Patient Centricity, Innovative Technology, and Site Engagement: What's Next for Clinical Trials?

Conversations at the Bourne Partners 12th Annual Global Healthcare CEO Summit

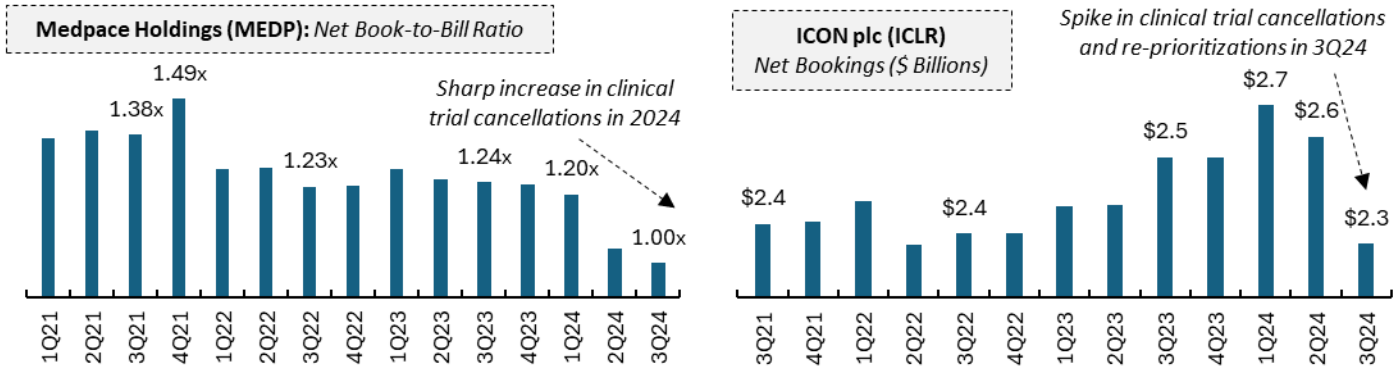
Last week, **we hosted the Bourne Partners 12th Annual Global Healthcare CEO Summit in Charlotte, North Carolina**, which featured a wide variety of panel discussions on key healthcare topics. The Summit also included informal meetings with industry executives allowing for a greater shared visibility around trends and experiences.

One panel discussion, featuring executives from Eximia Research and Scout, focused on the use of software technologies and site networks to accelerate clinical trials and improve patient experience. We see the environment for clinical trials as particularly conducive for disruptive innovation, and we expect to see significant consolidation of services and software companies in the clinical trials space in the coming years. For more discussion, see our recent deep-dive research on the site network marketplace *(Link; September 12)* as well as takeaways from our private equity and executive meetings at the recent Society of Clinical Research Sites Summit *(Link; September 30)*.

1) Volatile Market Conditions to Catalyze More Consolidation

We continue to be optimistic for the fundamentals of pharma services (and software) companies, including site networks, over the next decade. However, the panel discussions at the Summit confirmed what we have considered to be a "temporary correction period." Over the past six to twelve months, we have seen a significantly elevated volume of study delays and cancellations across all therapeutic areas, and this is having various negative downstream impacts on software and services companies across the pharma ecosystem. Our sense is that much of this comes from small/mid-sized biopharma sponsors who were initially funded during the "bubble years" of 2021 and 2022 and have since struggled to re-access capital markets to sustain their businesses. We are also hearing more and more anecdotes of larger pharma sponsors re-prioritizing their product development strategies in response to the prescription drug price cuts associated with the ongoing rollout of the *Inflation Reduction Act* (IRA) of 2022. Finally, adding to all of this, the surge in demand from COVID-19 related studies has winded down, resulting in many companies who became comfortable relying on 'easy' vaccine work now scrambling to find new work to fill in the lost COVID revenue.

Figure 1: Publicly Traded CROs Highlight Recent Spike in Clinical Trial Cancellations / Re-Prioritizations in 2024



Source: Medpace and ICON (October 2024)

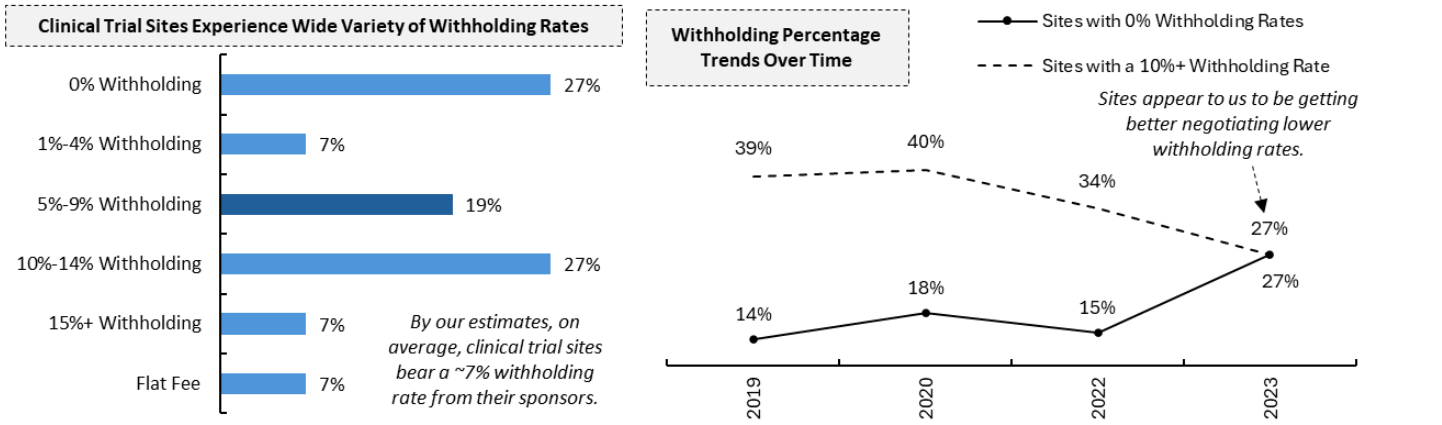
In our view, **this volatile demand environment will further catalyze consolidation activity among software and service providers** in the life sciences space -- particularly clinical trial site networks. In fact, based on our conversations at the Summit, we think the recent volatility in clinical trial activity has disproportionately negatively impacted smaller single sites who generally have a) less operational diversity and scale, b) less financial sophistication, and c) weaker sponsor and CRO relationships. We think being part of a larger clinical trial site network could help individual sites better persevere through the ebbs and flows in market demand. Thus, we see consolidation as an increasingly attractive option.

a) Operational and Therapeutic Diversity. We believe larger site networks with diversified models, geographies, and therapeutic specialization are best positioned to navigate volatile times. This can be achieved by having a broad mix of dedicated (free-standing) and embedded sites in order to maximize therapeutic and financial diversification.

- *Dedicated/Free-Standing Sites.* The dedicated site strategy involves a site network directly owning a clinical trial site and employing staff. Dedicated sites give the site network maximum control over operations, 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 requires constant outreach campaigns to develop and sustain relationships with local provider groups to ensure access to patients.

- *Embedded Sites.* The embedded site strategy involves a site network partnering with an existing physician practice and embedding research support staff and technology at the host physician practice. This can result in improved access to patients as it takes advantage of existing doctor-patient relationships, making it easier to recruit in therapeutically complex and specialty disease areas. The disadvantage of the embedded site strategy is the lack of control and focus caused by working within someone else's infrastructure. Clinical research must compete for time, attention, and resources against the other day-to-day priorities of the host medical practice.

Figure 2: Pharma Services Companies Need to be More Careful Negotiating Contracts in Volatile Times



Source: The Society for Clinical Research Sites (SCRS) Annual Site Landscape Survey (September 2024) and Bourne Partners

b) Financial Sophistication. We think that larger site networks are often able to bring greater financial budgeting and forecasting discipline. Volatility in demand can be particularly difficult on clinical trial sites given the need for sites to accurately allocate staffing and other resources in advance of a trial start-up to ensure timely patient recruitment and study execution. The clinical trial site business is one of the few businesses where one indicates interest in a project prior to getting a formal contract in place. This elevates the importance of budgeting and forecasting. Forecasting in the clinical

trial space requires a deep understanding of pipelines and backlogs, e.g., expected project start times, staffing needs, and physical space requirements. Financial acumen is an area where we hear many smaller/single sites are weak. In our experience, it is not uncommon to find smaller clinical trial sites to be working from simple excel-based cash budgets that only consider existing projects underway. And, not surprisingly, we heard feedback from several site executives we spoke to at the Summit of there being an increased demand from "rescue studies."

c) Sponsor and CRO Relationships. In our opinion, larger clinical trial site networks (and software and services vendors) are typically better positioned to develop relationships with more established and financially stable sponsors and CROs who, in turn, are better financial partners. Avoiding "bad" sponsor and CRO partners (and studies) is increasingly important for sites in today's environment. Many smaller sites, for instance, generate a high proportion of their work from sponsors who are essentially start-up companies. This adds an additional burden of having to better understand a sponsor customer's financial situation. It is critically important to construct contracts that document various scenarios that may come up during a project and how potential payment disputes are to be resolved. Finally, for clinical trial sites, in the current macro environment, contract negotiations should focus on establishing regular monthly payments based on procedure volumes (to avoid the costs and wasted time associated with "screen fails") and minimizing withholding percentages (to avoid the risk of a sponsor customer facing financial challenges).

2) A Preference Shift Towards Versatile, Comprehensive Software / Technology Platforms vs Single Point Solutions

The Bourne Partners CEO Summit highlighted an increasing appetite for versatile, comprehensive technology platforms (over best-of-breed single point solutions). There are many dozens of categories of software and services that have evolved over the years that help to accelerate and enhance clinical research related activities. Feedback from the Summit highlighted a strong preference by pharma companies, CROs, and clinical trial sites for a "one-stop-shop approach" with respect to technology (and service) procurement. Enterprise purchasing simplifies the contracting process and often allows the buyer to benefit from volume-based pricing. The concept of "one-stop-shop" purchasing applies geographically as well. For tech-enabled service companies, such as Scout, we heard that an important differentiator is the ability to offer a global platform that can track patient enrollment and retention across geographies. Altogether, in our opinion, this suggests there could be significant consolidation across the clinical trial software and technology space in the coming years -- similar to what we saw in the market for electronic data capture software.

The current fragmentation of the software/technology ecosystem in the life sciences sector is particularly problematic for clinical trial sites. The issue of "technology burden" originates from the fact that every pharma company has its own favorite technology for a given research function (and geography). As a result, active clinical trial sites, such as Eximia Research, who are involved in multiple clinical trials on a regular basis, find themselves drowning in disparate software solutions. Oftentimes, sites find themselves managing dozens of overlapping digital tools and software applications, many of which were designed for pharma sponsors and CROs but are pushed down on to the sites. This has become a tremendous burden on site investigators, nurses, and staff. In response, we have seen a number of single sign-on (SSO) solutions being introduced into the market over the past year or so by IQVIA, ICON, and Veeva, among others. Now, however, there are dozens of disparate single sign-on solutions, adding another layer of fragmentation.

3) A Focus on Patient and Provider Access and Retention

Patient access and retention was a consistent topic of conversations at the Bourne Partners CEO Summit. In our discussions, this came up in three dimensions. First, with shifting clinical trial protocols/timelines, we believe there is a

premium on clinical trial sites and technologies that can flexibly access and build trusted relationships with diverse patient populations quickly. Also, creating a good patient experience is key here since good patient experiences tend to lead to repeat patients (and better retention), resulting in easier recruiting in the future. Site networks, such as Eximia Research, that invest regularly in patient experience report a compounding benefit with recruitment and retention over time. Finally, with the elevated industry focus on genetic conditions and rare diseases, direct connectivity with provider/physician groups (and their electronic health record data) becomes more critical. Broad-based digital and social media outreach strategies were discussed among our panelists (e.g., Facebook and Instagram). However, in medically complex areas (e.g., cancer, rare diseases, etc.), patients want the involvement of their personal physician before entering a clinical trial. As such, it is critical for sponsors, CROs, and sites to develop tight collaboration with community provider/physician groups.

One aspect of patient access and retention that we think is particularly overlooked in the planning stages of a clinical trial is patient logistics and accommodations (e.g., payments and travel support). Clinical trial patient participation and retention rates can be significantly negatively impacted by financial issues, e.g., the costs of transportation, travel, childcare, and lost productivity, especially for patients with lower incomes. Also, patients can have very different health plan coverage, and many times elements of an experimental treatment (e.g., lab testing, scanning, and/or imaging) may fall outside of a patient's coverage policy. This could result in costs being passed on to the patient. The costs of participating in a clinical trial are often not discussed because the site might not know the patient's health plan or life circumstances. Panelists at the Summit broadly agreed that the typical standard stipend offered to clinical trial patients is often not sufficient. One of our panelists, Scout, is a company that offers software and services that help patients manage the costs and logistics of participating in clinical trials. According to Scout, every 30 miles a patient must travel to a clinical trial site reduces enrollment rates by 10%. And, 11%-13% of patients, on average, drop out of clinical trials due to not being paid sufficiently (or having to fund themselves while waiting to get paid at the end of a study).

Adding to this is the inconvenience of clinical trial payments being considered as taxable income, which creates a reporting burden for the patient and may negatively impact the patient's eligibility for other government benefit programs (e.g., food stamps, Medicaid, etc). There was optimism about two pieces of legislation introduced this year that could improve the ability of sponsors, CROs, and sites to offer stipends to patients. Currently, stipends over $600 are considered to be taxable income. The *Clinical Trial Modernization Act (H.R. 8412)* has been introduced in the U.S. Congress to increase this threshold to $2,000. Another proposed bill, the *Harley Jacobsen Clinical Trial Participant Income Exemption Act (HR 7418)*, similarly excludes certain payments to clinical trial participants from taxation. This bill has been referred to the House Ways and Means Committee; however, it has not yet been scheduled for mark up.

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