a common technology stack, with consistent operating procedures, and common branding. This shows up in superior performance for sponsor and CRO customers. Also, in Europe, the clinical trial site landscape is less developed so there are simply less opportunities for acquisitions. This results in site networks having to pursue de novo expansion strategies almost exclusively.

Site network expansion decisions, either via acquisitions or de novo expansions, should consider a variety of factors, including therapeutic focus, geography (breadth and density), and local population demographics as well as other factors.

Therapeutic Coverage
Most of the site networks we spoke with seek to be therapeutically diverse since the life sciences R&D pipeline can change. A site can be victim to therapeutic area lumpiness if it focuses exclusively on a single specialty.

Geographic Coverage
Sites need to balance geographic breadth with geographic density. It is helpful to cover multiple geographies in order to gain economies of scale. However, a minimal geographic density helps to leverage local recruitment.

Local/Area Demographics
Local demographics should be a major consideration given the increasing focus by regulators and sponsors on clinical trial diversity. Sites can be strategically located in areas where there are specific targeted demographics to avoid putting unrealistic expectations on individual sites to pursue certain patient profiles.

Other Factors
Other factors include local competition with other sites, the financial health of the acquiree, and cultural fit.

Source: Bourne Partners

Implications for the Broader Pharma Services Landscape

We expect clinical trial site networks to have disruptive implications for CROs, patient recruitment (and engagement) companies, and software developers as they get larger. In our view, much of the pharma services landscape is currently organized around sponsors and CROs -- because that is where the money is.

Contract Research Organizations (CROs)

In our view, site networks could become a new source of competition for CROs. As site networks become larger, they will become natural partners for pharma and biotech companies in various service areas traditionally reserved for CROs, e.g., protocol design assistance, medical monitoring, and data management. Also, we have seen an increasing appetite by pharma companies to outsource on a FSP basis to own the relationship with the investigator, who is the ultimate prescriber.

However, there are opportunities for CROs as well. Forward-looking CROs have been acquiring and developing their own site networks. And, therapeutically niche CROs can develop their own integrated site network in specific medical specialties.

Software and Analytical Application Vendors

We think there is an emerging opportunity for forward-looking software vendors to develop applications and analytical tools for clinical trial sites, as site networks gain relevance. Most site networks use third-party vendors, but the consistent feedback that we have received is that these applications and tools are designed for the back-office needs of sponsors and CROs, rather than the front-end needs of the sites.

Sites consistently tell us that they want an integrated CTMS platform with workflow enhancement, marketing/recruitment, and EHR mining applications. Finally, most of the sites we spoke with commented that there has been excessive hype around the use of decentralized clinical trials (DCTs).

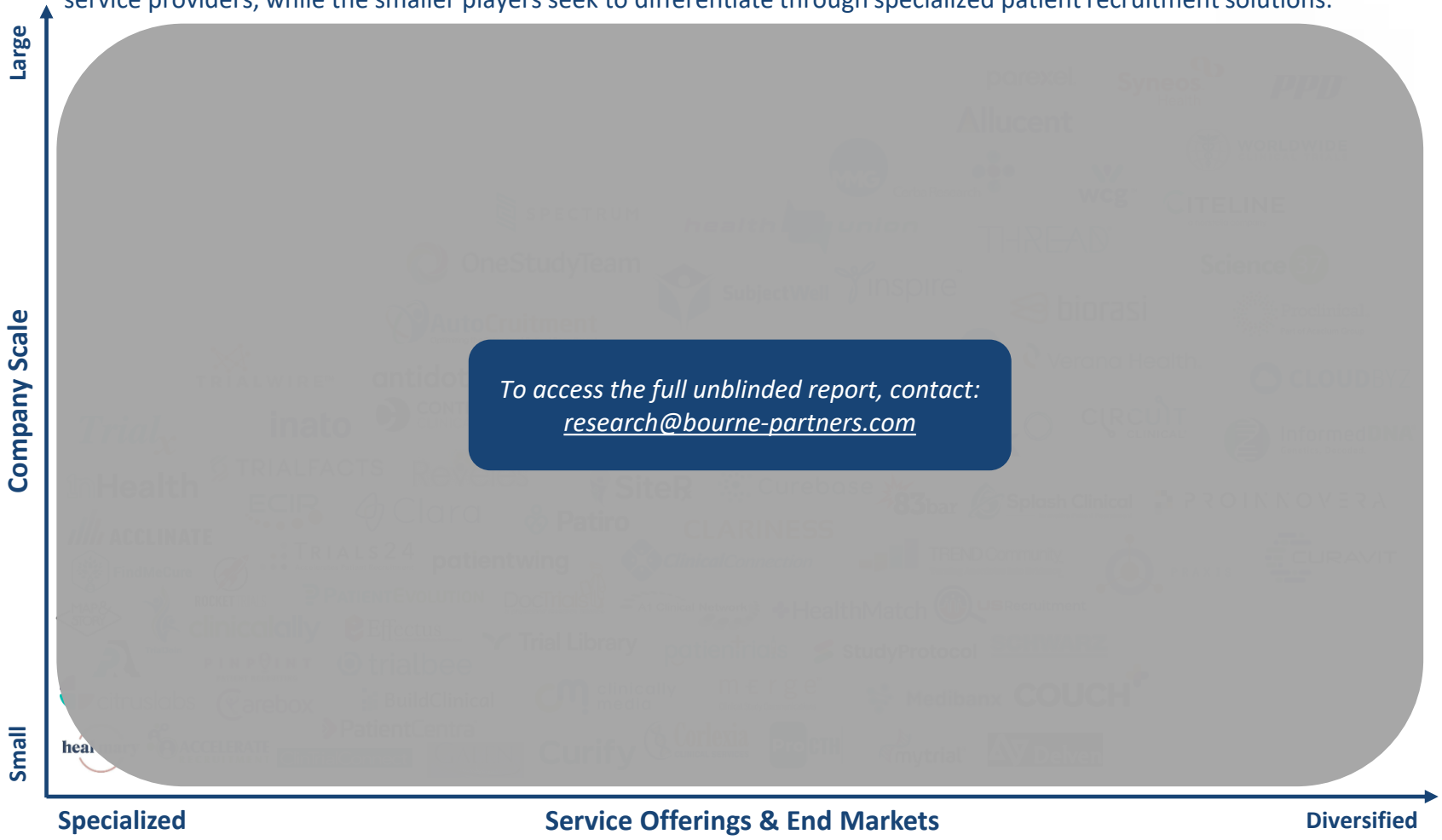
Patient Recruitment and Engagement Companies

We see the rising relevance of clinical trial site networks as noteworthy for patient recruitment and patient engagement companies. On the one hand, site networks offer sponsors and CROs local connections and expertise and this could be viewed as a competitive threat. However, most site networks do not have the resources or expertise (or time) to scale recruiting and retention, on an enterprise/network basis. Sites need guidance and new ways to find potential recruits. Also, we see evolving use cases for generative artificial intelligence (gen-AI), which would require significant technical know-how that a small/mid-sized site network may not have.

Source: Bourne Partners

Patient Recruitment Landscape

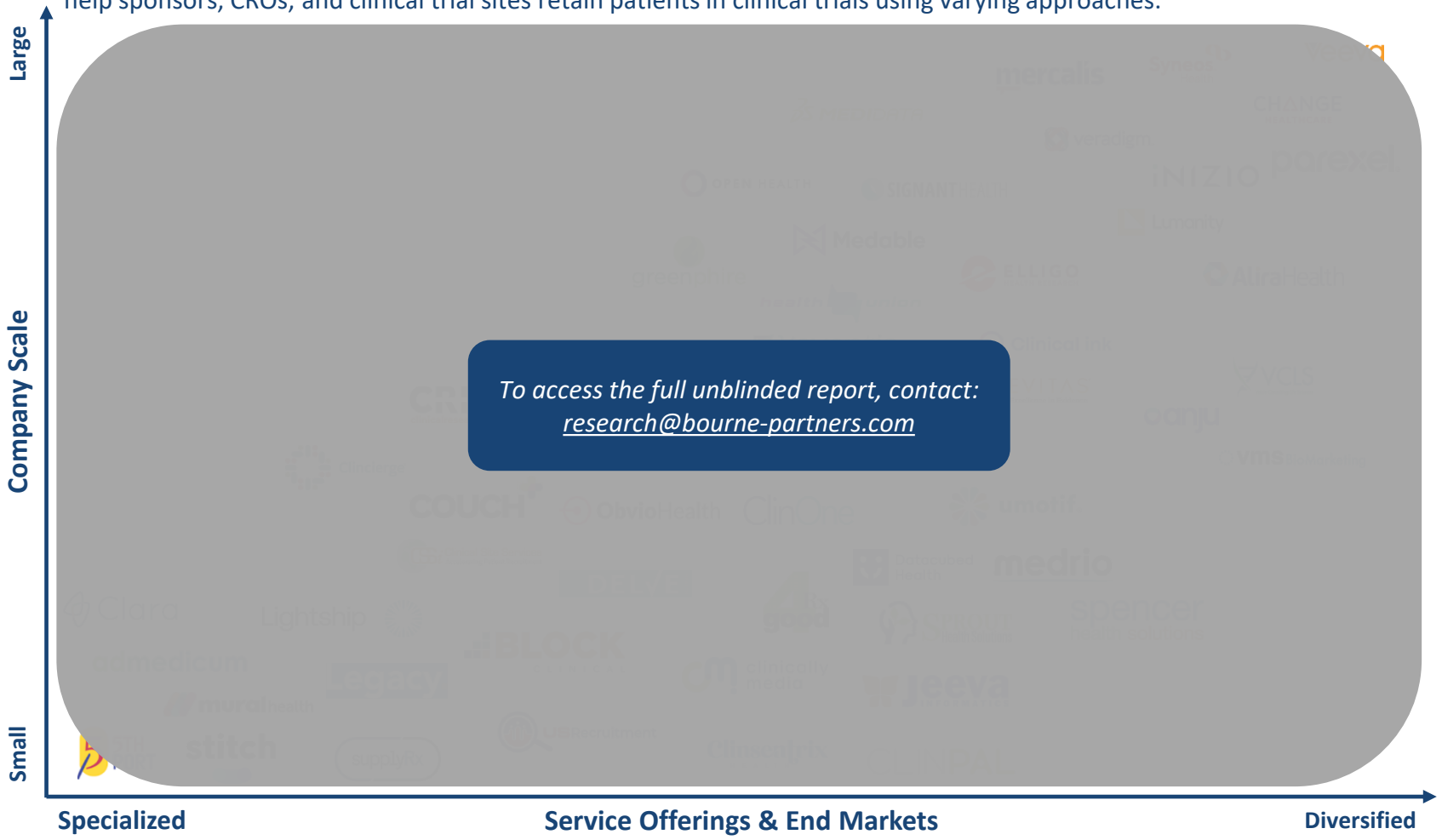
The marketplace of patient recruitment companies is fragmented. Large players are mostly highly-diversified clinical service providers, while the smaller players seek to differentiate through specialized patient recruitment solutions.



Source: Bourne Partners

Patient Engagement Landscape

There is a rapidly growing marketplace for "patient engagement" software and services providers. These companies help sponsors, CROs, and clinical trial sites retain patients in clinical trials using varying approaches.



Source: Bourne Partners

Profiles of Selected Clinical Trial Site Networks (1 of 7)

Velocity Clinical Research is the far-and-away largest non-CRO owned clinical trial site network in the world, by our knowledge. Velocity was purchased by GHO Capital in April 2021 from NaviMed Capital. Since then, Velocity has grown from 16 to 100+ sites across the United States and Europe.

Founded in 2017, **Velocity Clinical Research is the largest pure-play SMO with 100+ dedicated clinical trial sites in the United States and Europe** – behind ICON's Accellacare network and PPD's Accelerated Enrollment Solutions network. Also, Velocity has recently entered partnerships with health systems (and physicians) to get access to therapeutic areas that are typically reserved for academic medical centers -- e.g., oncology.

At this point, **Velocity Clinical Research has grown to the size and scale of being able to handle entire clinical trials on its own.** This is important because it allows Velocity to bring the full value of its network (with respect to site and investigator selection). Also, Velocity has its own internal training programs for investigators.

Of note, **in early 2024, Velocity launched its own proprietary technology platform ("Vision")**. Normally, in our view, software and information technology has been developed by vendors focused on sponsors and CROs (because that is where the money is). Then, the technology is pushed on to the sites. By contrast, Velocity has developed a software system specifically designed for dedicated clinical trial sites -- backed with significant data assets. We expect this will further differentiate Velocity from many of its site network (SMO) peers.

Name of Acquisition Target	Date
Clinical Research Institute of Sourthen Oregon	Dec-17
New Horizons Clinical Research (Cincinnati, OH)	Dec-17
MD Clinical (Hallandale Beach, FL)	Dec-18
Rapid Medical Research	Nov-19
Advanced Clinical Research (West Jordan, UT)	Nov-19
Omega Medical Research (Warwick RI)	Jun-20
Buynak Clinical Research (Valparaiso, IN)	Jun-20
eStudySite (La Mesa, CA)	Nov-20
Downtown Women's Health Care (Denver, CO)	Mar-21
Clarity Clinical Research (Syracuse, NY)	Jul-21
VitaLink Research (Greenville, SC)	Sep-21
National Research Institute	Sep-21
Trier Health (San Jose, CA)	Feb-22
Clinical Research Hamburg (Germany)	Jul-22
MedPharmics (Metairie, LA)	Sep-22
Egin Research (High Wycombe, U.K.)	Nov-22
Meridian Clinical (Omada, NE)	Dec-22
Greenfield Opening (Bristol, U.K.)	Oct-23
Greenfield Opening (Leicester, U.K.)	Oct-23
Greenfield Opening (Romford, U.K.)	Oct-23
Impact Research Institute (Waco, TX)	Oct-23
ClinMedica Research (Poland)	Dec-23
KO-MED (Poland)	Jan-24
PRI (Germany)	Jan-24
KLB Lübeck (Germany)	Jan-24

Source: Velocity Clinical Research and Bourne Partners

Profiles of Selected Clinical Trial Site Networks (2 of 7)

Adams Clinical
Watertown, Massachusetts
www.adamsclinical.com

In May 2024, InTandem Capital Partners partnered with the founders and management team of Adams Clinical, a high growth clinical trial site network with locations across the Northeast focused on central nervous system disorders (e.g., psychiatric and neurologic illnesses).

Adams Clinical specializes in Phase II and Phase III clinical trials in psychiatry and neurology. Adams employs nine full-time doctors.

Founded in 2011 in Watertown, Massachusetts, Adams Clinical differentiates itself with its clinical trial participant recruiting acumen and therapeutic area expertise.

Alcanza Clinical Research
Lake Mary, Florida
www.alcanzaclinical.com

Founded in December 2021, Alcanza operates 30+ clinical trial sites with a strategic focus on its ability to access underrepresented populations with a broad range of therapeutic coverage.

To a lesser extent, Alcanza offers "embedded" site services to independent provider groups. This is often used as a way to gain a foothold in a new geographic market.

Alcanza has been acquisitive, closing, by our count, 12 acquisitions over the past three years. This includes the July 2023 acquisition of Accel Research Site Network, which added 22 sites.

Alcanza is backed by Martis Capital.

Alliance for Multispecialty Research
Knoxville, Texas
www.amrllc.com

The Alliance for Multispecialty Research (AMR) began in 1994 as an association of clinical trial sites that shared marketing resources and research best practices. Membership in the network was based on peer review.

In 2017, 15 AMR sites formally merged into a single integrated company with shared corporate infrastructure. Since then, the AMR has grown to 32 clinical trial sites, through a series of acquisitions, including the recent acquisition of Affinity Health in December 2023.

In March 2022, Curewell Capital purchased a majority stake in the AMR, as part of a recapitalization.

Source: Company filings and Bourne Partners

Profiles of Selected Clinical Trial Site Networks (3 of 7)

Atlas Clinical Research
Durham, North Carolina
www.atlas-clinical.com

Atlas Clinical Research is a therapeutically-focused network of six clinical trial sites in upstate New York (two sites), the Philadelphia area (two sites), and the Tampa Bay area (two sites). This includes a new site recently opened in Buffalo, New York.

Atlas Clinical Research focuses exclusively on four therapeutic areas: internal medicine, central nervous system disorders, infectious diseases, and gastrointestinal.

BPOC launched Atlas Clinical Research in April 2023 in conjunction with a strategic partnership with Rochester Clinical Research, the foundational site on which the network will be modeled.

CenExel Clinical Research
Salt Lake City, Utah
www.cenexelresearch.com

Founded in 2018, CenExel Clinical Research operates 18 dedicated clinical trial sites (centers of excellence) with a therapeutic focus on pain management, neurology and psychiatry.

In late 2022, CenExel launched a new business called "Clinical Sciences by CenExel" that offers standalone scientific advisory services to pharma companies and CROs covering topics such as clinical development planning, study design, recruitment solutions, and dose selection criteria.

Webster Equity Partners recapitalized CenExel in August 2018 with a subsequent investment from Blackbrook Management.

Centricity Research
Columbus, Georgia
www.centricityresearch.com

Centricity Research owns and operates 35+ dedicated research sites in the United States and Canada across a broad range of therapeutic areas.

Centricity Research was formed by the merger of Georgia's IACT Health and Ontario's LMC Manna Research in November 2021 and True North Clinical Research in December 2021. Since then, Centricity Research acquired Aventiv Research (in mid-2022) and Lucas Research (in late 2023).

In May 2023, Trinity Hunt Partners announced a majority investment in Centricity Research. To support future growth, Centricity Research announced a new management team in late 2023.

Source: Company filings and Bourne Partners

Profiles of Selected Clinical Trial Site Networks (4 of 7)

DM Clinical Research
Houston, Texas
www.dmclinical.com

Founded in 2006, DM Clinical Research is a founder-owned clinical trial site network with 24 sites (15 dedicated and 9 embedded), covering an expanding range of therapeutic areas.

DM Clinical Research is heavily focused on patient enrollment diversity reporting that almost half (48.5%) of its clinical trial participants being identified as diverse in 2022.

Finally, DM Clinical Research is strategically focused on creating positive patient experiences with regular patient surveys, site-by-site scorecards, and on-site customer support teams. This has led to a 97% patient satisfaction score.

Elixia Health
Hollywood, Florida
www.elixiahealth.com

Elixia Health, formerly American Clinical Research Services (ACRS), consists of two synergistic operations: 1) a site network and 2) a patient recruitment business. The site network includes 12 locations (and growing) therapeutically focused on psychiatry and nephrology.

Also, Elixia has a clinical trial patient recruitment business based on two acquisitions in 2023: Clinical Site Services and Patient Advertising Guru. With these acquisitions, Elixia now offers traditional, digital, and social media and local enrollment specialists that can be embedded at sites.

Elixia is a portfolio company of Latticework Capital Management.

Evolution Research Group (ERG)
New Providence, NJ
www.ergclinical.com

Evolution Research Group (ERG) operates a site network with a focus on central nervous system (CNS) disorders, including psychiatry, neurology, and pain management. Linden Capital Partners acquired ERG in May 2018.

Today, ERG consists of 20+ clinical trial units, including a *Phase I* unit, several early-phase specialty units, a purpose-built research facility in acute pain, and two postoperative surgical facilities, as well as a network of affiliated sites.

Of note, in November 2021, ERG acquired Lotus Clinical Research, a niche CRO focused on CNS disorders. This gave Lotus access to ERG's 130+ bed *Phase I* CNS facility in Miami.

Source: Company filings and Bourne Partners

Profiles of Selected Clinical Trial Site Networks (5 of 7)

Eximia Research
Raleigh, North Carolina
www.eximiaresearch.com

Eximia Research owns and operates nine (9) research sites across six states with 25+ investigators across a variety of specialties. Eximia Research also offers a range of related services including feasibility analysis, protocol design, study start up services, and patient enrollment.

VSS Capital Partners and Dr. Ella Grach (CEO of Eximia Research) formed Eximia in October 2023 to leverage centralized services to support a network of sites and partner with leading pharma, biotech and CROs.

As part of the launch, Eximia formed a strategic partnership with Sundance Clinical Research with a site in Missouri.

Flourish Research
Apex, North Carolina
www.flourishresearch.com

Created in 2021, Flourish Research operates 24+ clinical trial sites across the United States. Flourish Research is focused in three therapeutic categories: i) cardio/metabolic, ii) neuroscience, and iii) infectious diseases.

Flourish has been acquisitive, having closed 11 acquisitions over the past three years. Just recently, in June 2024, Flourish acquired ENCORE Research Group, adding 8 locations in Florida.

Flourish Research was formed by NMS Capital in August 2021 through the recapitalization of Clinical Trials of Texas (CTT), a clinical trial "super site" in San Antonio, Texas. CTT, in turn, was founded in 2001.

Headlands Research
Lake Worth, Florida
www.headlandsresearch.com

Headlands Research operates 18 dedicated clinical trial sites in the United States and Canada -- as well as a variety of partnerships with third-party provider organizations.

Headlands Research is particularly focused on central nervous system (CNS) disorders and accessing diverse populations. In May 2022, Headlands Research entered a multi-year partnership with Pfizer focused on increasing diversity in clinical trials. This partnership now includes five sites.

KKR purchased Headlands Research in January 2018. In December 2023, KKR also acquired a majority stake in Worldwide Clinical Trials.

Source: Company filings and Bourne Partners

Profiles of Selected Clinical Trial Site Networks (6 of 7)

Helios Clinical Research
New York, New York
www.heliosclinical.com

Helios Clinical Research is a network of 20 sites across five states with a focus on Phase II-IV clinical trials across a range of therapeutic areas. Helios also partners with independent hospitals and physician clinics, embedding staff and providing training and support.

For sponsors, Helios also offers a variety of clinical development services such as feasibility studies, site selection, training and patient engagement.

Grant Avenue Capital created and launched Helios Clinical Research in November 2022 with an eye on building a site network in middle America, with a demonstrated ability to grow through acquisitions.

IMA Clinical Research
Hickory, North Carolina
www.imaresearch.com

IMA Clinical Research operates a network of over 20 dedicated sites coupled with many dozens of satellite locations. Significant recent acquisitions include Clinical Trials of America (January 2023) and Accelemed Research (April 2023).

Also, IMA Clinical Research offers decentralized (digital) clinical trial solutions and capabilities.

IMA Clinical Research is a division of the IMA Group, owned by private equity firms Centre Partners and Linden Capital Partners, among others. IMA Group, in turn, consists of IMA Clinical Research and various evaluation services, e.g., workers comp, disability, and occupational health.

M3 Wake Research
Raleigh, North Carolina
www.wakeresearch.com

M3 Wake Research owns and operates 20+ dedicated clinical trial sites across nine states -- all sharing common patient recruitment, marketing and operating procedures. M3 Wake Research was founded by a large multi-specialty group practice and has conducted clinical research studies as far back as 1989.

M3 Wake Research is owned by M3 Inc., a publicly-traded Internet company on the Tokyo Stock Exchange with subsidiaries in Asia, Europe, and the United States. M3 had 5.8M+ physician members globally via its physician websites, e.g., *mdlinx.com*, *m3.com*, *research.m3.com*, *doctors.net.uk*, *medigate.net*, and *medlive.cn*.

Source: Company filings and Bourne Partners

Profiles of Selected Clinical Trial Site Networks (7 of 7)

Paradigm Clinical Research
Redding, California
www.paradigm-research.com

Paradigm Clinical Research owns and operates six dedicated clinical trial sites with plans to open several more sites in the very near-term. All of Paradigm's expansion has been organic, which has resulted in a highly coordinated site network with common tech stack, processes, and branding.

Founded in 2009, much of Paradigm's revenues to-date, have been generated from vaccine studies. However, the company has successfully diversified into other areas, such as dermatology, pulmonology, and neurology.

Crane Street Capital acquired Paradigm in February 2022, and Crane helped to bring in an experienced management team from well-known organizations.

Profound Research
Nashville, Tennessee
www.profoundresearch.io/

Profound Research is a founder-owned clinical trial network with investments from Rubicon Founders and Oak HC/FT. Profound embeds dedicated staff, tech, and equipment to support clinical trials by independent physician groups across a range of therapeutic areas.

Currently, Profound partners with seven medical practices with a total of 15 locations and 700+ physicians in Southern California and metropolitan Detroit. This includes the recent addition of Cardiology and Vascular Associates in August 2024.

Profound continues to add additional partnerships to both build geographic density in its current markets and to seed new markets.

Tekton Research
Austin, Texas
www.tektonresearch.com

Founded in 2006, Tekton Research owns and operates seventeen (17) research locations across seven states, including eight sites in Texas, four sites in Oklahoma, and three sites in Colorado. Recently, Tekton Research has expanded into Georgia, Kansas, Virginia, and North Carolina.

Tekton Research covers a variety of therapeutic specialties, including endocrinology, neurology, dermatology, and rheumatology, among others. Also, Tekton has experience with pediatric, adult, maternal, and elderly populations, with attention on diversity.

In August 2023 Havencrest Capital Management acquired a majority ownership in Tekton Research.

Source: Company filings and Bourne Partners

Vertical Integration Strategies

Accelerating Interest by Corporate and Institutional Investors

Since the mid/late-2010s, we have seen an increasing number of corporate, private equity investors, and venture capitalists entering the site network (SMO) space. In our view, this trend accelerated with the onset of the COVID-19 pandemic due to the need to quickly recruit large numbers of patients to develop a vaccine.

Select Corporate and Institutional Investors

First Trust Capital Partners
KKR
Webster Equity Partners
M3, Inc.
Impact Engine
VSS
IQVIA
BainCapital Ventures
KMG Capital Partners
Lapa Capital
Curewell Capital
BPOC
121
Norwest Venture Partners
Vitruvian Partners
Havencrest
Linden
Alpha Leonis
Grant Avenue
Ally Bridge Group
Rubicon Founders
Bourne Strategic Capital
Primark Capital
FCA Venture Partners
CFT Capital Partners
Oak HC/FT
ICON
ppd
BIP Ventures
Walmart
Kroger Health
Walgreens
NMS | Capital
Crane Street Capital
ICP Group
General Atlantic
CentrePartners
Trinity Hunt Partners
Pine Brook
GHO Capital
Morgan Stanley Investment Management
Martis Capital

Selected Acquired / Created Site Networks

Velocity Clinical Research
M3 | Wake Research
Headlands Research
profound research
ALCANZA Clinical Research for All
Accellacare
CenExel
Eximia Research
Paradigm Clinical Research
Centricity Research
JAVARA
Avacare Clinical Research Network
AES Accelerated Enrollment Solutions
HELIOS Clinical Research
Flourish Research
Atlas Clinical Research
Tekton Research
Elligo Health Research
ERG Evolution Research Group
DM Clinical Research
IMA Clinical Research An IMA Group Company
Topography Health
AMR
Headlands Research
Care Access
SiteBridge Research
Nucleus Network
ObjectiveHealth
AMR

Source: Company filings and Bourne Partners

Vertical Integration Between CROs and Site Networks

In recent years, **we have seen CROs directly acquiring clinical trial sites themselves** to secure patient access for their customers and address the challenges bottlenecking their site relationships. By owning sites themselves, CROs get maximum control over site operations resulting in more focused patient enrollment, site performance, and project management. Examples of this vertical integration strategy include PPD, ICON, and IQVIA Holdings.

CRO-owned clinical trial site networks can mitigate many of the frustrations that we commonly hear from standalone sites by allowing for the standardization of technologies and training, improved communications, and streamlined study start-up processes, etc. Unsurprisingly, these CRO-owned sites tend to outperform standalone independent sites due to the ability of the CRO to ensure best practices. In our view, most data shows that CRO-owned site networks tend to result in faster study timelines and a need for fewer sites due to their ability to recruit more patients.

Positive / Negatives. For CROs, owned investigator sites are a strong negotiating advantage when contracting with sponsors. Use of these sites is also useful for hybrid/FSP-style arrangements in which pharma companies outsource a delimited number of activities on a functional basis (vs full-service outsourcing). The most common argument that we hear against captive site networks is the potential for channel conflict with other CROs (and site networks).

CRO-Owned Sites Most Applicable:

In our view, **these CRO-owned dedicated sites are best suited for large-scale clinical trials in saturated markets** where it can be difficult to recruit/retain patients. This includes chronic diseases (e.g., diabetes), health conditions (e.g., weight management), and vaccines. Also, CRO-owned dedicated sites are also useful in therapeutic areas that require tracking patients over time. Positive patient experience can be critical to 'compete' for patients in these types of clinical trials.

CRO-Owned Sites Less Applicable:

However, **we see these dedicated sites as generally less relevant for niche and complex therapeutic areas**, such as oncology. These specialized therapeutic areas typically require the alignment with small numbers of key opinion leaders in specialized departments at academic hospitals. However, in some cases, CROs have developed at-home clinical trial services to engage with rare disease studies, pediatric studies, or studies involving patients with limited mobility.

Source: Bourne Partners

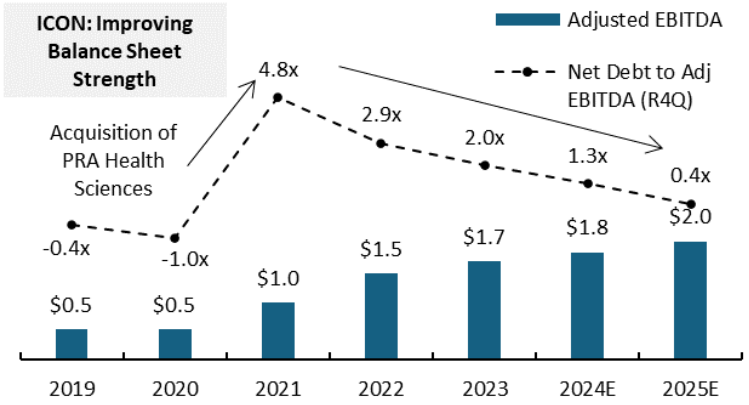
Case Studies of CRO-Owned Dedicated Site Networks (1 of 2)

Global CRO ICON owns and operates one of the largest clinical trial site networks in the world consisting of 100+ locations across the United States and Europe. This is an area of strategic emphasis for ICON, and we expect ICON to be actively evaluating acquisitions in the clinical trial site space going forward, based on management's commentary.

By our estimates, **ICON is one of the largest contract research organizations (CROs) in the world** with revenues of ~$8.5 billion and free cash flow of $1.1 billion in 2024. Also, ICON ended June 2024 with a net debt ratio of only ~1.5x, suggesting significant "dry powder" to pursue acquisitions (and share repurchases). Stated areas of interest include site networks, late-stage research, and labs.

Core to the ICON story is its proprietary site network business, called "Accellacare," which consists of 100+ dedicated and embedded sites -- two-thirds in the United States and one third in Europe. The Accellacare site network reportedly recruits 60% faster than the independent sites that ICON works with, on a like-for-like basis, while maintaining equal or superior quality. Currently, Accellacare accounts for ~10% of ICON's active sites, and management wants to increase this to 30%+ over time.

Accellacare complements its site network with on-demand outsourced clinical trial staffing support to independent sites that ICON works with and with at-home clinical trial services (e.g., traveling nurses) across 55 countries.



Source: Company filings and Bourne Partners

Case Studies of CRO-Owned Dedicated Site Networks (2 of 2)

ppd

PPD is a global contract research organization (CRO) with a full suite of clinical development and lab services. In late 2021, PPD was acquired by Thermo Fisher Scientific (NYSE: TMO), and TMO no longer reports results on PPD on a standalone basis.

In 2017, PPD launched a proprietary site network called "Accelerated Enrollment Solutions" (AES) based on two prior acquisitions (Acurian and Synexus) as well as several subsequent acquisitions. Today, AES consists of 160+ dedicated research sites across 17 countries. These sites are owned by PPD and staffed by PPD employees.

Also, PPD offers outsourced staff and technology to third-party clinical trial sites (co-located sites). For these co-located sites, PPD and the provider split investigator grant fees. To a lesser extent, the AES offers operational support for independently owned and managed provider sites with pre-negotiated contracts and terms.

The AES business is backed with significant investments in information technology, automation, and digital health. This includes a data warehouse of identified and consented information on 20M+ previously screened study candidates.

IQVIA™

IQVIA is the largest provider of outsourced services, software, and advanced analytics for the global biopharma industry with upwards of $15.4 billion of consolidated revenues expected in 2024. This includes $8.6 billion of revenues reported by its R&D solutions segment (which includes its CRO).

IQVIA has been focused on enabling clinical trial sites with its own proprietary site network (re-branded as the "Avacare Clinical Research Network") as well as its alliances with independent sites. Today, the Avacare Clinical Research Network includes nearly 50 embedded and dedicated sites throughout the United States. Recently, IQVIA acquired CCT Research in 2023 and Benchmark Research in 2024.

In June 2024, IQVIA released the "One Home for Sites" software platform for its Avacare Clinical Network and for its "Prime Sites." This new software platform is designed to integrate all the different software applications that an investigator site may be using, regardless of the vendor, into a single dashboard accessible through a single sign-on. This allows site staff to have one place to go for all of their software applications (with one password and a common interface).

Source: Company filings and Bourne Partners

Valuation Considerations

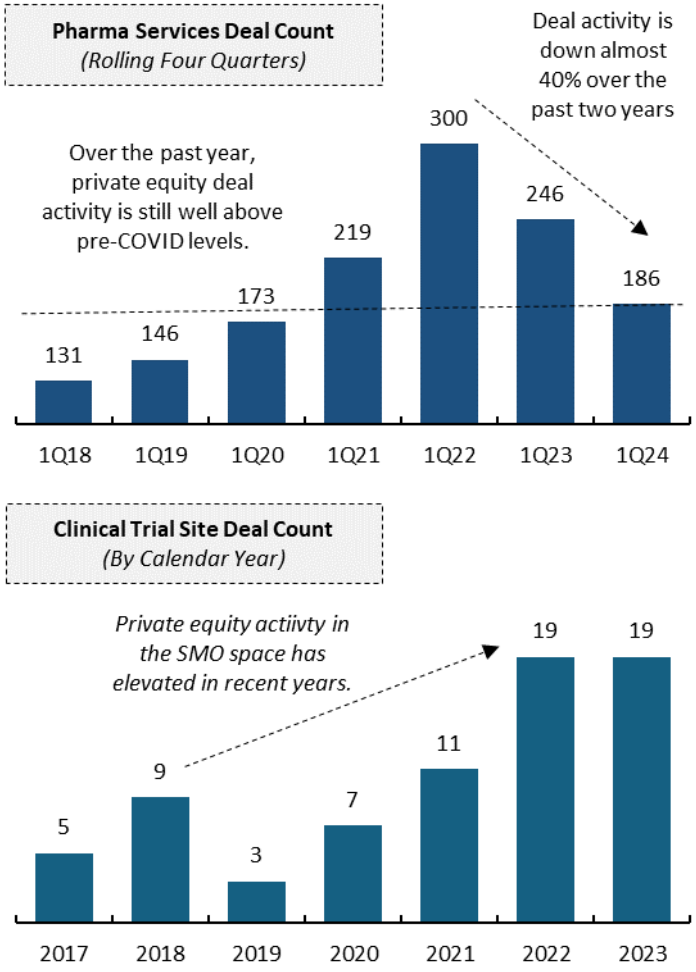
Private Equity Deal Activity in Site Networks

Overall pharma services private equity deal activity remains healthy, in our view. Although deal activity has fallen from the "bubble levels" in 2021 and 2022, it still remains above pre-COVID levels -- despite higher interest rates. Underpinning this interest in pharma services has been the tremendous scientific advances seen in the life sciences in recent years.

Within the pharma services space, **private equity interest has been particularly notable in site networks** with multiple platform deals being announced in recent years, including Adams Clinical (InTandem Capital Partners; May 2024), Eximia Research (VSS Capital Partners; October 2023), Tekton Research (Havencrest Capital Management; August 2023), Centricity Research (Trinity Hunt; May 2023), and Atlas Clinical Research (BPOC; April 2023), among others.

In our view, the clinical trial site marketplace is particularly interesting for private equity investors given the opportunity to create economies of scale in a highly fragmented (and sizable) market -- essentially acquiring a group of small investigator sites at a single digit multiple of EBITDA and selling them, as a platform, with an aggregate EBITDA multiple in the mid-teens.

Platform transactions are a good leading indicator of future private equity deal activity. Each of the site networks we spoke with voiced significant expansion plans for the coming years.

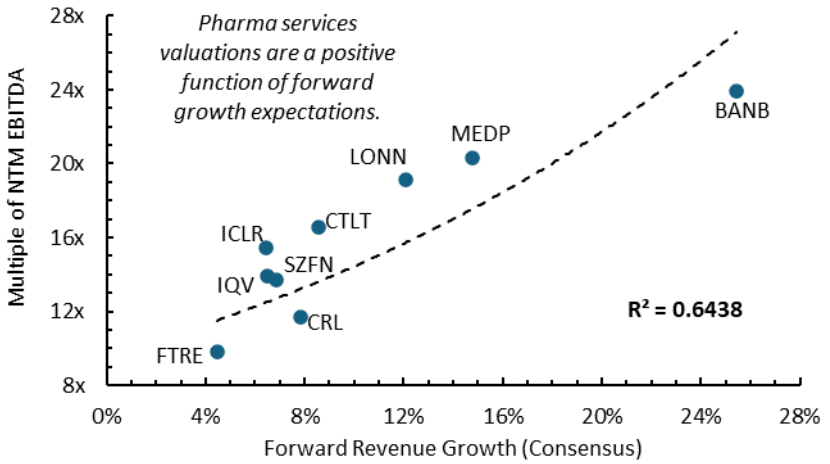


Source: Pitchbook (Pharma Services Launch Report; June 2024) and Bourne Partners

Pharma Services Is A "Growth" Sector

The pharma services space continues to enjoy strong valuations led by the CROs, notably Medpace (MEDP: up 30%+ YOY) and ICON (ICLR: up 20%+ YOY). Strong CRO valuations, in turn, reflect a pick-up in demand from small/mid-sized biopharma customers over the past year.

Pharma services valuations vary, largely a function of growth expectations. On the high growth end, Bachem (BANB) and Medpace (MEDP) are growing in the mid-teens with a low 20xs valuation. On the low end, Fortrea (FTRE) and IQVIA (IQV) are growing at sub-7% with a valuation in the low teens.



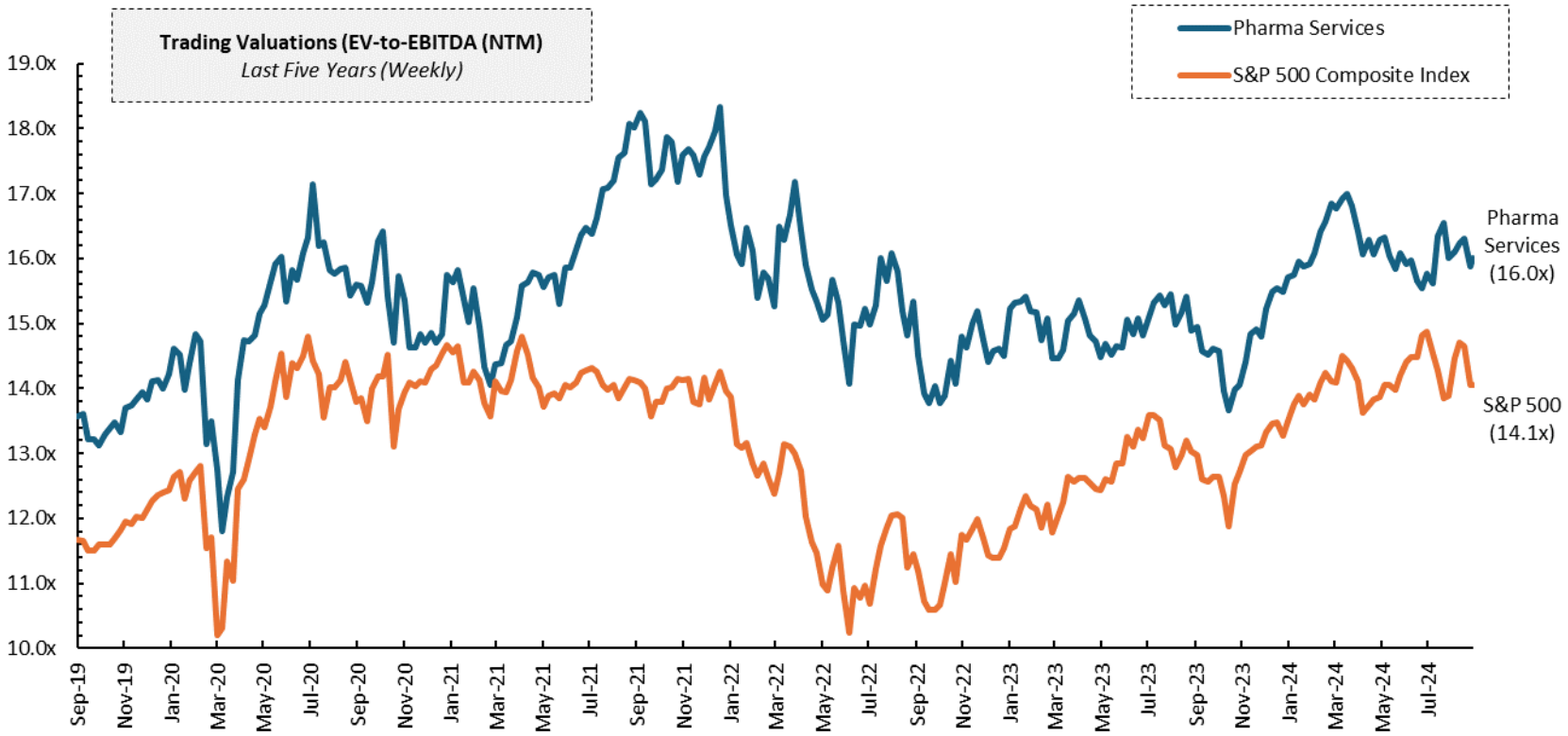
Company Name	Ticker	Enterprise Value	Projected CY2025 Revenue	Projected CY2025 Growth	Projected CY2025 EBITDA	Projected CY2025 Growth	Projected CY2025 Multiple	Debt Ratio
Bachem Holding AG	BANB	$6,504	$928	25.4%	$278	28.6%	23.4x	-0.7x
Balchem Corporation	BCPC	5,662	1,028	5.5%	259	5.9%	21.9x	0.9x
Catalent, Inc.	CTLT	15,541	4,890	6.4%	1,007	7.8%	15.4x	4.7x
Charles River Laboratories	CRL	12,473	4,152	7.8%	1,059	9.6%	11.8x	2.5x
Eurofins Scientific SE	ERF	14,249	8,340	7.5%	1,864	10.5%	7.6x	1.6x
Fortrea Holdings Inc.	FTRE	2,860	2,736	4.5%	295	13.4%	9.7x	3.6x
ICON Public Limited Company	ICLR	26,342	9,214	6.9%	2,029	8.5%	13.0x	1.5x
IQVIA Holdings Inc.	IQV	54,792	16,510	6.5%	4,018	7.7%	13.6x	3.0x
Lonza Group AG	LONN	48,655	9,066	12.1%	2,569	17.0%	18.9x	0.8x
Medpace Holdings, Inc.	MEDP	9,782	2,418	14.8%	500	16.5%	19.6x	-0.7x
Siegfried Holding AG	SFZN	6,078	1,657	8.5%	375	13.3%	16.2x	1.1x
West Pharmaceutical Services	WST	22,033	3,089	8.8%	861	14.0%	25.6x	-0.2x
WuXi AppTec Co., Ltd.	SHSE:603259	14,216	6,082	11.4%	2,183	12.9%	6.5x	-0.5x
Average (Mean)				**9.7%**		**12.7%**	**15.6x**	**1.4x**
Average (Median)				**7.8%**		**12.9%**	**15.4x**	**1.1x**

Note: Market values are as of the close of business September 10, 2024.
Source: S&P Global Market Intelligence and Bourne Partners

Consistent Premium Valuations for Pharma Services Over Time

Pharma services, as a group, has consistently traded (on a multiple of NTM EBITDA) in the mid-teens (currently: 16.0x), ranging from a low of 11.8x to a high of 18.3x. On average, pharma services companies have traded at 17.6% premium to the S&P 500 over the past five years. In our opinion, this reflects superior growth expectations for pharma services as well as the "capital light" nature of these business models in a higher interest rate environment.

Today, **pharma services is currently trading at a somewhat more modest 13.9% premium to the S&P 500** due to an appreciation of the share prices for a small group of tech stocks within the S&P 500 (Microsoft, Apple, Nvidia, Alphabet and Amazon.com).



Note: Market values are as of the close of business September 10, 2024.
Source: S&P Global Market Intelligence and Bourne Partners

Appendix: Bourne Partners Overview

Bourne Partners Overview

Our Service Offering

For over twenty years, Bourne Partners has focused exclusively on providing investment banking advisory services and making direct investments in the Pharmaceutical, Pharma Services, Pharmacy Services, and Consumer Health and Wellness industries. Since 2015, we have successfully executed on **over $10B** in transactions, having worked with many leading companies and private equity investors in these core focus areas.

Value Beyond the Deal

Total Perspective
Experience advising, investing in, building, operating, buying, and selling companies
Unmatched 360° perspective for every project

Uncompromised Service
Direct involvement of senior management throughout process
High level of attention regardless of transaction value

Global Reach
Experience working with companies around the globe
Extensive network of potential international buyers

Investment Banking

Mergers and Acquisitions
Sell-side and buy-side assignments
Transaction Experience: $10M - $3.5B

Capital Sourcing
Debt / Equity / Hybrid
$10 - $500 million raises

Business Development Support
Development stage and approved products
Local and international

Geographic Coverage

Sector Expertise

Pharma & Life Sciences | Pharma Services | Healthcare Services | Consumer Health

Bourne's Leadership in Pharma Services

Proven Expertise

Over recent years, Bourne has successfully completed numerous key transactions, solidifying its position as a leading M&A advisor in the pharma services, pharma, consumer health, and healthcare services verticals.

Sector Expertise

Clinical & Drug Discovery Services

- Full-Service & Specialty CROs
- Site Networks & SMOs
- Patient Recruitment
- Patient Engagement & Retention
- Patient Logistics & Payments
- eClinical & Tech-Enabled Trial Automation
- Clinical Data Services
- RWD, RWE, & Data Analytics

Bourne's Value Add

- Unmatched industry expertise and strong relationships with counterparties
- Expert-level attention from senior bankers throughout the process
- Bespoke process strategy and comprehensive outcome evaluation
- Negotiating favorable deal terms and economics on a swift timeline

Relevant Recent Tombstones

- Clincierge has been acquired by greenphire, a portfolio company of THOMABRAVO
- Bourne Strategic Capital has completed a growth investment in Eximia Clinical Research
- optimal research has been acquired by PPD and SYNEXUS
- accelovance has been acquired by Clinical Development Partner Linical
- reverba, a portfolio company of 424 Capital, has acquired Six Degrees Medical
- spencer health solutions has received a growth investment from RCT Research Corporation Technologies

The Bourne Team

Senior Leadership

Banks Bourne
Founder & CEO

Jeremy Johnson
Senior Managing Director

Aaron Olson
Managing Director

Xan Smith
Managing Director

Todd Bokus
Director

Robert Stanley
Director

Strategic Advisory & Administration

Matt Bullard
Strategic Advisor

Scott Emerson
Strategic Advisor

Bruce Montgomery
Strategic Advisor

Paul Campanelli
Strategic Advisor

Martin Zentgraf
Strategic Advisor

Minor Hinson
CIO, BPSC

Chris Inklebarger
Chief Operating Officer

Calli Lewis
Chief of Staff

Transaction Execution Team

Vice Presidents




Associates



Analysts






- **Deep Industry Expertise**
- **Excellent M&A Execution**
- **Thorough Sponsor Coverage**
- **Broad Senior Support**
- **Detailed Thought Leadership**

Thought Leadership

Bourne Perspective

After 20+ years of exclusive industry and capital markets coverage, we know the space and we are committed to providing actionable insights to our clients. We provide cutting-edge thought leadership on all things Pharma, Pharma Services, and Consumer Health.

Through leveraging resources and insights of both Bourne Partners Strategic Capital and Investment Banking divisions, **we provide differentiated perspectives to our clients from our unique vantage point**. Our goal is to deliver heavy-hitting, timely reports in an easy-to-read format tailored specifically for executives within our industry coverage.

Deal Profiles

Market Conference Commentary

Industry Update Posts

Weekly Newsletter

Market Reports

Expert Interviews

Sector Updates

Meet Us at an Upcoming Industry Conference

Site Solutions Summit | SCOPE Summit for Clinical Ops Executives | DPHARM Disruptive Innovations to Advance Clinical Research | DIA Global Annual Meeting | CNS Summit Collaborating for Novel Solutions | J.P.Morgan

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