
Consolidation in Clinical Research Sites and COVID's Impact

The Clinical Research Sites sector is heavily fragmented and consists of many small-scale players. Consolidation is being driven by CROs, diversified strategics, and private equity.

Trends Driving Consolidation in Pharma Services Research Sites

There are several factors including market fragmentation, growth trends and operational efficiencies driving consolidation in the clinical research sites space. Despite the COVID pandemic's initial effect, we expect high levels of M&A in the sector for the remainder of 2020 and for 2021.

The research sites market is highly fragmented, made up of mostly physician practices, performing studies on a part time basis, and stand-alone clinics. The total market for clinical research sites is also estimated at \$13.8 billion and in the United States, an estimated 40,000 doctors, 4% of total physicians, have participated in at least one clinical trial. However, commercial sponsors and CROs utilize about 3,000 research sites for clinical trial execution. There is a "one and done" factor that is at play for physicians. Doctors typically participate in a trial, only to never participate in another study. The problem could be alleviated with site engagement through increased consolidation.

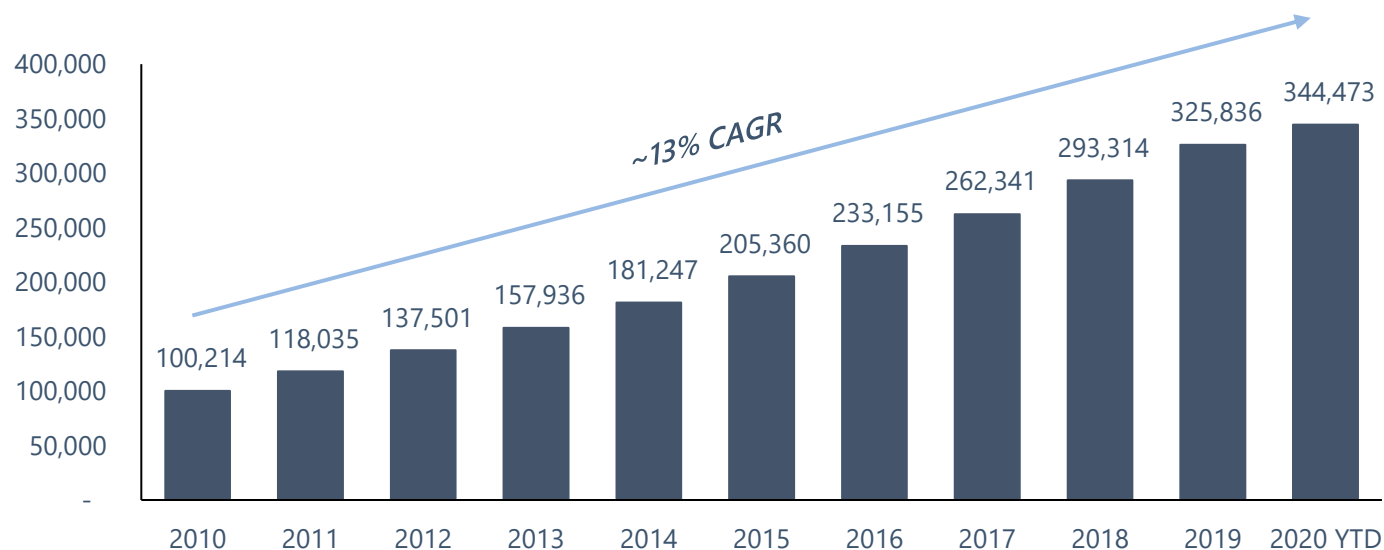
The number of registered clinical trials in the US has significantly increased year over year at a CAGR of 13%, since trials were followed and monitored in 2000. The major catalyst for the growth of the

clinical research trials sector has been the outsourcing of pharmaceutical services that has increased over the last decade. Initially, the outsourcing trend was largely a move to reduce costs associated with drug development. However, other attributes of outsourcing include reduced time-to-market and improved quality.

Additionally in the research sites space, there are operational inefficiencies, largely due to a lack of adoption of technologies by site operators. These characteristics create an opportunity for investors and large-scale players to create value through partnerships.

There has been an increasing trend of private equity involvement in the clinical research sites space due to the continued growth of outsourced pharmaceutical services and heavy fragmentation of the clinical research sites market. In addition to private equity, consolidators in the space include larger acquisitive research sites looking to diversify their service offering, as well as CROs looking to vertically integrate and gain operational control of clinical trials.

Number of Registered United States Clinical Research Studies by Year



Post-Transaction Integration and Synergies

Within an acquisition, key areas of integration include accounting, human resources, patient recruiting, centralized budgets, contract integration systems and business development. An integrated site allows for an acquirer to enhance performance and save costs. Additionally, an integrated network across one clinical trial management system (CTMS) improves operational performance and service efficiency.

CROs Vertical Integration

As such, leading CROs continue to drive success and differentiate by adding specialized capabilities that accelerate and enhance the quality across the clinical development lifecycle. The largest opportunity to increase drug sponsor and CROs' effectiveness in terms of drug approvals, commercialization, and improved outcomes, is through increasing the access and control of patients. Site ownership also provides CROs control over execution from patient identification, enrollment and retention, to following defined protocols and maintaining the highest quality throughout.

Recently, CROs have focused on becoming full service providers and expanding their service offering by acquiring sites. The next step after acquiring a site is then to integrate technology and operations to increase access to patient information. Ultimately, this leads to increased efficiency in the recruitment and feasibility stages of studies.

Additionally, consolidators have made major improvements to technology, infrastructure and systems in sites themselves. The improved services include recruitment, selection, enrollment, retention and statistical analysis and analytics. Overall, this has improved process management and patient participation at the site level.

Figure 1: Dynamics Driving M&A in the Clinical Research Sites Industry

Vertical Integration from CROs

- CROs have an opportunity to add specialized services and enhance quality through control of research sites

Interest from Private Equity Investment

- Growing demand for research sites through roll up investment strategies to expand geographic, patient and service reach

Inefficient Operations

- Increasing scale and adding technological integration allows for increased operational efficiency

Favorable Industry Dynamics for Consolidation

- Highly fragmented market, and an increasing need for outsourced pharma services

Private Equity Involvement in Clinical Research

Over the past decade, private equity has been increasingly interested in the clinical research sites space. Compared with an investment in a pharmaceutical company, an investment in a research site provides less risk and still capitalizes on the tailwinds of the biotech and biopharmaceutical investments. A pharma company could spend hundreds of millions of dollars over a decade developing a drug or device, only to see it fail in trials, resulting in no return on investment. Research sites businesses on the other hand, provide a service revenue stream at inception. A site gets paid regardless of whether or not a drug is approved.

Additionally, the market dynamics of the research sites space and need for increased efficiency have provided private equity an actionable investment strategy in a highly critical clinical trials industry.

Private equity investors are looking to purchase and integrate assets in order to capitalize on economies of scale for site services. The dynamics of the clinical trials business allow for acquirers to establish integrated platforms to address

challenges, such as recruitment and operational efficiency, that face independently owned research sites.

The most common investment strategy has been a roll-up of freestanding sites typically with a minimum revenue threshold of \$5-15 million. Larger sites typically see higher multiples than smaller players, which is driven by buyer competition for large, well run sites. These sites might already have well established management teams, back office operations, centralized infrastructure, and digital technologies.

A lot of interest will also be given to companies providing a differentiated and specialist service offering. Private equity will allocate more capital to companies that are efficient with resources, providing advanced capabilities and developing innovative solutions to tackle unmet needs and regulatory requirements.

Figure 2: Illustrative Private Equity Backed Clinical Research Sites

Research Site	Owner/Investor
Velocity Clinical Research	Navimed Capital
CenExcel	Webster Capital
Headlands Research	KKR
Evolution Research Group	Linden Capital
Meridien Research	Avego Healthcare Capital
Wake Research	M3
Altasciences	Audax Private Equity
Alliance Biomedical Research	Great Point Partners
PMG Research	ICON
Jasper Clinical Research & Development	MPI Research
BioClinica	Cinven

Example Buy and Build Strategy: Headlands Research

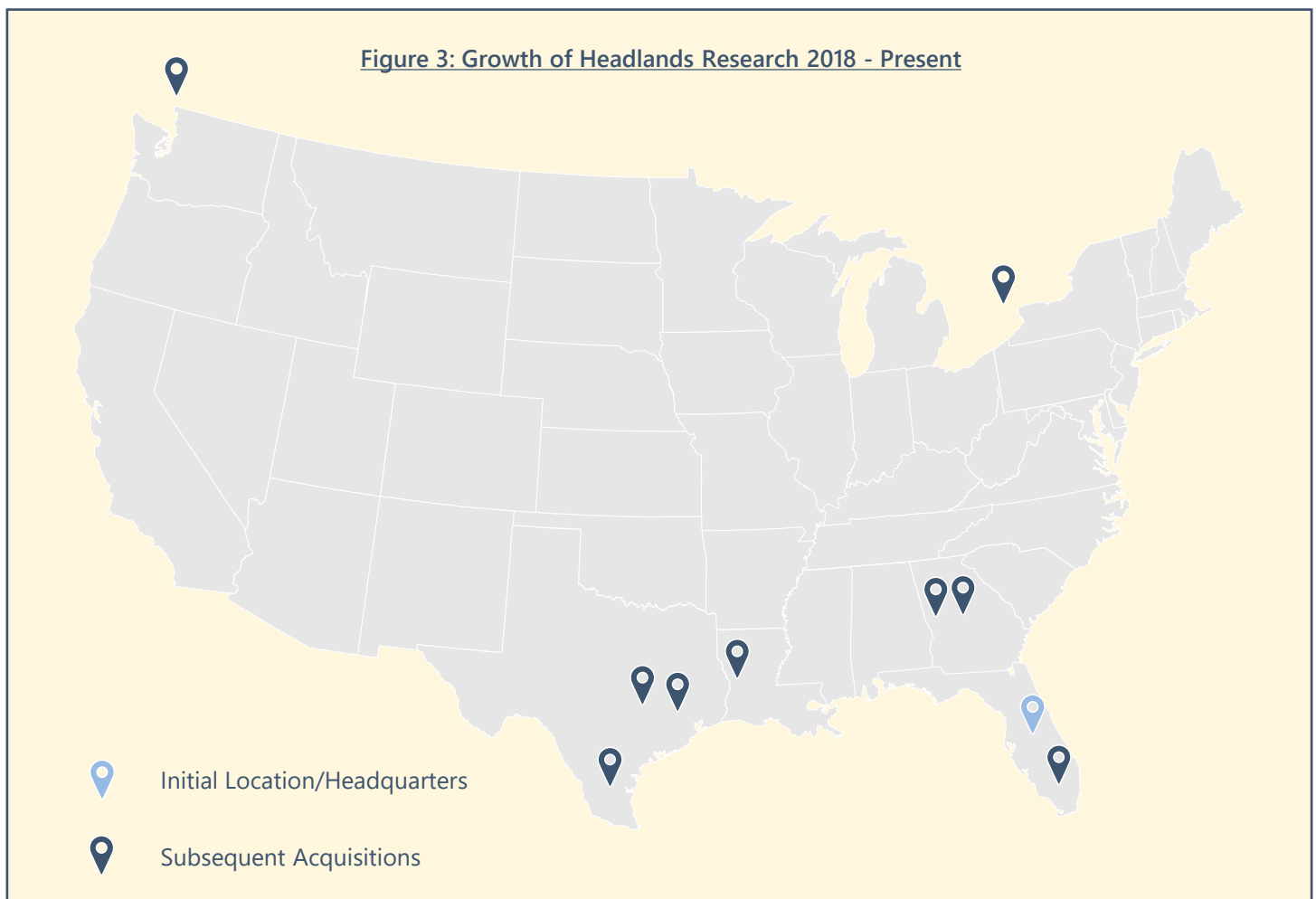
In 2018, KKR, a New York-based private equity firm, invested in Headlands Research (“Headlands”) at an undisclosed valuation. The deal marks a growing trend of consolidation in the clinical research sites sector. Headlands is a globally integrated clinical trial site organization that has completed over 1000 studies across a wide variety of different therapeutic areas.

Headlands is looking to dramatically improve and change the clinical trials process. The company is doing this by leveraging patient-centric best practices to recruit large numbers of test subjects and by providing superior data quality.

Headlands Research’s roll-up strategy has included nine research centers across the U.S. and Canada. Centex Studies, comprised of multi-

specialty research centers in Texas and Louisiana. Clinical Research Atlanta, a multi-specialty group with an expertise in recruitment of specialty populations. Okanagan Clinical Trials located in Vancouver, British Columbia, specializes in addressing Central Nervous System (“CNS”) conditions. JEM Research Institute and Toronto Memory Program are leading CNS research sites located in Lake Worth, Florida and Toronto, respectively.

These acquisitions are the first moves in Headlands Research’s effort to transform the sites space. The company is positioned to deploy capital in sites with a focus on patient-centricity and data quality.



COVID's Impact on Clinical Trials

The effect of COVID across the pharmaceutical services industry has halted clinical trial enrollment in lower-priority initiatives. In total, \$36 Billion of NIH's research money allocated to clinical trials is on hold due to the potential risks facing research professionals and patients.

WCG ("WIRB-Copernicus Group") has reported that 86% of clinical trial sites currently tracked have ceased enrollment as of April 2020 10th, 2020. Tracking by Medidata also shows overall global clinical trial enrollment down 74% across all therapeutic areas as of May 2020.

Within the CRO space, the research sites sector has been one of the most affected by COVID. Sites have experienced reduced participation due to the risks of contracting COVID at sites, and studies in regions where participants have been unable to leave their homes have been hit hardest.

The reasons for reduced participation in clinical trials are two-fold, ethics and a shifting of medical attention. Ethically, the core step for clinical research, checking patients' health status, isn't safe at times when hospitals are occupied with virus cases. Given that these subjects are enrolled in trials to find solutions or reduce effects of their illnesses, putting them in harms way via trials would do more harm than good.

In hospitals, attention and resources have been reallocated away from research in order to treat COVID. This has made it harder for patients and providers to continue with trials. For example, in one ongoing brain hemorrhage study, providers are unable to perform surgery due to the lack of ventilators that might be needed for test subjects.

As part of Provident's research & outreach efforts, we have spoken with multiple research site

operators who have experienced a 50-75% drop in bookings. However, the backlog and pipeline indicate that 2021 will be a record-breaking year from a revenue basis, suggesting Q3 and Q4 will be ideal windows of opportunity to prepare for M&A market approach in 2021.

Many ongoing trials are expected to continue despite risks if they are crucial for patients with severe/fatal conditions, like cancer. In these cases, the risk of not continuing a potentially life saving trial is greater than the risk of COVID. Other companies have turned to monitoring and running tests in the home setting instead of hospitals or research sites. Vaccine-related clinical trials are also providing a strong tailwind for bookings.

The FDA has required that sites assess safety of current research procedures and implement changes where necessary, or switch to digital/telemedicine. Furthermore, the FDA is allowing companies to switch protocols for patient safety without needing regulatory approval. Also, sponsors have been permitted to send investigational products directly to participants or may alter administration of care to in-home or alternative settings.

Conclusion

The clinical trial sites landscape is expected to undergo much change in the coming years, as it observes increased interest from consolidators, CROs and private equity. The outcome from M&A in the space make the landscape very different than it is today. There will be a few dominant players, focused on sites with a differentiated approach and specialized therapeutic treatments .

An integrated site, with a built out back office will become the optimal model for acquisition. Also, adoption of eRegulatory will allow for standardization and centralized regulatory compliance for trials. These features allow for turnkey access to geographic expansion and additional service lines.

Equally important is the role of technology for providing increased operational efficiency and the capability of Telehealth and home based studies. Previously, these features were “nice to haves,” but the COVID pandemic has shown them to be a requirement going forward.

Sites that have digital platforms and telehealth based studies are already fairing better than competitors. Telehealth and home based studies will continue to provide superior growth potential as they provide increased test subject reach and easy implementation.

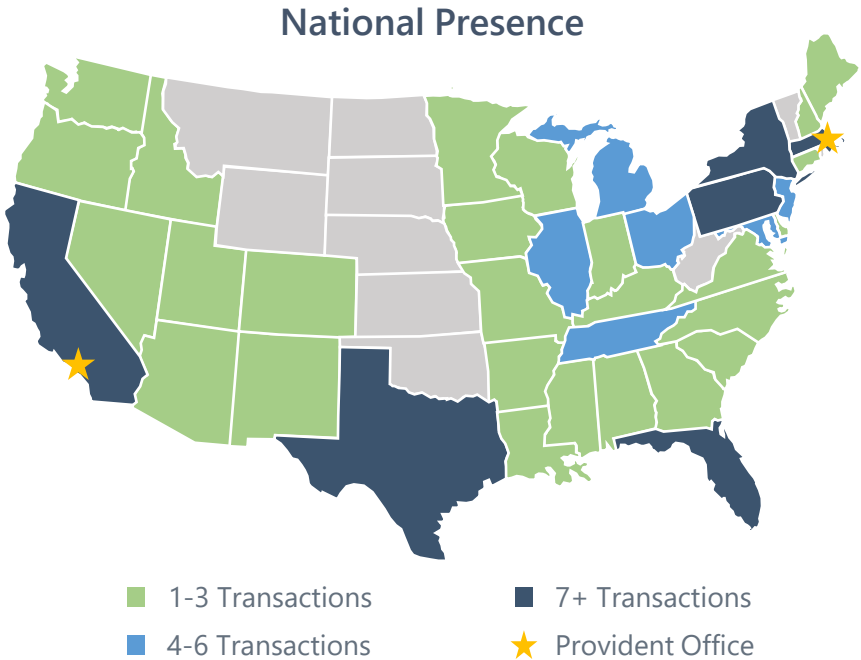
As the research sites industry continues to grow through pharma funding, private equity will continue to pursue a seat at the table for acquisitions to cut costs, promote efficient care, and create the next powerhouse players. There is no doubt that M&A activity will increase, though the COVID pandemic may incentivize a different approach to deals.

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PROVIDENT HEALTHCARE PARTNERS

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Note: The above map represents states where Provident clients were headquartered. Provident has successfully closed transactions with clients operating in 45 states and Puerto Rico.

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